
RECALIBRATING VACCINATION LAWS

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The United States is in the midst of a vaccine crisis. States utilize their police power to establish vaccine mandates, but the federal government—via the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”)—maintains responsibility for incentivizing vaccine innovation, ensuring a stable vaccine market, and affording compensation for vaccine-related injuries. Although the Vaccine Act may have been the cure for the vaccine woes of the 1980s, the law has failed to keep pace with technological advancements and evolving public policy concerns. As was the case during the 1980s, today’s vaccine market is highly consolidated and the public depends on one or two manufacturers for most childhood vaccines. This has led to vaccine shortages and a lack of competition in vaccine design. Rather than incentivizing timely adjustments to vaccine formulas, the Vaccine Act’s broad legal immunities for vaccine manufacturers have created a regulatory vacuum whereby manufacturers are not obligated to incorporate scientific developments into marketed vaccines. Furthermore, the Act’s complex compensation mechanism has failed to resolve vaccine-injury claims fairly and expeditiously. Meanwhile, declining public trust in government and industry fuels vaccine hesitancy and creates population health challenges for public health officials.

Recalibrating vaccination laws can help remedy these imbalances. While the Vaccine Act may not be a primary cause of vaccine hesitancy, amendments to the law can be part of the solution. Grounded in a comprehensive analysis of the historical context preceding the enactment of the Vaccine Act, this Article details how statutory levers can address modern-day concerns in vaccine policy and provides draft legislation that furthers the Vaccine Act’s public health, compensation, and market stabilization goals. Using law as a means of furthering the public health and building public trust in vaccines, the proposals focus on increasing safety and efficacy research, adjusting preemption provisions, and expanding the safety net for vaccine-related injuries.

INTRODUCTION

Just as the health benefits of vaccines cannot be questioned seriously, neither can the shortcomings of the legal framework governing immunizations be ignored. The National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”)—the federal regime governing vaccine innovation, the vaccine market, and compensation for vaccine-related injuries—was established over three decades ago, at a time when there were fewer vaccine doses and vaccine-preventable diseases,¹ electronic health records and health information technology were in

¹ For children eighteen and younger, in 1986 there were seven vaccine-preventable diseases and eleven total doses, while in 2017 there are sixteen vaccine-preventable diseases and fifty-two total doses. Compare U.S. CTRS. FOR DISEASE CONTROL & PREVENTION,

their infancy,² and lawmakers heavily favored corporate welfare and deregulation over consumer protection.³ Although the statute nurtured a pro-business environment that contributed to the development of new vaccines,⁴ the Vaccine Act lacks the necessary incentives to ensure that manufacturers keep pace with vaccine science. Manufacturers enjoy robust immunity from tort claims for vaccine-related injuries.⁵ However, once a vaccine is approved and made available to the public, a manufacturer does not have a statutory obligation to actively collect and analyze safety and efficacy data, nor are manufacturers obligated to update vaccine formulas in light of new scientific advancements.⁶

RECOMMENDED SCHEDULE FOR ACTIVE IMMUNIZATION OF NORMAL INFANTS AND CHILDREN 1 (1983) [hereinafter 1983 CDC VACCINE SCHEDULE], with U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, RECOMMENDED IMMUNIZATION SCHEDULE FOR CHILDREN AND ADOLESCENTS AGED 18 YEARS OR YOUNGER 2 (2017) [hereinafter 2017 CDC VACCINE SCHEDULE]. The 1983 schedule, which was in effect in 1986, included: (1) four doses of the oral attenuated polio virus vaccine; (2) five doses of the diphtheria, tetanus, and pertussis vaccine (“DTP”), with a tetanus-diphtheria booster at age sixteen and every ten years thereafter; and (3) one dose of the measles, mumps, and rubella (“MMR”) vaccine. 1983 CDC VACCINE SCHEDULE, *supra*, at 4. The 2017 schedule includes: (1) three doses of the hepatitis B vaccine; (2) three doses of the *haemophilus influenzae* type b (“hib”) vaccine; (3) four doses of the pneumococcal conjugate vaccine; (4) five doses of the diphtheria, tetanus, and acellular pertussis (“DTaP”) vaccine, with a booster at age eleven; (5) three doses of the rotavirus vaccine; (6) four doses of the inactivated poliovirus vaccine; (7) two doses of the hepatitis A vaccine; (8) two doses of the MMR vaccine; (9) two doses of the varicella vaccine; (10) three doses of the human papillomavirus (“HPV”) vaccine; (11) two doses of the meningococcal vaccine; and (12) eighteen doses of the seasonal flu vaccine. 2017 CDC VACCINE SCHEDULE, *supra*, at 2.

² See, e.g., A.L. Rector et al., *Foundations for an Electronic Medical Record*, 30 METHODS INFO. MED. 179 (1991) (detailing efforts during 1970s and 1980s to develop standards for electronic medical records); Huibert J. Tange et al., *Medical Narratives in Electronic Medical Records*, 46 INT’L J. MED. INFORMATICS 7 (1997) (describing development of health information systems since their inception in late 1970s).

³ See generally JOHN EHRMAN, *THE EIGHTIES: AMERICA IN THE AGE OF REAGAN* (2005) (discussing political, economic, and societal changes that took place in America during Reagan Administration).

⁴ Geoffrey Evans, *Update on Vaccine Liability in the United States: Presentation at the National Vaccine Program Office Workshop on Strengthening the Supply of Routinely Recommended Vaccines in the United States*, 42 CLINICAL INFECTIOUS DISEASES S130, S134 (2006) (crediting Vaccine Act with stabilizing vaccine market and incentivizing development of new vaccines).

⁵ 42 U.S.C. §§ 300aa-21, -23 (2012); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (holding that “[Vaccine Act] pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by a vaccine’s side effects”).

⁶ See *Bruesewitz*, 562 U.S. at 250 (Sotomayor, J., dissenting) (pointing out that Court’s decision eliminates vaccine manufacturers’ duty to improve vaccine designs).

The net result is an outdated system whereby opportunities for improving health and enhancing vaccine safety and effectiveness fall through the legal cracks.

As has been the case with many public health laws, the Vaccine Act was born amidst a crisis. According to congressional debates from the 1980s, the two key aspects of the crisis were vaccine manufacturers leaving the market because of litigation risk stemming from vaccine-related injuries and uncompensated vaccine-related injuries stemming from the legal roadblocks that injured plaintiffs faced.⁷ To address these concerns, the Vaccine Act established a compensation program for vaccine-related injuries and granted manufacturers broad legal immunities that significantly mitigate the risks from vaccine-related litigation.⁸ The legal immunities include preemption of state tort claims—most notably, claims alleging design defects and warning defects.⁹

As a comprehensive report succinctly concluded, however, “[m]any of the [Vaccine Act’s] promises have gone unfulfilled.”¹⁰ Although lawmakers indicated their goal was to help injured children by providing a “no fault” compensation scheme for vaccine-related injuries, the program “has simply failed to offer compensation as consistently, as quickly, as easily, or as simply as its proponents had predicted.”¹¹ Over the past decade, there has been increased criticism regarding “the adversarial nature” of the compensation program, the massive surplus in the Vaccine Injury Compensation Trust Fund (“Trust Fund”), and the slow pace of listing on-table vaccine-related injuries; yet, no amendments to the Vaccine Act have materialized.¹² As health policy

⁷ *Id.* at 227-28 (majority opinion). While “fairness to persons subject to mandatory vaccination did not drive the creation of the [Vaccine Injury Compensation Program], it is frequently cited as an *ex post* justification for the program.” Michelle M. Mello, *Rationalizing Vaccine Injury Compensation*, 22 *BIOETHICS* 32, 37 (2008).

⁸ *Bruesewitz*, 562 U.S. at 228-30. This “replacement regime,” which “jettisons tort law,” has been characterized as a “go-to weapon” for “serious tort reformers.” Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 *U. PA. L. REV.* 1631, 1640 (2015) (evaluating successes and failures of Vaccine Injury Compensation Program).

⁹ *Bruesewitz*, 562 U.S. at 233-40.

¹⁰ Engstrom, *supra* note 8, at 1698.

¹¹ *Id.* at 1675.

¹² Evans, *supra* note 4, at S135 (evaluating strengths and weaknesses of vaccine injury compensation program). Fundamental problems with the compensation program have been highlighted in several reports and congressional hearings, including: H.R. REP. NO. 106-977 (2000) (initiating “oversight investigation into the implementation and operation of the [Vaccine Act]”); U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-15-142, *VACCINE INJURY COMPENSATION: MOST CLAIMS TOOK MULTIPLE YEARS AND MANY WERE SETTLED THROUGH NEGOTIATION* 9, 13-15, 17-18 (2014) [hereinafter 2014 GAO REPORT]; U.S. GEN. ACCOUNTING OFFICE, B-284440, *VACCINE INJURY TRUST FUND: REVENUE EXCEEDS CURRENT NEED FOR PAYING CLAIMS* 4-5 (2000) (discussing, *inter alia*, whether tax used to finance compensation fund should be lower due to excess funds available); U.S. GEN. ACCOUNTING OFFICE, B-281968, *VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE*

expert Michelle Mello explains, “[t]he history of vaccine injury compensation has been that when the government closes a door, it opens a window.”¹³

Embedded in the Vaccine Act are complex legal hurdles for obtaining compensation, and over time the legal standards have become more rigorous.¹⁴ The Act distinguishes between “on-table” and “off-table” injuries. On-table injuries are injuries that federal regulators have previously determined are caused by a vaccine.¹⁵ To receive compensation for an off-table injury, however, a petitioner must prove that a vaccine caused their injury.¹⁶ While in theory this may seem like a reasonable requirement, in practice it creates a nearly insurmountable burden for petitioners.

Prior to enactment of the Vaccine Act, the Institute of Medicine (“IOM”) warned that the “difficulty of proving or disproving a causal relationship between a given vaccine and a particular injury suggests that . . . outcomes will depend on who is required to carry the burden of proof.”¹⁷ Following the Vaccine Act’s enactment, the Federal Circuit candidly remarked that demonstrating causation for off-table injuries requires “heavy lifting” on a petitioner’s part, and “it is not surprising that petitioners have a difficult time proving off-table cases.”¹⁸ Speaking in the context of on-/off-table injuries, even the Chief Special Master of the vaccine injury compensation program “chastised the government for ‘alter[ing] the game so that it’s clearly in their favor.’”¹⁹

Notwithstanding the extensive challenges in demonstrating an off-table vaccine injury, between 1999 and 2016 six vaccines were added to the vaccine table, none of which had an on-table injury.²⁰ Moreover, the table has been

CLAIMS QUICKLY AND EASILY 2-3 (1999) (criticizing procedures associated with compensation fund for being too slow).

¹³ Mello, *supra* note 7, at 34.

¹⁴ See Claire Laurier Decoteau & Kelly Underman, *Adjudicating Non-Knowledge in the Omnibus Autism Proceedings*, 45 SOC. STUD. SCI. 471, 474 (2015) (outlining how standards of proof for claims brought under vaccing injury compensation program have become more onerous over time).

¹⁵ *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011).

¹⁶ *Id.* at 228-29. This includes general causation—a medical theory linking the vaccine with an adverse health consequence—and specific causation, which looks to whether the vaccine caused the petitioner’s injury. Betsy J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 HARV. J. ON LEGIS. 343, 347 (2011) (describing causation issues in cases brought under Vaccine Act).

¹⁷ INST. OF MED., VACCINE SUPPLY AND INNOVATION 155 (1985) [hereinafter 1985 IOM REPORT].

¹⁸ *Althen v. Sec’y of Health and Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

¹⁹ Engstrom, *supra* note 8, at 1704 (alterations in original) (quoting ARTHUR ALLEN, VACCINE: THE CONTROVERSIAL STORY OF MEDICINE’S GREATEST LIFESAVER 266 (2007)).

²⁰ 2014 GAO REPORT, *supra* note 12, at 17. For seven vaccines (hepatitis A, hib, HPV, influenza, meningococcal, pneumococcal, and varicella), a rule incorporating on-table injuries was finalized on January 19, 2017. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294 (Jan. 19, 2017) (codified

narrowed over the years.²¹ For example, in 1995, when the Secretary of the Department of Health and Human Services (“HHS”) removed many injuries from the table, the agency admittedly did not consider reported vaccine adverse events from major databases, stating that “it was unnecessary for the information it relied upon to be ‘definite and conclusive before any changes are made.’”²² Since that time, the percent of petitions alleging off-table injuries has risen considerably. In 1999, off-table petitions comprised 25% of all claims; by 2005 and 2014, the figures were 59% and 98%, respectively.²³ Although the Vaccine Injury Table was recently expanded in light of findings from a 2012 IOM study,²⁴ several fundamental issues remain. Of the 158 potential vaccine-related adverse events that the IOM examined, the committee rejected causality in five (3.2%) cases, accepted causality in four (2.5%) cases, and found that the evidence convincingly supports causality in fourteen (8.9%) cases; notably, the committee concluded that more data were needed to evaluate causality for 135 (85.4%) of the identified adverse events.²⁵

Yet, the Vaccine Act does not mandate that data integral to evaluating causation be collected by manufacturers, submitted to regulators, or made available to the public.²⁶ As experts from the Centers for Disease Control and Prevention (“CDC”) and Food and Drug Administration (“FDA”) note, “[no] vaccine is perfectly safe or effective,” and risk-benefit analysis for each vaccine is “a dynamic process” that requires continuous monitoring.²⁷ This is particularly true for vaccine-related injuries that are rare, materialize over time, or manifest only if a vaccine is combined with other medical treatments or

at 42 C.F.R. pt. 100). The revised table became effective on March 21, 2017, though it does not apply to vaccine-injury petitions filed prior to that date. *See* 42 C.F.R. § 100.3 (2017) [hereinafter Vaccine Injury Table].

²¹ *See* Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 789-90 (2011) (stating that table “has been significantly changed and narrowed over the years so that today it plays only a limited role in Vaccine Act cases”).

²² *Id.* at 800.

²³ 2014 GAO REPORT, *supra* note 12, at 20 (finding, inter alia, that changes to table led to increase in claims for off-table injuries).

²⁴ *See supra* note 20. Notably, the updates to the table became effective five years after a comprehensive IOM report called for the revisions. *See* INST. OF MED., ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY (2012) [hereinafter 2012 IOM REPORT] (describing results of extensive vaccine safety study).

²⁵ *Id.* at 719-33 tbl.D-4.

²⁶ 42 U.S.C. §§ 300aa-21, -23 (2012).

²⁷ Robert T. Chen et al., *The Vaccine Adverse Event Reporting System (VAERS)*, 12 VACCINE 542, 542 (1994). Before a vaccine is licensed and made available to the public, it undergoes extensive lab testing and studies. For a thorough overview of vaccine development, see generally Jeffrey P. Baker & Samuel L. Katz, *Childhood Vaccine Development: An Overview*, 55 PEDIATRIC RES. 347 (2004).

environmental factors.²⁸ As such, robust post-market research related to safety and efficacy is necessary to uncover the breadth and depth of vaccine-related adverse health effects. As CDC and FDA officials explain, however, “no active effort is made to search for, identify and collect information [on vaccine adverse events], but rather information is passively received from those who choose to voluntarily report their experience.”²⁹

Although “Congress assumed that better evidence regarding harms caused by vaccines would develop over time,” this assumption has not manifested due to serious limitations in vaccine adverse event collection and analysis.³⁰ In turn, the extent of vaccine risks is not entirely known, and it is immensely difficult to succeed on a claim alleging an off-table injury. Furthermore, whereas Congress intended for vaccine-injury compensation claims to be handled “quickly, easily and with certainty and generosity,”³¹ several special masters³² have indicated that the government is “‘over-litigating’ and ‘behaving like an adversary,’ contrary to the intent of the program.”³³ The average petition takes more time to adjudicate than the average tort or medical malpractice case.³⁴ Moreover, in some cases where a petitioner successfully proved that a vaccine caused an injury, the government threatened to appeal the matter if the petitioner did not agree to keep the decision confidential. This quid pro quo served to prevent disclosure of evidence that could be used in other cases.³⁵

In practical terms, this has resulted in a large decrease in the percentage of compensation awards and a large increase in the time, cost, and effort needed to

²⁸ 1985 IOM REPORT, *supra* note 17, at 65-68 (addressing challenges associated with determining accurate frequency of vaccine-related adverse events). As the IOM noted, “[a]lthough hundreds or thousands of individuals may . . . receive[] a vaccine prior to full licensure, these numbers are insufficient to identify rare untoward events resulting from the vaccine.” *Id.* at 3. Furthermore, some vaccine-related injuries may be triggered by individual reactions to vaccine components or trace elements, such as eggs, antibiotics, or gelatin. PHARM. RESEARCH & MFRS. OF AM., VACCINE FACT BOOK 23 (2013).

²⁹ Tom T. Shimabukuro et al., *Safety Monitoring in the Vaccine Adverse Event Reporting System (VAERS)*, 33 VACCINE 4398, 4398 (2015).

³⁰ Grey, *supra* note 16, at 346.

³¹ H.R. REP. NO. 99-908, pt. 1, at 3 (1986).

³² Special masters are appointed by the Court of Federal Claims and are charged with adjudicating vaccine compensation petitions. *See Vaccine Claims/Office of Special Masters*, U.S. COURT OF FED. CLAIMS, <http://www.uscfc.uscourts.gov/vaccine-program-readmore> [<https://perma.cc/8SA7-AD5W>] (last visited Nov. 14, 2017).

³³ MOLLY T. JOHNSON ET AL., FED. JUDICIAL CTR., USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 44 (1998).

³⁴ Engstrom, *supra* note 8, at 1686-87.

³⁵ Myron Levin, *Vaccine Injury Claims Face Grueling Fight; Victims Increasingly View U.S. Compensation Program As Adversarial and Tightfisted*, L.A. TIMES, Nov. 29, 2004, at A1.

bring a successful claim.³⁶ At the same time, the Trust Fund—an account composed of proceeds from a seventy-five cent excise tax on each vaccine dose—has a balance of over \$3.6 billion,³⁷ and in many years the interest on the Trust Fund has been sufficient to cover payment of all claims.³⁸ Notwithstanding the bulging surplus, the government quibbles over minor requests, even from successful claims. In one case, the government argued that a fourteen-year-old girl who suffered vaccine-related “profound mental retardation and severe spastic quadriplegia” was not entitled to forty-dollar high-top tennis shoes; in another, the government disputed whether a ten-year-old girl who was crippled by a vaccine was entitled to eight hours per day of a nurse assistant—the government urged the special master to grant only five hours.³⁹ According to Congressman Henry Waxman, a sponsor of the Vaccine Act, the Trust Fund was not intended to be a moneymaker, but rather was created to “err on the side of compensating the victim.”⁴⁰

Taken together, there are important questions as to whether the Vaccine Act adequately encourages research into vaccine safety and efficacy, and whether the law affords children who suffer vaccine-related injuries appropriate remedies. Questions also remain as to whether the Vaccine Act has incentivized competition in the vaccine market. In 1982, for the three recommended childhood vaccines—polio; measles, mumps, and rubella (“MMR”); and diphtheria, tetanus, and pertussis vaccine (“DTP”)—there was one manufacturer for polio and MMR, and three for DTP.⁴¹ By 1985, litigation risk drove two of the DTP manufacturers out of the market, leading to higher costs and a temporary shortage.⁴² Though one of the DTP manufacturers returned, lawmakers argued that the Vaccine Act was necessary to incentivize competition and avoid the risks of a consolidated market, such as unstable supply, vaccine shortages, higher costs, and stunted research and development.⁴³

³⁶ *Id.* The majority of petitions took more than five years to be adjudicated, and many took ten years or more. *Id.*; see also 2014 GAO REPORT, *supra* note 12, at 9-12.

³⁷ U.S. DEP’T OF HEALTH & HUMAN SERVS., ADVISORY COMM’N ON CHILDHOOD VACCINES, VACCINE INJURY COMPENSATION TRUST FUND STATEMENT (2016) [hereinafter TRUST FUND STATEMENT].

³⁸ Levin, *supra* note 35, at 2.

³⁹ Engstrom, *supra* note 8, at 1692 (collecting examples of disputes that arose under vaccine injury compensation program).

⁴⁰ Levin, *supra* note 35, at 3.

⁴¹ Baker & Katz, *supra* note 27, at 352.

⁴² *Id.*

⁴³ Engstrom, *supra* note 8, at 1657. At the time, some commentators questioned the motives of manufacturers, and wondered whether they were “orchestrating a program to encourage Congress to relieve them of liability.” Arnold W. Reitze, *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 195 (1986).

Three decades later, however, the vaccine market remains highly consolidated, and anticipated savings have not materialized.⁴⁴ Today, four companies dominate the market (Merck, Sanofi-Pasteur, Pfizer, and GlaxoSmithKline),⁴⁵ notwithstanding the fact that the vaccine industry has experienced a “spectacular growth rate” of ten to fifteen percent per year, which is more than double the rate for pharmaceuticals.⁴⁶ Prices have increased significantly, particularly for vaccines for which there is only one manufacturer. Between 1986 and 2014, the cost to vaccinate a child rose from \$100 to \$2192.⁴⁷ Of the childhood vaccines marketed in the United States in 2017, eleven vaccines have one manufacturer and eight vaccines have two manufacturers.⁴⁸

As was the case prior to the Vaccine Act, today’s vaccine supply is largely dependent on a very small number of manufacturers, and market consolidation remains a factor that threatens public health.⁴⁹ The Vaccine Act’s legal protections for manufacturers are sufficient to ensure that litigation risk is unlikely to be a factor that drives a company out of the market. However, the consolidated market also means that companies have little to no competition, and thus little incentive to allocate resources to improve their products, particularly because federal law preempts design defect claims.⁵⁰ Moreover, manufacturers often have encountered disruptions in production or contamination of vaccine lots, and vaccine shortages have resulted. Since 2000, the United States “has experienced an unprecedented series of shortages” for thirteen vaccines, and none of the shortages was caused by litigation or fear of litigation.⁵¹ Although the economic forces that have led to a consolidated market

⁴⁴ Engstrom, *supra* note 8, at 1716 n.394; Elisabeth Rosenthal, *The Price of Prevention: Vaccine Costs Are Soaring*, N.Y. TIMES, July 2, 2014, at A1.

⁴⁵ VFC CDC Vaccine Price List Archives, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION [hereinafter *CDC Vaccine Price List*], <https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/archive.html> [<https://perma.cc/SK5T-HC7V>] (last updated Sept. 1, 2017).

⁴⁶ Miloud Kaddar, Senior Adviser, World Health Org., Address: Global Vaccine Market Features and Trends 4 (Jan. 16, 2013).

⁴⁷ Rosenthal, *supra* note 44. The price increase is due to several factors, including, but not limited to, additional vaccines, exploitation of monopoly status, and manufacturing costs. *Id.*; see also Weiwei Chen et al., *Trends in Childhood Vaccine Purchase Costs in the US Public Sector: 1996-2014*, 34 VACCINE 4706, 4706-11 (2016).

⁴⁸ Rosenthal, *supra* note 44; see also David Ridley et al., *No Shot: US Vaccine Prices and Shortages*, 35 HEALTH AFF. 235, 236 (2016); *CDC Vaccine Price List*, *supra* note 45. Currently, only two vaccines have more than two manufacturers: hib (three manufacturers) and influenza for children over the age of three (four manufacturers). *Id.*

⁴⁹ 1985 IOM REPORT, *supra* note 17, at 2; Chen et al., *supra* note 47, at 4706-11.

⁵⁰ 1985 IOM REPORT, *supra* note 17, at 146.

⁵¹ Alan R. Hinman et al., *Vaccine Shortages: History, Impact, and Prospects for the Future*, 27 ANN. REV. PUB. HEALTH 235, 235 (2006); see also GERRY FAIRBROTHER & ARFANA HAIDERY, VACCINE PURCHASE AND DISTRIBUTION: PROPOSED CHANGES IN VACCINE SUPPLY AND DELIVERY POLICIES 11-12 (2002); PAUL A. OFFIT, THE CUTTER INCIDENT: HOW

are different today than they were in the 1980s,⁵² the potential pitfalls are no less significant. Yet, notwithstanding rising costs and frequent vaccine shortages, lawmakers have not stepped in to remedy the vaccine regime, let alone with the zeal exhibited three decades ago.

Meanwhile, the past decade has witnessed intense public debate surrounding vaccine mandates and a rise in vaccine-hesitant parents.⁵³ While commentators often portray vaccine hesitant parents as ill-informed dilettantes clinging to unscientific Internet chatter or a debunked study that linked vaccines and autism,⁵⁴ there is much more to the story. One recent study found that thirteen percent of parents believe that vaccines are most likely a cause of autism (a claim for which there is no scientific evidence),⁵⁵ yet other studies have found that more than seventy-five percent of parents have concerns with vaccine safety and that four percent of pediatricians have refused a vaccine for their own child.⁵⁶

AMERICA'S FIRST POLIO VACCINE LED TO A GROWING VACCINE CRISIS xii (2005) ("Since 1998, there have been severe shortages of nine of the twelve vaccines routinely given to young children."); Evans, *supra* note 4, at S134 (asserting that recent vaccine shortages are not due to liability concerns); Ridley et al., *supra* note 48, at 235-38 (examining how price fluctuations impact vaccine supplies). Vaccine production problems can arise from myriad sources, including: "potency variation"; "stability problems"; "quantitative imbalance of microbial components in polyvalent or combination vaccines"; "variations in responses to inactivation problems"; "excessive undesirable biological activity, e.g., neurovirulence"; and "inadvertent contamination." 1985 IOM REPORT, *supra* note 17, at 29.

⁵² 1985 IOM REPORT, *supra* note 17, at 34-40, 50-63. To be sure, consolidation within the vaccine industry occurred throughout the second half of the twentieth century. Between 1967 and 1985 the number of vaccine manufacturers decreased from twenty-seven to fifteen, in part due to litigation stemming from vaccine-related injuries. As with any industry, however, no single factor led to market consolidation in the vaccine industry. *Id.*; Baker & Katz, *supra* note 27, at 352; *see generally* Julia Porter Liebeskind et al., *Corporate Restructuring and the Consolidation of US Industry*, 44 J. INDUS. ECON. 53 (1996).

⁵³ Kathryn Edwards & Jesse Hackell, *Countering Vaccine Hesitancy*, 138 PEDIATRICS e1, e1 (2016).

⁵⁴ *See, e.g.*, Peter J. Hotez, Editorial, *How the Anti-Vaxxers Are Winning*, N.Y. TIMES, Feb. 8, 2017, at A25; Eric Kodish, Opinion, *The Ethical Negligence of Parents Who Refuse to Vaccinate Their Children*, WASH. POST (June 26, 2014), https://www.washingtonpost.com/news/to-your-health/wp/2014/06/26/the-ethical-negligence-of-parents-who-refuse-to-vaccinate-their-children/?utm_term=.759cde9d9b9f [<https://perma.cc/29LL-H5Q6>]; Arthur Caplan, Opinion, *Ethicist: Why Jim Carrey Is Wrong About Vaccines*, NBC NEWS (July 1, 2015), <https://www.nbcnews.com/health/health-news/commentary-why-jim-carrey-wrong-about-vaccines-n385321> [<https://perma.cc/2XGC-LGSF>]; Eli Watkins, *Anti-Science Claims Dog Green Party's Jill Stein*, CNN (Aug. 17, 2016, 11:59 AM), <http://www.cnn.com/2016/08/16/politics/jill-stein-vaccine-gmo-science/index.html> [<https://perma.cc/56UV-B5ZG>].

⁵⁵ Ruth Fischbach et al., *Is There Concordance in Attitudes and Beliefs Between Parents and Scientists About Autism Spectrum Disorders?*, 20 AUTISM 353, 356 (2016) (noting that no scientist surveyed believed that vaccines are most likely a cause of autism).

⁵⁶ Douglas J. Diekema, *Responding to Parental Refusal of Immunization of Children*, 115 PEDIATRICS 1428, 1428 (2005); Douglas J. Opel et al., *The Relationship Between Parent*

These studies suggest that, while a majority of parents do not believe that vaccines cause autism, a majority nonetheless has concerns with vaccine safety. These concerns are captured by the term “vaccine hesitancy,” which comprises a “spectrum of parental attitudes,” including individuals who “accept all vaccines but remain concerned about them, . . . refuse or delay some vaccines but accept others, or . . . refuse all vaccines.”⁵⁷

A common thread underlying vaccine hesitancy is a lack of trust in government and industry.⁵⁸ Insofar as trust in an institution impacts trust in the message proffered by the institution, source credibility is particularly important for vaccine-related information.⁵⁹ Yet public trust in government has decreased enormously over the past six decades, and trust in the CDC and FDA is decreasing at a significantly faster rate than the general rate of other governmental agencies.⁶⁰ Trust in industry is also lacking, and many Americans “believe that government regulators and vaccine manufacturers work in

Attitudes About Childhood Vaccines Survey Scores and Future Child Immunizations, 167 JAMA PEDIATRICS 1065, 1066 (2013).

⁵⁷ Edwards & Hackell, *supra* note 53, at e2. For example, a survey of over eleven thousand parents found that 25.8% delayed immunization, 8.2% refused a vaccine, and 5.8% both delayed and refused a vaccine. Philip Smith et al., *Parental Delay or Refusal of Vaccine Doses, Childhood Vaccination Coverage at 24 Months of Age, and the Health Belief Model*, 126 PUB. HEALTH REP. 135, 137 (2011).

⁵⁸ See, e.g., Alvin Nelson El Amin et al., *Ethical Issues Concerning Vaccination Requirements*, 34 PUB. HEALTH REV. 1, 14 (2012) (“[A] significant number of today’s parents are suspicious of government.”). A recent case filed against Merck, alleging that the company hid efficacy concerns of the mumps component of the MMR vaccine, might add to such mistrust. See Ed Silverman, *Merck Is Accused of Stonewalling over Effectiveness of Mumps Vaccine*, DOW JONES INSTITUTIONAL NEWS (June 8, 2015), available at <https://blogs.wsj.com/pharmalot/2015/06/08/merck-is-accused-of-stonewalling-over-effectiveness-of-mumps-vaccine/>. Merck’s motion to dismiss was denied, though the court has yet to rule on the merits. See *United States ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 587 (E.D. Pa. 2014). Meanwhile, nationwide there have been several outbreaks of mumps amongst vaccinated individuals, raising questions as to the vaccine’s effectiveness. See Helen Branswell, *Mumps Outbreaks Are Spiking—and Raising Questions About Vaccine Effectiveness*, STATNEWS (Mar. 20, 2017), <https://www.statnews.com/2017/03/29/mumps-outbreaks/> [<https://perma.cc/QG4W-UL6X>]; Dina Fine Maron, *What’s Behind the 2016 Mumps Spike in the U.S.?*, SCI. AM. (Dec. 16, 2016), <https://www.scientificamerican.com/article/whats-behind-the-2016-mumps-spike-in-the-u-s/> [<https://perma.cc/S6H8-TDLF>]; see also Steven A. Rubin et al., *Recent Mumps Outbreaks in Vaccinated Populations: No Evidence of Immune Escape*, 86 J. VIROLOGY 615, 615 (2012).

⁵⁹ Ioannis Kareklas et al., *Reexamining Health Messages in the Digital Age: A Fresh Look at Source Credibility Effects*, 44 J. ADVERT. 88, 88 (2015).

⁶⁰ PEW RESEARCH CTR., *THE PEOPLE AND THEIR GOVERNMENT: DISTRUST, DISCONTENT, ANGER AND PARTISAN RANCOR 2* (2010). One comprehensive study found that twenty-two percent of Americans trusted their government “almost always” or “most of the time,” down from seventy-three percent in 1958. *Id.*

collusion.”⁶¹ The rise in anti-establishment and anti-government rhetoric (notably, during the 2016 presidential election, but also present in the Tea Party and Occupy Wall Street movements) underscores the real-world impact of declining trust and the resonance that such positions have with the public. Politics aside, declining public trust in government creates massive hurdles for public health officials.⁶²

The question of whether vaccine laws need recalibration commands serious attention. Although there are significant public health implications in reduced vaccination rates—concerns that do not remain within state borders—the Vaccine Act does little to address the core reasons underlying vaccine hesitancy. To be sure, the unique federal-state dynamic surrounding immunization laws further complicates the inquiry. Each state uses its police power to establish vaccine mandates, yet federal law affords vaccine manufacturers preemption from state tort claims for vaccine-related injuries. At the same time, the Vaccine Act’s mandate is to “achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.”⁶³ In this hybrid model, the state mandates that citizens engage in conduct that the state has determined is necessary for the public health and welfare, but the federal government maintains integral public health goals and precludes state tort claims should an injury occur from the state-mandated action. Few areas of the law are analogous.⁶⁴

Notwithstanding the imminent need to address vaccine-related issues, there are frequent and consistent roadblocks to debating the limitations of immunization law and policy. In the face of challenges to vaccine orthodoxy, scholars, commentators, and public health officials are quick to characterize dissent as mere propaganda of “anti-vaxxers.”⁶⁵ Even suggestions for reform

⁶¹ El Amin et al., *supra* note 58, at 14; *see generally* Michelle M. Mello et al., *Pharmaceutical Companies’ Role in State Vaccination Policymaking: The Case of Human Papillomavirus Vaccination*, 102 AM. J. PUB. HEALTH 893 (2012) (examining Merck’s role in shaping vaccine policy).

⁶² This impact is exacerbated by the hyper-politicization of health care and health law, which has spillover effects in the context of vaccine mandates and may exacerbate the perceived risks of vaccines. *See, e.g.*, EULA BISS, ON IMMUNITY 37 (2014); Diekema, *supra* note 56, at 1428. The ubiquity of social media compounds these concerns, as theories of vaccine safety can spread quickly prior to scientific inquiry. *See* Douglas J. Opel et al., *Social Marketing as a Strategy to Increase Immunization Rates*, 163 ARCHIVES PEDIATRICS ADOLESCENT MED. 432, 433 (2009).

⁶³ 42 U.S.C. § 300aa-1 (2012).

⁶⁴ For an excellent analysis of the unique circumstances presented by public health and constitutional law, *see* Wendy K. Mariner, George J. Annas & Leonard H. Glantz, Jacobson v. Massachusetts: *It’s Not Your Great-Great-Grandfather’s Public Health Law*, 95 AM. J. PUB. HEALTH 581 (2005).

⁶⁵ Brian Martin, *On the Suppression of Vaccine Dissent*, 21 SCI. ENGINEERING ETHICS 143, 152 (2015).

have led to ad hominem attacks.⁶⁶ If the mere questioning of vaccine law or policy leads to stereotyping as an anti-vaxxer,⁶⁷ rather than any serious inquiry into the underlying issues, there can be little room for intelligent debate regarding the merits and demerits of the current regime. Focusing contemporary vaccine policy debate on anti-vaxxer rhetoric detracts from adequate consideration of important vaccine-related issues.

Although the shortcomings of the Vaccine Act may not be a primary cause of vaccine hesitancy,⁶⁸ addressing the shortcomings can be part of the solution. However, rather than exploring the use of legal levers to adjust aspects of the Vaccine Act, hard paternalism has been the typical response to vaccine hesitancy. This has included more stringent enforcement of vaccine mandates,⁶⁹ elimination of non-medical exemptions to vaccine mandates,⁷⁰ and deprivation of rights and welfare benefits for the families of vaccine-hesitant parents.⁷¹ Often lacking from the policy response is a meaningful examination into the reasons for diminishing public trust in vaccine safety, and whether amendments to the legal and regulatory framework can help make vaccines safer or more effective—something that might help rebuild public trust. While the government should be mindful not to allocate undue resources to combating junk science, the public health can benefit from additional scientific inquiries into vaccine safety and efficacy, particularly because of the known limitations of premarket review and post-market surveillance, and the fact that legal immunities fail to incentivize incorporation of scientific innovations into vaccine design.⁷²

Given the complexity of the vaccine regime, recalibrating vaccine laws requires an analysis that goes beyond the headlines. In this Article, I explain how adjusting levers in the Vaccine Act can help fill compensation and scientific innovation gaps while maintaining legal immunities for vaccine manufacturers. Bridging scholarship in law, medicine, bioethics, and public health, this Article also provides draft legislation that can be utilized by lawmakers, public health

⁶⁶ See, e.g., Watkins, *supra* note 55 (discussing how politicians and other public figures, who simply question aspects of vaccine policy, have been subject to swift criticism).

⁶⁷ See, e.g., *id.* (“Critics have said Stein played toward so-called ‘anti-vaxxers’ when she told the *Washington Post* people had ‘real questions’ over vaccines and their potential side-effects.”).

⁶⁸ See Efthimios Parasidis, *Public Health Law and Institutional Vaccine Skepticism*, 41 J. HEALTH POL., POL’Y & L. 1137, 1138-41 (2016) (outlining oft-cited reasons for vaccine hesitancy).

⁶⁹ See, e.g., Alex Dubov & Connie Phung, *Nudges or Mandates? The Ethics of Mandatory Flu Vaccinations*, 33 VACCINE 2530, 2531 (2015).

⁷⁰ See, e.g., Soumya Karlamangla, *Vaccination Foes Sue to Nullify Law*, L.A. TIMES, July 6, 2016, at B4.

⁷¹ See, e.g., Dubov & Phung, *supra* note 69, at 2533.

⁷² See Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 934 (discussing how legal immunities for manufacturers of medical products negatively impact health outcomes).

officials, and advocates involved in the vaccine debates. The proposals include: (1) adjusting the requirements for adverse event reporting and post-market analysis of vaccine safety and efficacy, (2) predicating limited liability for vaccine manufacturers on compliance with post-market analysis requirements, (3) exempting design defect claims from the preemption provision of the Vaccine Act in cases of negligent failure to utilize a safer alternative design, (4) restructuring the burden of proof for claims alleging off-table vaccine-related injuries, and (5) mandatory minimum investment of Trust Fund proceeds for vaccine research and development. At its core, this Article is a law reform piece that draws on a thorough historical investigation of the nuanced legal and political developments leading up to the enactment of the Vaccine Act. The non-partisan proposals in this Article endeavor to promote the public health goals of immunizations by aligning the interests of patients, public health officials, and vaccine manufacturers, and in doing so, aim to build and maintain public trust in vaccinations.

I. PLACING THE VACCINE ACT IN HISTORICAL CONTEXT

The common narrative is that the Vaccine Act was necessary to provide adequate remedies for injured plaintiffs and to ensure a stable vaccine supply because litigation risk was driving manufacturers out of the vaccine market.⁷³ Although this depiction is not false, a more accurate description considers the broader legal, political, and public health issues preceding the enactment of the Vaccine Act. Contemporary vaccine debates largely have failed to place the Vaccine Act in accurate historical context, notwithstanding the benefits that may be gained from serious reflection on the development of doctrinal nuances and evolving public health challenges.

I focus my historical framing using a tripartite analysis. First, I explore the issue of manufacturer liability for vaccine-related injuries. From the 1950s through the 1980s, courts across the country were mixed on several key issues such as: (1) the contours surrounding the causation elements of a negligence claim; (2) the availability of products liability causes of action for manufacturing, warning, and design defects; and (3) whether market share liability should apply to vaccine-related injuries. Second, I explain how vaccine-injury litigation following the 1976 swine flu immunization program caused the federal government to be cautious about assuming financial responsibility for compensating vaccine-related injuries, and how the swine flu program led manufacturers to demand indemnification from the government for all vaccine-related injuries. Third, I unpack the 1980s-era perfect storm of dissent created by patient advocacy groups, think tanks, and industry lobbyists, whereby the FDA was portrayed as an unnecessary bureaucratic hindrance to access to

⁷³ See, e.g., HEALTH RES. & SERVS. ADMIN., U.S. DEPT. OF HEALTH & HUMAN SERVS., WHAT YOU NEED TO KNOW ABOUT THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP) 3 (2016) [hereinafter HRSA: WHAT YOU NEED TO KNOW]; Evans, *supra* note 4, at S130.

medicines, rather than a consumer protection agency serving the public health. During this period, lawmakers and the public questioned the value of federal regulation of medical products, which provided ample fuel to the Reagan Administration's deregulatory agenda.

Understanding this multi-faceted historical framework not only helps place the Vaccine Act in context, it provides important insights into whether, and to what extent, the Vaccine Act should be amended to account for contemporary issues and trends in vaccine innovation, vaccine-related injuries, and public health policy.

A. *Manufacturer's Liability for Vaccine-Related Injuries*

1. The Cutter Incident and Vaccine-Induced Polio

Lawsuits against manufacturers for vaccine-related injuries were extremely rare during the first half of the twentieth century.⁷⁴ That would change after 1955, the first year that Jonas Salk's polio vaccine became commercially available in the United States.⁷⁵ Cutter Laboratories—one of the five manufacturers licensed to produce the vaccine—employed an unsatisfactory

⁷⁴ After considerable research, I could locate only two published opinions prior to 1955 where a vaccine manufacturer was named as a defendant in a case alleging a vaccine-related injury. *Carmen v. Eli Lilly & Co.*, 32 N.E.2d 729, 732 (Ind. App. 1941) (finding for manufacturer because plaintiff was warned of risk of death from vaccine); *Tremaine v. H.K. Mulford Co.*, 176 A. 212, 214 (Pa. 1935) (finding for manufacturer because plaintiff did not demonstrate vaccine caused his injury). Notwithstanding the dearth of cases against vaccine manufacturers, throughout the first half of the twentieth century, it was not uncommon for employers to provide vaccination programs for their employees (sometimes pursuant to a program initiated by a state or local public health authority); individuals who suffered vaccine-related injuries under such programs sometimes brought claims for compensation against their employer, their insurance company, or both. *See, e.g.*, *Jefferson Printing Co. v. Indus. Comm'n*, 144 N.E. 356, 357 (Ill. 1924); *Neudeck v. Ford Motor Co.*, 229 N.W. 438, 439 (Mich. 1930); *Krout v. J.L. Hudson Co.*, 166 N.W. 848, 848 (Mich. 1918); *Alewine v. Tobin Quarries*, 33 S.E.2d 81, 82 (S.C. 1945); *Texas Emp'rs' Ins. Ass'n v. Mitchell*, 27 S.W.2d 600, 601 (Tex. Civ. App. 1930). The cases typically proceeded under state workers' compensation laws, with plaintiffs alleging the vaccine-related injuries were employment-related. In many cases, compensation was awarded if the vaccination program was not conducted pursuant to an immunization mandate from a public health authority, since courts deemed the vaccination programs to be employment-related. *See, e.g.*, *Neudeck*, 229 N.W. at 439; *Alewine*, 33 S.E.2d at 87; *Texas Emp'rs'*, 27 S.W.2d at 603. However, when employers conducted or sponsored immunization programs pursuant to a request or mandate from a public health authority, compensation typically was unavailable on the grounds that the program was not employment-related but, rather, related to the public health goals as set forth by a governing public authority. *See, e.g.*, *Jefferson Printing*, 144 N.E. at 358; *Krout*, 166 N.W. at 848-49.

⁷⁵ Paul Offit, *The Cutter Incident, 50 Years Later*, 352 NEW ENG. J. MED. 1411, 1411 (2005).

method to inactivate the live polio virus.⁷⁶ One of Salk's researchers told Salk that he had found defective vaccines upon inspecting Cutter's facilities, but neither Cutter, the researcher, nor Salk disclosed this important information to regulators, physicians, or the public.⁷⁷ Moreover, although Cutter provided regulators with vaccine lots for testing, it only submitted lots that had passed internal company safety tests.⁷⁸ In turn, over two hundred thousand American children were administered a defective polio vaccine; approximately forty thousand children contracted polio, two hundred were paralyzed, and ten died.⁷⁹ The children who contracted vaccine-induced polio also caused a "polio epidemic" amongst their families and communities.⁸⁰ According to Paul Offit, a pediatrician and expert on vaccine policy, this "was one of the worst pharmaceutical disasters in U.S. history."⁸¹

Several lawsuits were filed against vaccine manufacturers.⁸² The first one to reach trial was *Gottsdanker v. Cutter Laboratories*, a consolidated case brought

⁷⁶ *Id.* ("[T]wo production pools made by Cutter Laboratories (accounting for 120,000 doses) contained live poliovirus.")

⁷⁷ OFFIT, *supra* note 51, at 63-65. Fifty years later, the researcher, Julius Youngner, remarked:

There is not a day that goes by when I don't feel personally responsible for what happened. . . . I could have done something, but I didn't. I was too trusting, too naïve. I blamed Jonas, but I should only blame myself. . . . My relationship with Salk was never the same again. I saw him a few years ago and reminded him of what happened the day I returned from Cutter. He was passive—said nothing, as if he had blanked it out.

Id. at 65.

⁷⁸ *Id.* at 67 (stating that regulators were unaware that Cutter was submitting only prescreened lots).

⁷⁹ Michael Fitzpatrick, Book Review, 99 J. ROYAL SOC'Y MED. 156, 156 (2006) (citing OFFIT, *supra* note 51).

⁸⁰ Offit, *supra* note 75, at 1411 ("Cutter's vaccine also started a polio epidemic: 113 people in the children's families or communities were paralyzed, and 5 died.")

⁸¹ *Id.*

⁸² In addition to lawsuits against vaccine manufacturers, several cases were filed against the Division of Biologic Standards ("DBS"), the governmental agency responsible for issuing licenses that granted manufacturers the legal authority to produce and sell vaccines. For example, in a consolidated action surrounding oral polio vaccine ("OPV") and Lederle Laboratories, plaintiffs alleged that DBS violated regulations governing vaccine production by:

(1) issuing a product license to Lederle on the basis of inadequate epidemiological data and laboratory test results which demonstrated that Lederle's original strains and seeds were not sufficiently safe, (2) approving for use and/or not retesting the seeds from which the doses injuring them were derived and (3) approving for release the specific lots containing the injurious doses.

In re Sabin Oral Polio Vaccine Prods. Liab. Litig., 743 F. Supp. 410, 413 (D. Md. 1990). The court dismissed the case in part, finding that DBS's issuance of the license constituted a "discretionary function" under the Federal Tort Claims Act, and thus the court was precluded from reviewing DBS's decision. *Id.* at 414-16. The court also granted summary judgment for

on behalf of two children who contracted polio after being administered a defective vaccine.⁸³ Plaintiffs alleged that Cutter (1) negligently produced the vaccine, (2) breached an implied warranty of merchantability, and (3) breached an implied warranty of fitness.⁸⁴ While the jury found Cutter not negligent,⁸⁵ the jury also ruled that Cutter breached the implied warranties of merchantability and fitness, and awarded each plaintiff approximately \$73,000.⁸⁶

Cutter appealed, but a California appellate court affirmed the jury's verdict.⁸⁷ One issue on appeal was whether Cutter could be legally responsible, given that it sold the vaccine to a pharmacy, the doctor purchased the vaccine from the pharmacy, and the doctor administered the vaccine to the child.⁸⁸ As the court noted, "privity of contract (i.e., direct sale from defendant to plaintiff) remains a requirement for implied warranty liability in substantially all American jurisdictions."⁸⁹ While the rule also applied generally in California, the court indicated that "the modern trend" was to "modify the strictness of the requirement in some situations."⁹⁰ Insofar as California courts had relaxed the privity requirement in cases alleging harm from food-borne illnesses, the

the government on several points, including plaintiff's claims regarding the insufficiency of data submitted by Lederle to DBS, and DBS's failure to adequately evaluate the seeds from which the initial vaccine lots were produced. *Id.* at 421. One issue to survive summary judgment was whether the seed material or vaccine lots satisfied the neurovirulence requirements in the governing regulations. *Id.* at 417-18 (denying summary judgment for government because neurovirulence determinations required qualitative comparative evaluation, and the proffered test results provided merely numerical comparison).

⁸³ *Gottsdanker v. Cutter Labs.*, 6 Cal. Rptr. 320, 322 (Cal. Dist. Ct. App. 1960). One of the plaintiffs, Anne Gottsdanker, was a five-year-old girl whose leg was paralyzed after inoculation with a defective vaccine. *See Offit, supra* note 75, at 1411. In total, sixty lawsuits were filed against Cutter. *See OFFIT, supra* note 51, at 133.

⁸⁴ *Gottsdanker*, 6 Cal. Rptr. at 322.

⁸⁵ *Id.* The opinion does not state the reason for this finding. For one analysis of why the negligence claim was difficult to prove, see Note, *The Cutter Polio Vaccine Incident: A Case Study of Manufacturer's Liability Without Fault in Tort and Warranty*, 65 YALE L.J. 262, 263-65 (1955). Interestingly, by the late 1970s, animal vaccine-injury cases "far outnumbered" human vaccine-injury cases. Thomas E. Baynes, *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 ST. LOUIS U. L.J. 44, 45-47 (1977). Most cases were based on negligence theories, and they were largely unsuccessful because plaintiffs had difficulties demonstrating causation. *Id.*

⁸⁶ *Gottsdanker*, 6 Cal. Rptr. at 322 ("The actions were consolidated for trial. Jury verdicts were in favor of the two children for a total of \$139,000, and for their parents for \$8,300 in special damages."). Adjusted for inflation, \$73,000 equates to about \$600,000 in 2017. *See U.S. Inflation Calculator*, COINNEWS MEDIA GRP., <http://www.usinflationcalculator.com> [<https://perma.cc/6NP3-BD54>] (last visited Nov. 14, 2017).

⁸⁷ *Gottsdanker*, 6 Cal. Rptr. at 326.

⁸⁸ *Id.* at 322.

⁸⁹ *Id.*

⁹⁰ *Id.*

Gottsdanker court held that “[w]e have no hesitation in holding that the absence of privity does not bar recovery on implied warranty from the manufacturer of the vaccine.”⁹¹

The *Gottsdanker* court distinguished vaccine efficacy claims from vaccine safety claims. As the court noted, the vaccine label contained “a clear disclaimer as to the efficacy of the vaccine, but that is not an issue here. Plaintiffs do not claim that the vaccine failed to protect them against poliomyelitis. They do assert that the vaccine itself caused the disease.”⁹² The court rejected Cutter’s position that the disclaimer on the vaccine bottle was sufficient to negate plaintiff’s allegations that Cutter breached implied warranties of merchantability and fitness. Specifically, the court found that the argument carries “little weight where, as here, the warranty is limited to an assurance that the product will not actively cause the very disease it was designed to prevent.”⁹³ At the same time, however, the court theorized that Cutter’s argument “might have merit if the warranty involved had to do with the mere failure of a medicine to cure or of a vaccine to prevent.”⁹⁴ In drawing this line, the court distinguished a claim related to a vaccine-induced adverse event from one related to the failure of a vaccine to confer immunity, allowing damages for the former but suggesting that the latter may not be actionable.⁹⁵

The court also addressed the policy impact of its decision, noting that Cutter “strongly argues that public policy will best be served by denying recovery in warranty for ‘new’ drugs. The argument is that development of medicines will be retarded if manufacturers are held to strict liability for their defects.”⁹⁶ The court rejected this contention, indicating that the California legislature was aware of the issue but decided not to incorporate an exception to strict liability for vaccine-related injuries.⁹⁷

The Cutter Incident, as this tragic episode would later be known,⁹⁸ is important for several reasons. First, *Gottsdanker* set a precedent that manufacturers may be liable for vaccine-induced diseases. Insofar as all five manufactures of the polio vaccine had difficulty inactivating the polio virus,

⁹¹ *Id.* at 323. In finding that a relaxed privity requirement was appropriate, the court cited to *Vaccarezza v. Sanguinetti*, 163 P.2d 470 (Cal. Dist. Ct. App. 1945). In *Vaccarezza*, a mother and her two children suffered food poisoning after eating contaminated salami. *Id.* at 472. Even though the salami was purchased at a retail market, the plaintiffs successfully sued the salami manufacturer. *Id.*

⁹² *Gottsdanker*, 6 Cal. Rptr. at 325-26.

⁹³ *Id.* at 326.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* (“If a sound public policy requires extension of this exception to biologics generally, or to polio vaccine specifically, the argument properly is one for the Legislature.”).

⁹⁸ See generally OFFIT, *supra* note 51.

this was a significant holding that led to several settlements in analogous cases.⁹⁹ Second, the California court opened the door to strict liability claims for vaccine-related adverse events. Although the facts in *Gottsdanker* were limited to a vaccine-induced disease, the court did not preclude extension of its reasoning to other vaccine-related adverse events. Indeed, the court's distinction between a vaccine-induced disease and the failure to confer immunity may be characterized as a demarcation between vaccine safety and vaccine efficacy—with liability attaching to the former but not the latter. Third, following the Cutter Incident, a congressional committee found that the National Institutes of Health (“NIH”) Laboratory of Biologics Control—the government entity responsible for certifying the Cutter polio vaccine—received advance warning of the problems with the Cutter vaccine but failed to take appropriate measures to address them.¹⁰⁰ The congressional committee's findings underscored the importance of robust regulatory oversight in the licensing, production, and distribution of vaccines, and the negative impact on public health that may flow from insufficient oversight. Fourth, the court squarely rejected Cutter's argument regarding the policy impact of legal liability on vaccine innovation.¹⁰¹ Indeed, one year after the lawsuits, Cutter executives boasted of the company's “financial soundness,” and by 1962 company assets were “80% greater than when the polio disaster had occurred.”¹⁰²

As is often the case following a public health catastrophe, the Cutter Incident motivated action from public officials and regulators. Within days of the Cutter Incident, the Surgeon General recommended that all polio vaccinations be halted “pending inspection of each manufacturing facility and thorough review of the procedures for testing vaccine safety.”¹⁰³ Shortly thereafter, “every senior US government employee involved in the Cutter incident lost his or her job, right up to the director of the [NIH] and the secretary for health, education, and welfare.”¹⁰⁴ In addition, the NIH Laboratory of Biologics Control “was raised to

⁹⁹ See, e.g., *id.* at 100-33.

¹⁰⁰ EDWARD SHORTER, *THE HEALTH CENTURY 68-70* (1987).

¹⁰¹ *Gottsdanker*, 6 Cal. Rptr. at 326.

¹⁰² OFFIT, *supra* note 51, at 166-68. As Gottsdanker's lawyer later observed, the lawsuits and settlements “didn't hurt business or consumers.” *Id.* at 168. In the 1970s, Cutter Laboratories was purchased by the German pharmaceutical firm, Bayer. *History of Bayer, 1974-1988*, BAYER, <https://www.bayer.com/en/1974-1988.aspx> [<https://perma.cc/4KD2-X38C>] (last visited Nov. 14, 2017).

¹⁰³ *Vaccine Timeline*, IMMUNIZATION ACTION COALITION, <http://www.immunize.org/timeline/> [<https://perma.cc/53QA-MJAT>] (last visited Nov. 14, 2017). As Offit explains, “[i]ronically the Cutter Incident—by creating the perception among scientists and the public that Salk's vaccine was dangerous—led in part to the development of a polio vaccine [OPV] that was more dangerous.” OFFIT, *supra* note 51, at 124.

¹⁰⁴ Meredith Wadman, *Germ Warfare: The Battle for the Key to Modern Vaccines*, *GUARDIAN* (Feb. 2, 2017, 1:00 PM), <https://www.theguardian.com/society/2017/feb/02/vaccines-battle-germ-warfare-antiviral-leonard-hayflick-wistar-hilary-koprowski> [<https://perma.cc/5TH8-3EF9>]; see also OFFIT, *supra* note 51, at 118.

division status within NIH,” a move that permitted expanded oversight of vaccines.¹⁰⁵

Thereafter, Congress enacted the Polio Vaccination Assistance Act of 1955.¹⁰⁶ This Act provided grants to states for creating immunization programs and purchasing and distributing polio vaccines.¹⁰⁷ The public, however, was alarmed by the Cutter Incident and hesitant to receive polio vaccines.¹⁰⁸ At the same time, the government feared a shortage would ensue because of virus inactivation challenges faced by vaccine manufacturers.¹⁰⁹ As the chief of the Public Health Service’s Bureau of State Services stated, the new program afforded “the public health profession . . . the opportunity and obligation to achieve widespread acceptance and use” of the newly marketed polio vaccine.¹¹⁰

Notwithstanding the importance of *Gottsdanker* and the public health measures implemented in the wake of the Cutter Incident, courts in most states disagreed with the California court’s holding. For example, many courts denied vaccine-injury claims, concluding that privity of contract did not exist because the injured patient did not buy the vaccine directly from the manufacturer.¹¹¹ This legal loophole insulated vaccine manufacturers and made compensation for vaccine-related injuries nearly impossible in many states. Indeed, the *Gottsdanker* court noted that, as of 1960, a relaxed privity requirement was the “minority rule” that was “followed in some 15 to 18 states.”¹¹² Consequently, many individuals who died, became paralyzed, or otherwise suffered vaccine-related injuries had no legal recourse against the vaccine manufacturer.

2. Cancer and SV40 Contaminated Polio Vaccines

The Cutter Incident was linked to forty thousand cases of vaccine-induced polio, but in its wake a new polio-vaccine-related scare was unfolding. Between 1955 and 1963, over ninety-eight million Americans were inoculated with a polio vaccine that was potentially contaminated with simian virus 40 (“SV40”),¹¹³ a virus that has been found in certain types of cancer such as

¹⁰⁵ IMMUNIZATION ACTION COALITION, *supra* note 103.

¹⁰⁶ See Otis L. Anderson, *The Polio Vaccine Assistance Act of 1955*, 45 AM. J. PUB. HEALTH 1349, 1349 (1955).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ See, e.g., *Berry v. Am. Cyanamid Co.*, 341 F.2d 14, 19 (6th Cir. 1965).

¹¹² *Gottsdanker v. Cutter Labs.*, 6 Cal. Rptr. 320, 323 (Cal. Dist. Ct. App. 1960). By 1968, however, a majority of states had relaxed the privity requirement. See, e.g., *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 127 (9th Cir. 1968) (assuming “Montana would follow the majority of other states in finding that liability can attach to the sale of drugs . . . despite lack of privity”).

¹¹³ Keerti V. Shah, *SV40 and Human Cancer: A Review of Recent Data*, 120 INT’L J. CANCER 102, 215 (2006) (“An unknown proportion of formalin-inactivated poliovirus

mesothelioma, brain tumors, and non-Hodgkin lymphoma.¹¹⁴ The contaminated vaccines included Salk's inactivated injectable vaccine and the newly licensed oral polio vaccine.¹¹⁵ The contamination occurred during development because the vaccines were produced in monkey kidney cell cultures that harbored SV40.¹¹⁶ Across the United States vaccination rates during this time period were high, and approximately ninety percent of children were inoculated against polio.¹¹⁷

The presence of SV40 in the vaccines was not discovered until 1960, five years after the first vaccines were contaminated. Although regulators required vaccine lots produced after 1961 to be SV40-free, they did not recall lots produced prior to that date.¹¹⁸ This was despite the fact that, at least as early as 1962, studies had found SV40 to be "oncogenic in rodents and capable of transforming human cells *in vitro*."¹¹⁹ Since regulators did not recall the potentially contaminated lots, "vaccine-related human exposure to SV40 may have continued until 1963."¹²⁰ At the same time, however, experts do not know how many individuals who received SV40-contaminated vaccines actually were infected with SV40.¹²¹ Moreover, because SV40 can be transmitted human-to-human, experts posited that the virus was likely to have spread substantially.¹²²

vaccine lots administered to millions of US residents between 1955 and 1963 was contaminated with small amounts of infectious simian virus 40 (SV40), a polyomavirus of the rhesus macaque." The CDC estimates that up to thirty percent of polio vaccines in the United States were contaminated with SV40. See Tam Dang-Tan et al., *Polio Vaccines, Simian Virus 40, and Human Cancer: The Epidemiological Evidence for a Causal Association*, 23 ONCOGENE 6535, 6535 (2004). In addition, SV40-contaminated polio vaccines were administered throughout the world. Danielle L. Poulin & James A. DeCaprio, *Is There a Role for SV40 in Human Cancer?*, 24 J. CLINICAL ONCOLOGY 4356, 4356 (2006).

¹¹⁴ Shah, *supra* note 113, at 215 ("It has been reported that mesothelioma, brain tumors, osteosarcoma and non-Hodgkin lymphoma (NHL) contain SV40 DNA sequences and that SV40 infection introduced into humans by the vaccine probably contributed to the development of these cancers.").

¹¹⁵ In clinical trials conducted between 1959 and 1961, about ten thousand research participants were inoculated with a Sabin oral polio vaccine that was potentially contaminated with SV40. Poulin & DeCaprio, *supra* note 113, at 4356. In the United States, OPV was licensed in 1963, after the federal government required that polio vaccines be SV40-free. *Id.* Thus, Salk's inactivated polio vaccine ("IPV") is the primary source of exposure, as about ninety-eight million Americans received at least one dose of IPV between 1955 and 1963. *Id.*

¹¹⁶ Dang-Tan et al., *supra* note 113, at 6535.

¹¹⁷ *Id.*

¹¹⁸ Shah, *supra* note 113, at 215.

¹¹⁹ Dang-Tan et al., *supra* note 113, at 6535. A 1964 study found that the "transformed cells were capable of tumor growth when injected into terminally ill human volunteers." *Id.*

¹²⁰ Shah, *supra* note 113, at 215.

¹²¹ *Id.*

¹²² Dan Ferber, *Monkey Virus Link to Cancer Grows Stronger*, 296 SCI. 1012, 1013 (2002) ("Those who point to the vaccine link say that SV40 from contaminated vaccines has spread

Thousands of studies have examined the biology of SV40 and whether SV40-contaminated vaccines are a direct cause of cancer in humans.¹²³ Although the “debate on the possible adverse effects of SV40 for humans has been contentious,” the data are inconclusive.¹²⁴ A 2002 IOM report came to the same conclusion, finding that “the evidence was inadequate to conclude whether or not the contaminated polio vaccine caused cancer.”¹²⁵ As a 2006 meta-analysis underscored, however, “[i]t is important to note that SV40 has shown oncogenic activity in cellular and animal models in a manner similar to human papillomavirus [(“HPV”).”¹²⁶ Moreover, SV40 “clearly can cause cancer when given to newborn animals.”¹²⁷

More than four decades after the vaccines were found to be contaminated with SV40, experts continue to call for additional research to determine whether SV40 is causally linked to cancer in humans. According to Keerti Shah, who has researched SV40 contaminated polio vaccines since the 1960s, additional studies are needed to update the science, “maintain public confidence in vaccines,” and answer “legitimate questions related to vaccine safety . . . as fully as possible.”¹²⁸ Yet, decades after SV40-contaminated polio vaccines were administered, some researchers have been reluctant to publicize data linking SV40 with cancer in humans; according to one such researcher, “I don’t want to be responsible for scaring people so that they are afraid to use the polio vaccine.”¹²⁹

from person to person. SV40 can replicate in people, Butel and others say, and it can also be excreted in feces and urine.”).

¹²³ See, e.g., *id.* at 1012; Poulin & DeCaprio, *supra* note 113, at 4356 (“The question of whether Simian Virus 40 (SV40) can cause human tumors has been one of the most highly controversial topics in cancer research during the last 50 years.”); Shah, *supra* note 113, at 215.

¹²⁴ Shah, *supra* note 113, at 216-21.

¹²⁵ INST. OF MED., IMMUNIZATION SAFETY REVIEW: SV40 CONTAMINATION OF POLIO VACCINE AND CANCER I (Kathleen Stratton et al. eds., 2003) (calling for additional research and recommending development of more sensitive tests for SV40).

¹²⁶ Poulin & DeCaprio, *supra* note 113, at 4358.

¹²⁷ Ferber, *supra* note 122, at 1012.

¹²⁸ Shah, *supra* note 113, at 221.

¹²⁹ Ferber, *supra* note 122, at 1013 (statement of Janet Butel). Some vaccine-hesitant individuals fear that data suppression continues. See, e.g., Emily Willingham, *A Congressman, a CDC Whistleblower and an Autism Tempest in a Trashcan*, FORBES (Aug. 6, 2015), <https://www.forbes.com/sites/emilywillingham/2015/08/06/a-congressman-a-cdc-whistleblower-and-an-autism-tempest-in-a-trashcan/#19f6a0c53963> [<https://perma.cc/DJF2-WPVZ>]. For example, a CDC whistleblower alleged that the CDC suppressed data on vaccine adverse events, including a potential link between vaccines and neurodevelopmental disorders. *Id.* This alleged cover-up gained national attention following the 2016 release of a documentary film, *Vaxxed: From Cover-Up to Catastrophe*. See, e.g., Laurie Tarkan, *Why Robert De Niro Promoted—then Pulled—Anti-Vaccine Documentary*, FORTUNE (Mar. 29,

Notwithstanding extensive studies examining the possible link between SV40 contaminated vaccines and adverse effects in humans, the first SV40-related lawsuits were filed after 2000. It is not clear why there was such a long delay, though it may be attributed to factors such as the latency period in developing an SV40-associated disease and the lack of conclusive evidence that SV40 causes cancer in humans. The enactment of the Vaccine Act further complicated litigation surrounding SV40-contaminated vaccines, because it does not apply to claims if the vaccine-related injury occurred more than eight years prior to the statute's enactment.¹³⁰ At the same time, however, for more than twenty-five years prior to the enactment of the Vaccine Act, patients, manufacturers, and the government feared the far-reaching consequences should SV40 contaminated vaccines be causally linked to cancer in humans.¹³¹ For these reasons, potential litigation surrounding SV40 contaminated vaccines was an important consideration when the Vaccine Act was debated and enacted.

In many respects, the legal concerns mirrored those of the vaccine-induced polio cases. A review of SV40-related litigation is illustrative. Plaintiffs struggled with identification issues (namely, identifying which manufacturer supplied their vaccine) and causation issues (whether SV40 causes cancer, and, if so, whether SV40 caused the plaintiff's cancer). Plaintiffs in SV40 cases also questioned whether the government could be held liable for allowing SV40-contaminated vaccines to remain on the market or for failing to exercise due care in the oversight of vaccine production.

In *Asker v. Wyeth Pharmaceuticals, Inc.*,¹³² a California appellate court considered Alan Asker's claim that an SV40-contaminated polio vaccine was a substantial factor in his developing mesothelioma.¹³³ The complaint alleged that SV40 was found in his tumor, and Asker's only known exposure to SV40 was a polio vaccine he was administered in the early 1960s.¹³⁴ Asker alleged that defendants' "selection of monkey kidney tissue for the growth and harvest of polio virus was based on, *inter alia*, monetary gain, ease of kidney removal and a ready supply, rather than science or public safety," and that the vaccine had a "failure rate" of seventy-five percent or more.¹³⁵ Asker brought products liability

2016), <http://fortune.com/2016/03/29/robert-de-niro-anti-vaccine-documentary/> [https://perma.cc/B5HS-TJWQ] (outlining controversy surrounding release of film).

¹³⁰ 42 U.S.C. § 300aa-16(b)(1) (2012); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1339 (C.D. Cal. 1987).

¹³¹ Wadman, *supra* note 104 ("Tens of millions of American children had already received contaminated injections, and while the jury was still out on the tainted vaccine's long-term health consequences, the risks were of great concern to regulators in the US and further afield.").

¹³² No. A112658, 2007 WL 61912, at *1 (Cal. Ct. App. Jan. 10, 2007).

¹³³ *Id.* Asker also sued asbestos manufacturers, alleging that his exposure to asbestos was a substantial factor in causing his mesothelioma. *Id.* at *1 n.3.

¹³⁴ *Id.* at *1.

¹³⁵ *Id.* at *4.

and negligence claims against several vaccine manufacturers.¹³⁶ He argued that defendants failed to conduct adequate tests to detect SV40 and failed to warn patients and doctors of the potential contamination.¹³⁷

A trial court granted defendants' motion to dismiss, but the decision was reversed on appeal.¹³⁸ The appellate court noted that Asker "identifies a single product (polio vaccine) tainted by a particular contaminant (SV40), produced by a relatively small group of defendants."¹³⁹ Although Asker's complaint named several vaccine manufacturers, it did not identify the specific manufacturer(s) that supplied him with an SV40-contaminated polio vaccine.¹⁴⁰ Nevertheless, the appellate court held that the case could move forward, but that at trial Asker would have the burden of proving which defendant actually supplied him with an SV40-contaminated vaccine, as well as the burden of proving that SV40 was in fact a substantial factor in causing his injuries.¹⁴¹

In the same year that the California court decided *Asker*, an appellate court in New Jersey ruled on a case where the estate of a seven-year-old girl alleged that the girl's fatal brain tumor was caused by an SV40-contaminated polio vaccine.¹⁴² In *Rivard v. American Home Products, Inc.*, Lindsay Rivard received four oral live-virus polio vaccines during the 1990s, and upon her death scientists found SV40 in her tumor cells.¹⁴³ The vaccine administered to Rivard was developed using the original Sabin strain, which was known to be contaminated with SV40.¹⁴⁴ Although federal regulations permitted use of the Sabin strain, notwithstanding the fact that the FDA knew the strain contained SV40, the regulations also required that vaccine manufacturers utilize a neutralization process to rid the vaccine of SV40.¹⁴⁵ At issue was whether the

¹³⁶ *Id.* at *1.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.* at *3.

¹⁴⁰ *Id.* at *1. Plaintiff settled with one of the named defendants, Bayer Corporation. *Id.*

¹⁴¹ *Id.* at *3. On remand to the trial court, the case against Wyeth was dismissed without prejudice prior to trial and prior to Wyeth filing a motion for summary judgment. *See* Case Management Statement, *Asker v. Asbestos Corp.*, No. CGC-02407055 (Cal. Super. Ct. filed May 7, 2008); *see also* Statement of Dismissal, *Asker v. Asbestos Corp.*, No. CGC-02407055 (Cal. Super. Ct. filed June 4, 2008). Although the docket does not indicate the reason for the dismissal, *see id.*, the timing suggests that the parties reached a settlement.

¹⁴² *Rivard v. Am. Home Prods., Inc.*, 917 A.2d 286, 291 (N.J. Super. Ct. App. Div. 2007).

¹⁴³ *Id.* at 291-92 ("One of plaintiffs' experts confirmed that molecular tests performed on Lindsay's tumor tissue found the presence of SV40 DNA. Another of plaintiffs' experts also found SV40 in the 'tumor cells' but not in the 'adjacent non-malignant brain tissue.'").

¹⁴⁴ *Id.* at 292.

¹⁴⁵ *Id.* at 292-93 (citing 42 C.F.R. §§ 73.113(d), 73.114(a)(5) (1962)) ("In addition, the regulations required testing to ensure that each viral harvest was SV40 free.").

manufacturer's neutralization process failed to sufficiently remove "the virulent form of monkey virus from the resulting vaccine."¹⁴⁶

The defendants argued for dismissal because the Vaccine Act mandates that, before bringing suit in state court, the plaintiff must first exhaust administrative remedies. The trial court disagreed, finding that the Vaccine Act exempted the administrative process claim requirement where a "vaccine-related injury or death" is "associated with an adulterant or contaminant intentionally added to such a vaccine."¹⁴⁷ As the trial court reasoned, by using the original Sabin strain, which the manufacturer knew was likely to contain SV40, the manufacturer intentionally added SV40 to the vaccine that was administered to the young girl.

A New Jersey appellate court disagreed. Attempting to neutralize SV40, the court held, is evidence that the manufacturer tried to remove the contaminant; even assuming *arguendo* that the manufacturer employed a deficient neutralization process or was negligent in carrying out the neutralization, the manufacturer did not intentionally place SV40 into the vaccine.¹⁴⁸ Therefore, the court inferred, "[t]he possible inclusion of SV40 within the monkey tissue can be considered a risk the FDA was willing to assume in order to produce the vaccine."¹⁴⁹

Five years after *Asker and Rivard*, the New Jersey Supreme Court reviewed a case wherein Jamie Gannon alleged that SV40-contaminated polio vaccines he was administered in the 1970s caused his brain cancer, which was diagnosed in 2000.¹⁵⁰ Gannon brought claims in both state and federal courts.¹⁵¹ In the federal matter, Gannon alleged that the federal government was negligent in allowing the vaccine to be sold to the public because the government violated regulations by failing to confirm the absence of SV40 at various production stages.¹⁵² Although the federal court did not find that the matter was barred by the Federal Tort Claims Act or the Vaccine Act, the court held that Gannon failed to provide facts from which a reasonable fact finder could determine that SV40 causes cancer in humans, or that SV40 caused his brain cancer.¹⁵³

¹⁴⁶ *Id.* at 292. Previous cases against vaccine manufacturers involved similar claims regarding neutralization failures. *Id.* at 293 (citing *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 763 F. Supp. 811, 829 (D. Md. 1991), *aff'd*, 984 F.2d 124 (4th Cir. 1993); *Campagna v. Am. Cyanamid Co.*, 767 A.2d 996 (N.J. Super. Ct. App. Div. 2001)).

¹⁴⁷ *Id.* at 294 (citing 42 U.S.C.A. § 300aa-33(5)).

¹⁴⁸ *Id.* at 295-96 ("Even if the neutralization was not completely effective, the fact that defendants neutralized, or at least in good faith attempted to neutralize, the SV40 tends to negate any suggestion of an intention to add an adulterant or contaminant, and in fact indicates the exact opposite.").

¹⁴⁹ *Id.* at 296.

¹⁵⁰ *Gannon v. Am. Home Prods., Inc.*, 48 A.3d 1094, 1095-98 (N.J. 2012).

¹⁵¹ *Id.* at 1098; *see also* *Gannon v. United States*, 571 F. Supp. 2d 615 (E.D. Pa. 2007).

¹⁵² *Gannon*, 571 F. Supp. 2d at 616.

¹⁵³ *Id.* at 638-41 (finding that "[p]laintiffs have failed to demonstrate, by a preponderance of the evidence, that SV40 causes cancer, let alone medulloblastoma, in humans," and

The SV40 cases underscore the difficulties that plaintiffs often face in demonstrating causation in cases alleging vaccine-related injuries. They also represent a subset of vaccine-related injury claims that was contemplated by *Gottsdanker*—namely, an adverse health condition other than a vaccine-induced disease that the vaccine was intended to protect against.

3. Products Liability Claims for Vaccine-Related Injuries

The 1960s marked the beginning of a “nationwide trend toward strict products liability.”¹⁵⁴ Unlike with negligence claims, under products liability a manufacturer can be held “strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.”¹⁵⁵ Over the years, products liability claims have been subcategorized into manufacturing defects, design defects, and warning defects,¹⁵⁶ though the extent of liability under each type of claim varies considerably according to state law. Notwithstanding divergent legal remedies throughout the United States, several cases involving vaccine-related injuries have included products liability claims. Some of the earliest such cases stem from polio vaccine-related injuries.

Jonas Salk’s inactivated polio vaccine (“IPV”) was derived from a strain of the polio virus that had been “killed.”¹⁵⁷ The Sabin oral polio vaccine (“OPV”) entered the market in 1960, five years after IPV.¹⁵⁸ Unlike IPV, “OPV is produced from a live [polio] virus attenuated but not killed during the development process.”¹⁵⁹ In simple terms, those vaccinated with OPV are

“[p]laintiffs also have failed to demonstrate by a preponderance of the evidence that SV40 caused Mr. Gannon’s medulloblastoma”). The Third Circuit affirmed. *Gannon v. United States*, 292 F. App’x 170, 175 (3d Cir. 2008). In the parallel state court action, Gannon brought products liability claims against four vaccine manufacturers that sold polio vaccines at the time that Gannon received his immunizations. *Gannon*, 48 A.3d at 1095-96. The state trial court granted summary judgment for defendants, finding that plaintiff lacked sufficient evidence to prove which defendant produced the vaccines that he was administered; the court also held that Gannon was collaterally estopped from bringing the state claims because of the decision in the federal case. *Id.* Thereafter, a state appellate court reversed both aspects of the trial court’s decision, and remanded the case for additional discovery and a trial. *Id.* (citing *Gannon v. Am. Home Prods., Inc.*, 999 A.2d 522 (N.J. Super. Ct. App. Div. 2010)). In a divided opinion, the New Jersey Supreme Court disagreed with the state appellate court’s ruling on collateral estoppel. *Id.* at 1096. Since the court’s ruling on collateral estoppel was sufficient to uphold the state trial court’s decision to terminate the litigation, the court did not consider the issue of defendant identification. *Id.*

¹⁵⁴ *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 458 (Cal. Ct. App. 1985).

¹⁵⁵ *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900 (Cal. 1963).

¹⁵⁶ RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (AM. LAW INST. 1998).

¹⁵⁷ *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 743 F. Supp. 410, 412 (D. Md. 1990).

¹⁵⁸ *See id.* at 412-13.

¹⁵⁹ *Id.* at 412.

inoculated with a weakened version of the polio virus, whereas those immunized with IPV only receive a killed virus.¹⁶⁰

At the time, “[s]cientists perceived that OPV might have several advantages over IPV.”¹⁶¹ In addition to being “relatively less costly” and easier to administer, OPV could facilitate immunity in others “because a person who has not been administered the polio vaccine can pick up immunity from one who has been vaccinated” by “catching” a mild form of the virus.¹⁶² In addition, although those immunized with IPV are protected against the disease, “they can serve as carriers of the wild polio virus and pass it on to others.”¹⁶³ Given OPV’s use of an attenuated polio virus, however, “there is an inherent risk in the use of OPV” over IPV.¹⁶⁴ As with “other live virus vaccines . . . , OPV stimulates immunity by inducing a mild infection in vaccinees. Thus, a person vaccinated with OPV, or a person who comes into close contact with the vaccine’s virus (usually by exposure to the vaccinated person) may develop polio.”¹⁶⁵

During the early 1960s, after balancing the risks and benefits of the two options, public health officials selected OPV “as the vaccine of choice for mass immunization.”¹⁶⁶ Shortly after the decision, cases of OPV vaccine-induced polio began to emerge, and in 1964 the Public Health Service convened a special

¹⁶⁰ As its name suggests, OPV is administered orally; IPV is administered via injection. See generally WORLD HEALTH ORG., ORAL POLIOMYELITIS VACCINE: QUESTIONS & ANSWERS (July 2012), http://who.int/immunization_standards/vaccine_quality/qa_production_control_pq_11july2012.pdf [<https://perma.cc/GL3K-LDWL>].

¹⁶¹ *In re Sabin*, 743 F. Supp. at 412.

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 455 (Cal. Ct. App. 1985). For an overview of the deliberations, see OFFIT, *supra* note 51, at 124-31. Up to the enactment of the Vaccine Act, OPV continued to be the CDC-recommended vaccine for preventing polio, though the CDC changed its position in 1999. WORLD HEALTH ORG., *supra* note 160. Because OPV utilizes an attenuated polio virus, a small percentage of those inoculated with OPV will contract polio. According to the World Health Organization, of every 2.5 million doses of OPV, one will lead to polio. *Id.* Although this is a miniscule risk, it played a role in the CDC’s 1999 decision to recommend eliminating OPV from the United States, and using IPV in its stead. See U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Poliomyelitis Prevention in the United States*, MORBIDITY & MORTALITY WKLY. REP., Jan. 24, 1997, at 2. While the CDC’s decision meant that, in the United States, only Salk’s inactivated polio vaccine would be administered, OPV continues to be used in many parts of the world and American manufacturers supply many countries with OPV. As of 2017, OPV is the leading cause of polio worldwide. See Jason Beaubien, *Mutant Strains of Polio Vaccine Now Cause More Paralysis Than Wild Polio*, NPR (June 28, 2017), <http://www.npr.org/sections/goatsandsoda/2017/06/28/534403083/mutant-strains-of-polio-vaccine-now-cause-more-paralysis-than-wild-polio> [<https://perma.cc/B2SC-QEEM>] (indicating that “there have been 21 cases of vaccine-derived polio [in 2017]”).

advisory committee to examine the issue.¹⁶⁷ The committee confirmed that OPV was the cause-in-fact for several cases of polio, but “emphasized the need to continue mass immunization at full speed.”¹⁶⁸ Meanwhile, cases of vaccine-induced polio continued. In some instances, injured patients sued the vaccine manufacturer.

One notable case is *Kearl v. Lederle Laboratories*,¹⁶⁹ which was brought in a California state court. Shortly after receiving OPV, five-month old Elizabeth Kearl began to develop paralysis.¹⁷⁰ Kearl alleged design and warning defect claims against the vaccine manufacturer, and the jury awarded her \$800,000 at trial.¹⁷¹ On appeal, however, the verdict was set aside.¹⁷²

As to the design defect claim, the California appellate court indicated that a plaintiff may demonstrate that a product was defectively designed in one of two ways: (1) “the product failed to perform as safely as an ordinary consumer would expect,” or (2) if a plaintiff can show that the product’s design proximately caused an injury, then the burden shifts to the defendant to demonstrate that the benefits of the product’s design outweighed the inherent design risks.¹⁷³ The second category of design defect claims focuses on what are known as unavoidably unsafe products.¹⁷⁴ The key question in a vaccine-related design defect claim is whether the vaccine’s risks could have been avoided had the defendant used a different design that did not materially alter the vaccine’s effectiveness.¹⁷⁵

The California appellate court considered the policy implications of holding vaccine manufacturers liable for design defects. According to the court, the availability of strict liability for design defect claims may “substantially affect a

¹⁶⁷ *Kearl*, 218 Cal. Rptr. at 455.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.* at 453.

¹⁷⁰ *Id.* at 454-57.

¹⁷¹ *Id.*

¹⁷² *Id.* at 454.

¹⁷³ *Id.* at 457 (citing *Barker v. Lull Eng’g Co.*, 573 P.2d 443, 454, 455-56 (Cal. 1978)).

¹⁷⁴ *See id.* at 463-64.

¹⁷⁵ *See id.* at 464. Although manufacturing defect claims were not at issue in *Kearl*, other courts have examined such claims in the context of vaccine-related injuries. A product has a manufacturing defect when it deviates “from the manufacturer’s intended result or from other ostensibly identical units of the same product line.” *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1335 (C.D. Cal. 1987) (citing *Barker*, 573 P.2d at 454). Manufacturing defects result from “error[s] in the production process.” *Id.* (citing *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1163 (Cal. 1984) (Bird, C.J., dissenting)). A common example is a product that “comes off the assembly line in a substandard condition.” *Id.* at 1335-36 (citing *Barker*, 573 P.2d at 454). Unlike with design defect claims, the unavoidably-unsafe defense is inapplicable to manufacturing defect claims. As courts have noted, a product “that has a manufacturing defect is, by definition, not ‘unavoidably unsafe.’” *Id.* at 1336.

product's availability."¹⁷⁶ Coupled with a "problem of delayed release (or nonrelease)," the court speculated that the cost to insure against design defect claims would be prohibitively high, and thus would impact research and development of new products, particularly for smaller manufacturers.¹⁷⁷ High insurance costs, according to the court, would translate to higher prices, which "might 'place the price of necessary [products] outside the reach of those who most need them.'"¹⁷⁸ The court also noted that high costs "might cause manufacturers to remove some products from the market, or decline to develop them."¹⁷⁹ Taken together, the court reasoned that "with regard to some special products the scale may tip away from enhanced accountability," and thus "some special products should be exempted from the normal strict products liability design defect analysis."¹⁸⁰ Vaccines, the court held, constitute one such product.¹⁸¹

Importantly, however, *Kearl* did not conclude that design defect claims were categorically precluded in cases alleging vaccine-related injuries. Rather, although the court held that vaccine-related design defect claims should not be analyzed "in the light of ordinary consumer expectations or present scientific knowledge," the court indicated that such claims "should be reviewed according to the state of the art," which the court defined as "the manufacturer's actual or constructive knowledge—at the time of marketing."¹⁸² According to the court, in practical terms this meant that "some special products should be analyzed for design defects under a negligence standard, rather than a strict liability standard."¹⁸³

For example, *Kearl* highlighted a First Circuit case where a manufacturer produced two different oral contraceptives—one contained fifty milligrams of estrogen while the other contained one hundred milligrams.¹⁸⁴ The manufacturer produced the one hundred milligram contraceptive despite the fact that scientific evidence showed that additional estrogen provided no additional efficacy but came with additional risks.¹⁸⁵ In the contraception case, the First Circuit "held that . . . it was proper for the jury to have been instructed on a strict products liability design defects theory."¹⁸⁶ The *Kearl* court agreed with the First Circuit's analysis because, as it held, prescription drugs "should not be exempt from strict

¹⁷⁶ *Kearl*, 218 Cal. Rptr. at 459.

¹⁷⁷ *Id.* (citing *Feldman v. Lederle Labs.*, 460 A.2d 203, 209 (N.J. Super. Ct. App. Div. 1984)).

¹⁷⁸ *Id.* (alterations in original) (quoting *Feldman*, 460 A.2d at 209).

¹⁷⁹ *Id.* at 459-60.

¹⁸⁰ *Id.* at 460.

¹⁸¹ *Id.* at 463.

¹⁸² *Id.* at 460.

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 461.

¹⁸⁵ *Id.* (citing *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655 (1st Cir. 1981)).

¹⁸⁶ *Id.* (citing *Brochu*, 642 F.2d at 655).

liability design defect analysis if the evidence shows inter alia the availability, at the time of distribution, of an alternative product that would have as effectively accomplished the full intended purpose of the subject product.”¹⁸⁷ In essence, the First Circuit’s decision applied the unavoidably unsafe test and found that the product was *avoidably* unsafe—that is, the company knew, or should have known, that less estrogen would have made the drug safer without compromising efficacy. The *Kearl* court did not disagree with First Circuit’s rationale, and in fact further noted that, in the contraceptive case, the plaintiff also could have prevailed had there been a negligence standard for design defects.¹⁸⁸

Thus, while *Kearl* acknowledged that the unavoidably unsafe product exemption for medical products was justified as a general matter, the court was careful to elucidate the contours of the exception.¹⁸⁹ *Kearl* took issue with the “routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly drugs, are entitled to such special treatment.”¹⁹⁰ The court also noted that the “analysis poses a mixed question of law and fact and can be made only after evidence is first taken, out of the jury’s presence, on the relevant factors,”¹⁹¹ which include:

- (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable;
- (2) whether the then-existing risk posed by the product was both “substantial” and “unavoidable”; and (3) whether the interest in availability . . . outweighs the interest in promoting enhanced accountability through strict liability design defect review.¹⁹²

As to the second factor, the court further explained that “substantial” risk involves an inquiry into whether “the risk posed permanent or long-term disability . . . as opposed to mere temporary or insignificant inconvenience.”¹⁹³ In determining whether a risk is “unavoidable,” *Kearl* indicated that courts should examine

- (i) whether the product was designed to minimize—to the extent scientifically knowable at the time it was distributed—the risk inherent in the product, and (ii) the availability—again, at the time of distribution—of

¹⁸⁷ *Id.* at 462 (emphasis omitted).

¹⁸⁸ *Id.*

¹⁸⁹ *Id.* at 463.

¹⁹⁰ *Id.* As the court highlighted, “[t]he statement that drugs are unavoidably [dangerous], and therefore within the protection of Comment k, has become almost tautological.” *Id.* (alterations in original).

¹⁹¹ *Id.* (citing *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984)).

¹⁹² *Id.* at 464.

¹⁹³ *Id.*

any alternative product that would have as effectively accomplished the full intended purpose of the subject product.¹⁹⁴

Given this framework, *Kearl* held that the lower court erred by instructing the jury on the wrong legal standard, and by failing to consider evidence as to whether OPV qualifies for the unavoidably unsafe exception.¹⁹⁵

Shortly after *Kearl*'s nuanced analysis of vaccine-related design defect claims, the Idaho Supreme Court, in *Toner v. Lederle Laboratories*,¹⁹⁶ likewise held that a plaintiff could bring a negligence claim for design defect against a vaccine manufacturer.¹⁹⁷ The *Kearl* and *Toner* opinions are notable not only for their analyses, but also for their timing—the cases were pending as Congress debated the Vaccine Act, and thus the issues raised received considerable attention from lawmakers, the vaccine industry, and advocates.

In addition to a design defect claim, the *Kearl* court also considered two instances that could give rise to a warning defect claim. The first involves cases where a dangerous aspect of a product can be avoided if the consumer “is alerted to it and instructed how to avoid it.”¹⁹⁸ The second includes cases where a “product creates a danger that cannot be eliminated, but its utility is so great that it may be marketed without subjecting the manufacturer to liability, provided the user is made aware of the danger and is given the opportunity to make an informed decision whether to” use the product notwithstanding the potential danger.¹⁹⁹ The second category of claims relates to warnings that are necessary for unavoidably unsafe products. This was the category of warning defect claims at issue in *Kearl*.²⁰⁰

Although the court noted that it was “the commonly assumed and often asserted proposition” that warning defects “may be a basis for imposition of strict liability,” the court indicated that, as a practical matter, warning defect claims are reviewed pursuant to a negligence standard.²⁰¹ This is because, with warning defect claims, the core issue is whether the warning reflects the defendant’s actual or constructive knowledge of the product’s risks.²⁰² The focus on the defendant’s conduct—as opposed to the defendant’s product—is what renders the analysis one based on negligence.²⁰³ The court then explained: “Just as liability for failure to warn of product risk is based on negligence, the

¹⁹⁴ *Id.* (emphasis omitted).

¹⁹⁵ *Id.*

¹⁹⁶ 732 P.2d 297 (Idaho 1987).

¹⁹⁷ *Id.* at 310-11.

¹⁹⁸ *Kearl*, 218 Cal. Rptr. at 465.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *Id.* (emphasis omitted).

²⁰² *Id.* at 465-66 (citing *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 400 (Cal. Dist. Ct. App. 1971)).

²⁰³ *Id.*

adequacy of a warning is also judged under a reasonableness standard—even if the claim is made under the rubric of a strict products liability ‘defect.’”²⁰⁴ In the context of vaccine-related claims regarding failure to warn, this translates to a requirement that manufacturers directly inform patients in “clear and simple” terms of (1) the reasonably foreseeable risks inherent to the vaccine; (2) the reasonably available alternative vaccines and the reasonably foreseeable risks posed by such vaccines; and (3) in some cases, the reasonably foreseeable outcome of not receiving the vaccine.²⁰⁵ Applying this standard, the court found that the warnings provided by the manufacturer were adequate.²⁰⁶

As a whole, *Kearl* provides several key points. First, the case affirmed that vaccine-related adverse events are actionable under either negligence or products liability. Second, *Kearl* elucidated the contours under which design defect and warning defect claims could be brought for vaccine-related injuries. Third, the court underscored that, for a vaccine to be deemed unavoidably unsafe, the relevant inquiry involves an examination of what the manufacturer knew, or should have known, at the time it marketed the vaccine. As the court highlighted, in instances where a manufacturer could have used an alternative vaccine formula that was safer and no less effective, liability under a design defect theory is actionable.

While the California state court in *Kearl* considered and dismissed the plaintiff’s warning defect claims, the availability of warning defect claims was underscored decades earlier in cases from the Ninth and Fifth Circuits. In a landmark case from 1968—*Davis v. Wyeth Laboratories, Inc.*²⁰⁷—the Ninth Circuit held that a manufacturer has a duty to warn the patient, or to make adequate provisions for the health-care provider to warn the patient, as to vaccine risks.²⁰⁸ In *Davis*, the plaintiff contracted polio after a pharmacist administered OPV in an immunization clinic.²⁰⁹ Neither the drug company nor the local public health officials conveyed any risks to the pharmacist who administered OPV, and the pharmacist did not independently provide any warnings to the vaccinees.²¹⁰ The court held that, under Montana law, notwithstanding the fact that OPV was an unavoidably unsafe product and the

²⁰⁴ *Id.* at 466 (citing *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 992-93 (8th Cir. 1969)).

²⁰⁵ *Id.* at 466-67 (citing *Petty v. United States* 740 F.2d 1428, 1436-37 (8th Cir. 1984)).

²⁰⁶ *Id.* at 467. The manufacturer directly warned plaintiff about the risk of contracting polio from OPV, described the availability of IPV, noted that IPV does not cause polio, and indicated that most experts favor OPV over IPV because they believe that OPV is more effective. The court did not give merit to plaintiff’s contention that the warning should have said OPV “is the best way to get polio today,” nor did the court find that the manufacturer should have indicated that the risk of contracting polio from OPV was similar to the risk of contracting wild polio virus. *Id.* at 467-68.

²⁰⁷ 399 F.2d 121 (9th Cir. 1968).

²⁰⁸ *Id.* at 131.

²⁰⁹ *Id.* at 122-23.

²¹⁰ *Id.* at 125.

lack of privity between the manufacturer and vaccinees, the manufacturer had a duty to warn the vaccinee about the chance of contracting polio from OPV.²¹¹

The *Davis* court recognized that, when OPV was first administered in 1962, the manufacturer did not have a duty to warn of the risk because, at the time, the risk was not known or foreseeable.²¹² As the court reasoned, however, the manufacturer's "responsibility did not end there. When, after further experience, the danger became apparent, a duty to warn attached."²¹³ The court recognized that the nature of medicine is evolving and that new data becomes available almost constantly.²¹⁴ On this point, the court noted that if newfound risks are "trifling" or "de minimis," no duty to warn would arise.²¹⁵ Although the court found that the chance of contracting polio from OPV was small, the information was relevant to a patient's decision to accept the vaccine.²¹⁶ The court also found that warning the distributor was insufficient.²¹⁷ Rather, the court held, "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning."²¹⁸ In *Davis*, the manufacturer actually "knew that warnings were not reaching the consumer."²¹⁹ Specifically, the manufacturer assisted in the development and administration of the immunization program, and failed to convey any warnings to vaccinees.²²⁰

Six years after *Davis*, the Fifth Circuit reached a similar conclusion. In *Reyes v. Wyeth Laboratories, Inc.*,²²¹ an eighteen-month-old infant contracted polio after receiving OPV, and the court ruled that the vaccine was unreasonably dangerous as marketed because of inadequate warnings.²²² Although the nurse who administered the vaccine read the warnings provided by the manufacturer, the nurse did not convey those warnings to the child's mother.²²³ Specifically, the nurse testified that it was not the office's practice to disclose warnings to patients or their families.²²⁴ The court held that, notwithstanding the fact that OPV was unavoidably unsafe due to the chance that one who receives the

²¹¹ *Id.* at 127-31.

²¹² *Id.* at 129.

²¹³ *Id.*

²¹⁴ *Id.* (finding that there are many cases, "particularly in the area of new drugs, where the risk cannot be . . . narrowly limited and where knowledge does not yet explain the reason for the risk or specify those to whom it applies").

²¹⁵ *Id.*

²¹⁶ *Id.* at 129-30.

²¹⁷ *Id.* at 131.

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ 498 F.2d 1264 (5th Cir. 1974).

²²² *Id.* at 1277-78.

²²³ *Id.* at 1270.

²²⁴ *Id.*

vaccine might contract polio,²²⁵ there was a rebuttable presumption that the consumer would have read the warning and acted to minimize the risk (for example, by opting for IPV, which did not carry the risk of vaccine-induced polio).²²⁶

As with the *Davis* court, the *Reyes* court was mindful of the policy and economic implications of imposing strict liability for failure to warn.²²⁷ For example, the American Academy of Pediatrics filed an amicus brief arguing that warnings to patients are “unnecessary” and that “any effort to warn vaccinees will be futile and frightening, leading only to confusion.”²²⁸ The Fifth Circuit viewed the academy’s embrace of a policy “to warn no one” as an affront to “the right of the individual to choose and control what risk he will take.”²²⁹ While the court gave due weight to the individual and public health goals of immunizations, the court also underscored how the lack of a “comprehensive scheme of social insurance” dictates that courts must consider “the most just allocation of the risk of loss between the members of the marketing chain.”²³⁰ Accordingly, the court found that a manufacturer’s duty to warn must include “meaningful and complete” disclosure of risks.²³¹

4. Vaccine-Related Injuries and Market Share Liability

Market share liability aims to account for special situations where a plaintiff is harmed by the wrongful conduct of one or more defendants but is unable to identify which defendant caused the harm. Under such circumstances, the plaintiff seeks to hold several defendants responsible in relation to each defendant’s market share for the injury-causing product. Although the concept of market share liability first appeared in the early 1970s,²³² in the context of FDA-regulated products the theory gained doctrinal traction in 1980 in response to the public health catastrophe surrounding diethylstilbestrol (“DES”), a drug that was prescribed to pregnant women to prevent miscarriages.²³³

²²⁵ *Id.* at 1273 (“Although the living virus in the vaccine does not make the vaccine defective, it does make it what the Restatement calls an ‘unavoidably unsafe product’, one which cannot be made ‘safe’ no matter how carefully it is manufactured.” (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965))).

²²⁶ *Id.* at 1281-82.

²²⁷ *Id.* at 1293-95.

²²⁸ *Id.* at 1293.

²²⁹ *Id.* at 1294.

²³⁰ *Id.* (emphasis omitted) (quoting *Helene Curtis Indus., Inc. v. Pruitt*, 385 F.2d 841, 862 (5th Cir. 1967)).

²³¹ *Id.* at 1295.

²³² *Sindell v. Abbott Labs.*, 607 P.2d 924, 933-34 (Cal. 1980) (noting that market share liability, or “enterprise liability,” was suggested in 1972 case from New York (citing *Hall v. E. I. Du Pont de Nemours & Co.*, 345 F. Supp. 353 (E.D.N.Y. 1972))).

²³³ See, e.g., Aaron D. Twerski, *Market Share—A Tale of Two Centuries*, 55 BROOK. L. REV. 869, 869 (1989) (describing application of market share liability in *Sindell*).

Children of women who ingested DES developed abnormal tumors and various forms of cancer, and experts linked the adverse health consequences to in utero exposure to DES.²³⁴ The DES market was unique in many respects. About two hundred manufacturers produced DES, and each utilized a “mutually agreed upon” formula.²³⁵ DES manufacturers “collaborated in marketing, promoting and testing the drug, relied upon each other’s tests, and adhered to an industry-wide safety standard.”²³⁶ Moreover, “it was customary for doctors to prescribe the drug by its generic rather than its brand name and . . . pharmacists filled prescriptions from whatever brand of the drug happened to be in stock.”²³⁷

Given the unique properties of the DES market, plaintiffs typically could not specify which defendant supplied their DES, which meant that plaintiffs could not prove an integral component of their tort claims.²³⁸ In turn, claims against DES manufacturers often were dismissed, and injured plaintiffs were left with no other legal remedies.²³⁹ By some estimates, up to three million women ingested DES and “[h]undreds, perhaps thousands,” of children suffered from DES-related adverse health consequences.²⁴⁰ Accordingly, the uncompensated harms were significant.

It was in this context that market share liability entered the legal picture. In the landmark case *Sindell v. Abbott Laboratories*, the California Supreme Court ruled that market share liability was a viable legal option for harms caused by DES.²⁴¹ *Sindell* also set forth a general framework for market share liability that

²³⁴ *Sindell*, 607 P.2d at 925.

²³⁵ *Id.* at 926, 935.

²³⁶ *Id.* at 926. At the time DES was marketed, the manufacturers knew of the link between in utero exposure to DES and adverse health consequences. *Id.* at 925-26. Rather than disclose the information or conduct further studies of safety and efficacy, the manufacturers suppressed the information and continued to advertise DES as a safe treatment for preventing miscarriages. *Id.* at 926. Once this information became public, however, several cases against DES manufacturers were filed. *Id.* at 927.

²³⁷ *Id.* at 926.

²³⁸ See, e.g., Victor E. Schwartz & Liberty Mahshigian, *Failure to Identify the Defendant in Tort Law: Towards a Legislative Solution*, 73 CALIF. L. REV. 941, 945 (1985) (noting that many plaintiffs in DES cases were “unable to identify the manufacturer of the DES taken by their mother . . . in part because DES usually was prescribed by a generic and not a brand name”).

²³⁹ At the time of the *Sindell* decision, the court noted that many DES cases were pending. *Sindell*, 607 P.2d at 927-28.

²⁴⁰ *Id.* at 927.

²⁴¹ *Id.* at 937 (holding that each manufacturer of DES is “liable for the proportion of the judgment represented by its share of that market unless it demonstrates that it could not have made the product which caused plaintiff’s injuries”). The court explored several theories of tort liability where a plaintiff—due to no fault of their own—has an insurmountable obstacle to identifying the defendant that caused their harm, and found that each theory did not apply to the DES case. *Id.* at 928-36. The doctrines examined by the court included joint and several liability, concert of action, and enterprise liability. *Id.* An example of joint and several liability

applies when: (1) all defendants produce a drug from an identical formula and (2) the plaintiff—through no fault of their own—is unable to prove which manufacturer provided the harm-causing product.²⁴² Under these circumstances, the burden shifts to the defendants to provide exculpatory evidence.²⁴³ In the absence of such evidence, however, the defendants are liable for damages in proportion to their respective market share for the harm-causing product.²⁴⁴ The California court's decision was adopted by courts in some states (such as Illinois, New York, Washington, and Wisconsin) and rejected by others (such as Iowa and Missouri).²⁴⁵

Public policy considerations were a significant motivating factor underlying the application of market share liability in the DES cases. Specifically, the court reasoned that “[t]he manufacturer is in the best position to discover and guard against defects in its products and to warn of harmful effects; thus, holding it liable for defects and failure to warn of harmful effects will provide an incentive to product safety.”²⁴⁶ As the California Supreme Court further detailed, “[t]hese considerations are particularly significant where medication is involved, for the consumer is virtually helpless to protect himself from serious, sometimes permanent, sometimes fatal, injuries caused by deleterious drugs.”²⁴⁷ Given the

is the famous case of *Summers v. Tice*, where the plaintiff suffered an injury when two hunters shot in his direction. *Id.* at 928-31 (citing 33 Cal. 2d 80, 82 (Cal. 1948) (finding that, in a case where both defendants were negligent, it was proper to shift the burden to defendants, who then could provide exculpatory evidence; in the absence of such evidence, however, the court held that each defendant was jointly and severally liable for plaintiff's injuries)). First, the court found that joint and several liability was inapplicable because, unlike in the classic case, the DES defendants were not in a better position to identify which of them supplied the DES that actually led to plaintiff's injury. *Id.* Second, the court held that concert of action was not a good fit since the “allegations do not amount to a charge that there was a tacit understanding or a common plan among defendants to fail to conduct adequate tests or give sufficient warnings, and that they substantially aided and encouraged one another in these omissions.” *Id.* at 932-33. Third, the court hesitated to apply the traditional concept of enterprise liability, given the large number of DES manufacturers, the lack of evidence that the DES defendants jointly controlled the risk of DES, and the fact that DES was a product regulated by the FDA. *Id.* at 933-36.

²⁴² *Id.* at 936-37. To be successful, the plaintiff also must demonstrate that the named defendants controlled a “substantial share of the appropriate market.” *Id.*

²⁴³ *Id.*

²⁴⁴ *Id.*

²⁴⁵ See *Shackil v. Lederle Labs.*, 561 A.2d 511, 517 (N.J. 1989) (collecting cases).

²⁴⁶ *Sindell*, 607 P.2d at 936.

²⁴⁷ *Id.* The court was troubled by the potential for uncompensated harms that may result from “our contemporary complex industrialized society.” *Id.* The court highlighted that:

[A]dvances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer. The response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet these changing needs.

Id.

choice between “an innocent plaintiff and negligent defendants,” the court ruled that “the latter should bear the cost of the injury.”²⁴⁸

In the context of injuries related to childhood vaccines, market share liability was an integral component in cases alleging harms from the DTP vaccine. Deanna Marrero’s case, *Shackil v. Lederle Laboratories*,²⁴⁹ is illustrative. Two days before her second birthday, Marrero received the DTP vaccine.²⁵⁰ Within twenty-four hours the toddler was in extreme pain, and shortly thereafter she experienced a “rapid deterioration of her condition [that] resulted in the loss of her then-acquired verbal, motor, and mental capacities.”²⁵¹ She later was diagnosed with “chronic encephalopathy and severe retardation,” and at the time of the lawsuit she was “institutionalized and require[d] constant care.”²⁵²

Twelve years after the inoculation, Marrero’s parents learned of a link between Marrero’s injuries and the pertussis component of the DTP vaccine.²⁵³ Marrero argued that the vaccine was defectively designed because the pertussis component utilized a “whole-cell” preparation, whereby whole cells of the pertussis organism are “isolated and inactivated.”²⁵⁴ Other designs for the pertussis vaccine included: (1) “split-cell” preparation, whereby the pertussis cells are “split or fragmented by a chemical process” or (2) “acellular” preparation, whereby all the toxins of the pertussis organism are eliminated.²⁵⁵ The whole-cell version that Marrero received had the highest rate of adverse events, followed by the split-cell and acellular versions, respectively.²⁵⁶ In 1972 (the time of Marrero’s inoculation), five companies produced the whole-cell version of the DTP vaccine and one produced the split-cell version.²⁵⁷ The acellular version gained widespread use in Japan beginning in 1981, but as of 1989 it was not licensed in the United States.²⁵⁸ The severe injuries that Marrero

²⁴⁸ *Id.*

²⁴⁹ 561 A.2d 511 (N.J. 1989).

²⁵⁰ *Id.* at 512-13.

²⁵¹ *Id.* at 513. Although the New Jersey court uses the acronym “DPT,” the medical and public health literature commonly use DTP and DTaP (when referring to acellular pertussis vaccine). *E.g.*, Marta V. Pinto & Tod J. Merkel, *Pertussis Disease and Transmission and Host Responses: Insights from the Baboon Model of Pertussis*, 74 J. INFECTION S114 (2017).

²⁵² *Shackil*, 561 A.2d at 513.

²⁵³ *Id.*

²⁵⁴ *Id.* at 521.

²⁵⁵ *Id.*

²⁵⁶ *Id.*; see also Sheena Loosmore et al., *The New Generation of Recombinant Pertussis Vaccines*, in MODERN VACCINOLOGY 319, 326 (Edouard Kurstak ed., 2013) (discussing risks and benefits of whole cell, split-cell, and acellular pertussis vaccines).

²⁵⁷ *Shackil*, 561 A.2d at 521.

²⁵⁸ *Id.*

suffered were estimated to occur at the rate of 1 in 110,000 doses of the DTP vaccine.²⁵⁹

Given the time lag between administration of the vaccine and knowledge of the vaccine's side effects, as well as the pediatrician's incomplete medical records, Marrero was unable to demonstrate which company supplied her DTP vaccine.²⁶⁰ The pediatrician testified that he used Lederle's DTP vaccine "for the most part" but also noted that sometimes he used a DTP vaccine from one of four other manufacturers.²⁶¹ Because Marrero could not identify the defendant who supplied her vaccine, the trial court granted defendants' motion for summary judgment.²⁶² A New Jersey appellate court reversed, ruling that a "risk-modified market share" theory of liability "was most aptly suited to the circumstances of this case."²⁶³

The New Jersey Supreme Court disagreed. Assuming *arguendo* that the DTP vaccine was defectively designed and directly caused Marrero's injuries,²⁶⁴ the court nonetheless held that dismissing the lawsuit was appropriate.²⁶⁵ The court's decision was based primarily on public policy grounds; specifically, the court noted that tort law is "designed to accomplish certain social objectives" and that "innocent victims" should be afforded "avenues of legal redress, absent a contrary, overriding public policy."²⁶⁶ The court believed that the public policy goal of incentivizing vaccine development and marketing would be severely hindered by the application of market share liability to design defect claims for the DTP vaccine.²⁶⁷

By the late 1980s there were only three additional reported cases where courts addressed the viability of market share liability to vaccine-related injuries.²⁶⁸ The *Shackil* decision was in line with two of the three cases. In one case, the Oregon Supreme Court rejected market share liability for a design defect involving the DTP vaccine.²⁶⁹ Although the plaintiff was able to distill the number of potential manufacturers down to two,²⁷⁰ the Oregon Supreme Court

²⁵⁹ *Id.* At the time, immunization guidelines recommended five doses of DTP per child. 1983 CDC VACCINE SCHEDULE, *supra* note 1, at 5.

²⁶⁰ *Shackil*, 561 A.2d at 513.

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.*

²⁶⁴ *Id.* at 514 ("[W]e will assume that the vaccines manufactured by defendants were defectively designed and that Deanna's injuries were directly caused by a DPT inoculation and not from a hereditary immunological or neurological disorder.").

²⁶⁵ *Id.* at 512.

²⁶⁶ *Id.* at 522 (quoting *People Express Airlines, Inc. v. Consol. Rail Corp.*, 495 A.2d 107, 111 (N.J. 1985)) (quotation marks omitted).

²⁶⁷ *Id.* at 529.

²⁶⁸ *Id.* at 518.

²⁶⁹ *Senn v. Merrell-Dow Pharm.*, 751 P.2d 215, 224 (Or. 1988).

²⁷⁰ *Id.* at 216.

refused to apply market share liability and indicated that it was for the legislature to decide if market share liability should apply in vaccine injury cases.²⁷¹

The other two cases concerned the application of market share liability for manufacturing defect claims,²⁷² and the courts reached different conclusions. In *Sheffield v. Eli Lilly & Co.*,²⁷³ plaintiff alleged that the vaccine she received was defective because the manufacturer failed to properly neutralize the polio virus.²⁷⁴ Similar to the plaintiffs in *Gottsdanker* (the vaccine-induced polio case), shortly after receiving a polio vaccine, Kathryn Sheffield contracted a neurological and muscular disorder that left her paralyzed.²⁷⁵ Unlike the plaintiffs in *Gottsdanker*, however, Sheffield could not identify which manufacturer supplied the vaccine that she was administered, notwithstanding her good faith attempts and “extensive efforts” to do so.²⁷⁶ Under these circumstances, a California appellate court ruled that market share liability did not apply, and the court dismissed the case.²⁷⁷

The *Sheffield* court declined to apply market share liability for three reasons. First, unlike in *Sindell* (which involved a design defect that impacted all DES tablets), the polio vaccine at issue in *Sheffield* had a manufacturing defect.²⁷⁸ The court reasoned that it would be unfair to hold four innocent defendants responsible for an injury caused by one negligent defendant.²⁷⁹ Second, unlike in *Sindell*, in Sheffield’s case the “delay in discovering the alleged causation was in no way related to the nature of the defective product or any other act or omission of the unknown tortfeasor.”²⁸⁰ To the contrary, the Cutter Incident and cases of vaccine-induced polio were widely publicized; thus, the court opined, patients knew, or should have known, of the potential to contract polio from the vaccine.²⁸¹ Third, the court offered a policy reason to dismiss the case—namely, that imposing liability would “inhibit drug research and development,

²⁷¹ *Id.* at 223.

²⁷² Recall that *Shackil* and *Senn* were design defect claims in the context of market share liability.

²⁷³ 192 Cal. Rptr. 870 (Cal. Ct. App. 1983).

²⁷⁴ *Id.* at 880.

²⁷⁵ *Id.* at 874.

²⁷⁶ *Id.*

²⁷⁷ *Id.* at 880.

²⁷⁸ *Id.* at 876.

²⁷⁹ *Id.* at 880 (“It is obvious that if four innocent manufacturers are required to share in paying plaintiffs’ damages because none can prove that plaintiff daughter was not inoculated with its vaccine, the liability of each is in no way commensurate with its responsibility . . . By the same token the tortfeasor who manufactured the defective vaccine is receiving an undeserved contribution.”).

²⁸⁰ *Id.* at 877 (“[T]he delay was occasioned because the potential for harm was latent and did not manifest itself for many years, whereas in this case the onset of the illness occurred shortly after the victim was inoculated with the vaccine.”).

²⁸¹ *Id.*

unreasonably raise the cost of health care, and punish drug manufacturers who have done no wrong.”²⁸² The court theorized that “[i]t is not unreasonable to assume that if [market share liability] had been generally prevalent in the mid-1950s” the polio vaccine may have been delayed (or never marketed), and thus the public health benefits from the vaccine would have never materialized.²⁸³

Four years after the *Sheffield* decision, however, a federal district court in California held that *Sheffield*'s prohibition on the use of market share liability in vaccine-injury cases alleging a manufacturing defect does not apply to cases where the manufacturing defect exists industry-wide.²⁸⁴ That case—*Morris v. Parke, Davis & Co.*—was similar to *Shackil* in that it involved the DTP vaccine (though recall that *Shackil* involved an allegation of a design defect, not a manufacturing defect).²⁸⁵ The *Morris* court held that market share liability applied if the manufacturers of a vaccine shared a manufacturing defect that resulted “from common (perhaps for reasons of economy) substandard means of production, storage, transportation or marketing.”²⁸⁶ The “shared common inadequacies” distinguished the allegations in *Morris* (regarding the DTP vaccine) from *Sheffield* (regarding the polio vaccine).²⁸⁷ Thus, the *Morris* court held, there “is no unfairness” in allowing the plaintiff to proceed under a theory of market share liability.²⁸⁸ While the *Morris* court was mindful of the potential impact of its holding on the vaccine market and the availability of vaccines, the court afforded greater weight to providing legal recourse in cases where a plaintiff can demonstrate that a marketed vaccine contained a manufacturing defect.

B. *The 1976 Swine Flu Vaccine: Industry Demands Government Indemnification for Vaccine-Related Injuries*

In late January 1976, Army Private David Lewis reported to sick call at his base in Fort Dix, New Jersey.²⁸⁹ He was diagnosed with an upper respiratory infection and was told to rest; however, he went on a march and collapsed.²⁹⁰ Days later, he died.²⁹¹ Shortly thereafter several other army recruits at Fort Dix reported to sick call with upper respiratory disorders.²⁹² When the New Jersey

²⁸² *Id.* at 879.

²⁸³ *Id.* at 880.

²⁸⁴ *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1342 (C.D. Cal. 1987).

²⁸⁵ *Id.* at 1334.

²⁸⁶ *Id.* at 1342.

²⁸⁷ *Id.* (holding that plaintiff's legal theory was correct that market share liability applied to their claim because manufacturing defects were present in all of defendants' products).

²⁸⁸ *Id.*

²⁸⁹ Reitze, *supra* note 43, at 169.

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.*

Department of Public Health examined throat cultures from the sick men, the agency discovered two forms of the flu virus—one was the variation that had been diagnosed as the seasonal flu that year, but the agency could not identify the other.²⁹³ The cultures were sent to the CDC in Atlanta, where federal officials determined that the second virus was a variation of swine flu, the virus that caused the 1918-1919 flu pandemic that killed six hundred thousand Americans and wreaked havoc across the globe.²⁹⁴ Cases of swine flu in the United States were extremely rare; only two cases had been reported over the previous two years, and both involved individuals who had close contact with pigs.²⁹⁵ The CDC's analysis set in motion the most extensive emergency vaccination program in American history.²⁹⁶

On February 14, 1976, just ten days after the death of Private Lewis, representatives from the military, NIH, FDA, and the New Jersey Department of Health convened an emergency meeting during which they decided that additional research was necessary to determine the extent of swine flu cases.²⁹⁷ Subsequent surveillance and testing uncovered more than two hundred cases of flu, but only four cases of swine flu (including Private Lewis).²⁹⁸ Although not a single case of swine flu was found outside of Fort Dix, public health officials feared the possibility of an outbreak.²⁹⁹ In turn, a public health advisory committee recommended creating a swine flu immunization program “to prevent the effects of a possible pandemic.”³⁰⁰ Several options were considered, including immunizing the entire U.S. population or a portion of the population that was particularly susceptible to the virus.³⁰¹ Given the small number of swine flu cases, another option was to stockpile the vaccine and institute a vaccination

²⁹³ *Id.*; David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, 12 EMERGING INFECTIOUS DISEASES 29, 29 (2006). Influenza is not a single virus, but rather “a family of viruses that continually change molecular makeup.” Reitze, *supra* note 43, at 170. Influenza affects humans, birds, and animals, and a variation in the virus can cause the disease to spread from one species to another. *Id.* In addition, small changes in the molecular structure can have a devastating impact that makes one strain of influenza much more deadly than another. *Id.* Insofar as vaccines typically are developed to counter one or two variations of the influenza virus, slight variations in the virus “can make influenza vaccines obsolete.” *Id.*

²⁹⁴ Sencer & Millar, *supra* note 293, at 29; *see also* Maurice Hilleman, *Cooperation Between Government and Industry in Combating a Perceived Emerging Pandemic*, 275 JAMA 241, 241 (1996); Reitze, *supra* note 43, at 169. The 1918-1919 pandemic killed twenty million people worldwide, and about two billion people contracted the disease. *Id.* at 170.

²⁹⁵ Sencer & Millar, *supra* note 293, at 29.

²⁹⁶ *See* Reitze, *supra* note 43, at 169.

²⁹⁷ Sencer & Millar, *supra* note 293, at 29.

²⁹⁸ *Id.*; *see also* Reitze, *supra* note 43, at 171.

²⁹⁹ Reitze, *supra* note 43, at 171; Sencer & Millar, *supra* note 293, at 29-30.

³⁰⁰ Sencer & Millar, *supra* note 293, at 30.

³⁰¹ *Id.*

program only if additional cases surfaced.³⁰² For its part, the World Health Organization advocated a “wait and see” approach, rather than a full-scale immunization program.³⁰³

The CDC recommended a nationwide immunization program with a goal of immunizing ninety-five percent of the U.S. population.³⁰⁴ The CDC further recommended that private manufacturers produce the vaccine and that the federal government provide grants to state and local public health agencies so they could purchase and administer the immunizations.³⁰⁵ While most state public health officials supported the program, New Jersey opposed the plan and Wisconsin opposed federal involvement in vaccination efforts.³⁰⁶ Thereafter, President Gerald Ford convened a blue-ribbon committee that included Jonas Salk and Albert Sabin, among other notable public health experts. The committee concurred with the CDC’s recommendation.³⁰⁷ In April 1976, Congress authorized \$135 million for a swine flu immunization program.³⁰⁸ Prior to the authorization, industry executives lobbied for governmental indemnification for vaccine-related injuries, but Congress did not include this indemnification in the authorization bill.³⁰⁹

Several significant issues with the immunization program arose, including vaccine supply problems and continued debate as to whether the vaccine should be administered immediately or stockpiled until there was a “greater certainty of the threat.”³¹⁰ In June 1976, Dr. Sabin, who advocated earlier for a mandatory immunization program, publicly stated that stockpiling was the better option.³¹¹ Field trials on children and adults were conducted with two versions: a “whole” and “split” vaccine.³¹² For children, the whole version had significant adverse events, but the split version did not confer immunity.³¹³ The CDC later announced that children would not receive the vaccine.³¹⁴ Many public health officials cautioned against this approach, since children are considered to be

³⁰² *Id.*

³⁰³ Rebecca Kreston, *The Public Health Legacy of the 1976 Swine Flu Outbreak*, DISCOVER MAG. BLOGS (Sept. 30, 2013, 8:30 AM), <http://blogs.discovermagazine.com/body-horrors/2013/09/30/public-health-legacy-1976-swine-flu/> [<https://perma.cc/VXL9-ZM9Q>].

³⁰⁴ Sencer & Millar, *supra* note 293, at 30.

³⁰⁵ *Id.*

³⁰⁶ *Id.*

³⁰⁷ *Id.*

³⁰⁸ Baynes, *supra* note 85, at 63.

³⁰⁹ *Id.* at 64.

³¹⁰ Hilleman, *supra* note 294, at 241.

³¹¹ Reitze, *supra* note 43, at 175.

³¹² *Id.*

³¹³ *Id.*

³¹⁴ *Id.*

among primary influenza spreaders.³¹⁵ In the end, however, CDC's position against immunizing children was adopted.³¹⁶

A cadre of new laws was necessary to implement the vaccination program, including antitrust law exceptions for vaccine manufacturers.³¹⁷ Of particular concern was liability for vaccine-related injuries.³¹⁸ The insurance industry announced that, as of June 30, 1976, it would not provide coverage for swine flu vaccine manufacturers.³¹⁹ This was due, in part, to the *Reyes* warning defect decision from two years earlier.³²⁰ In turn, vaccine manufacturers sought to pass the liability risk onto the government.³²¹ While President Ford supported the vaccine industry's efforts to do so,³²² lawmakers were skeptical of assuming liability, and the liability issue nearly derailed the entire program.³²³ Although a swine flu indemnification bill was introduced in Congress on July 16, 1976, "Congress did not act on it because of the government's reluctance to accept the financial responsibility."³²⁴ In response, manufacturers stopped producing the vaccine.³²⁵

An unrelated incident during the summer of 1976 helped put the liability issue to rest. On August 2, 1976, deaths from an "influenza[-]like illness" surfaced from elderly men who attended an American Legion convention in Philadelphia.³²⁶ Although swine flu was ruled out within two days (the men succumbed to a bacterial pneumonia that later would be termed Legionnaires' disease), the outbreak revitalized the swine flu vaccination program.³²⁷ In the wake of the Legionnaires' outbreak, vaccine manufacturers provided the government with an ultimatum "that the federal government indemnify them

³¹⁵ *Id.*

³¹⁶ *Id.*

³¹⁷ See, e.g., Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 11-12 (2005) (discussing enactment and provisions of Swine Flu Act); Hilleman, *supra* note 294, at 241 ("New regulations were needed to permit temporary suspension of antitrust laws for manufacturers . . .").

³¹⁸ See Greenberger, *supra* note 317, at 11.

³¹⁹ *Id.*

³²⁰ *Id.* ("*Reyes* . . . held polio vaccine manufacturers strictly liable for failing to provide product warnings directly to vaccinees . . .").

³²¹ Baynes, *supra* note 85, at 64.

³²² *Id.* at 65 ("[The President] wrote in a letter to the Chairman of the House Subcommittee on Health, 'I directed Secretary Matthews on June 16 to submit legislation to Congress to enable the government to assume a proper share of risks . . .').

³²³ Greenberger, *supra* note 317, at 11-12.

³²⁴ *Id.*

³²⁵ *Id.* at 12.

³²⁶ Sencer & Millar, *supra* note 293, at 31.

³²⁷ *Id.*; see also Hilleman, *supra* note 294, at 242.

against claims of adverse reactions as a requirement for release of the vaccines.”³²⁸ According to David Sencer, the CDC Director at the time, “[w]hile the manufacturers’ ultimatum reflected the trend of increased litigiousness in American society, its unintended, unmistakable subliminal message blared ‘There’s something wrong with this vaccine.’”³²⁹

Publicly, the vaccine industry claimed that indemnification was necessary in light of recent products liability cases—such as the *Reyes* decision concerning warning defects.³³⁰ Were it not for the Legionnaires’ outbreak, however, “Congress likely would have dropped the legislative effort.”³³¹ As several commentators have observed, the remarkably fortuitous timing of the Legionnaires’ outbreak saved the swine flu vaccination program from being abandoned.³³² Vaccine manufacturers refused to provide the vaccine absent government indemnification, something that lawmakers refused to acquiesce to until the Legionnaires’ cases rekindled public fear of what might happen in the event of a swine flu outbreak.³³³

Ten days after the Legionnaires’ affair, Congress passed the Swine Flu Act, which provided government indemnification for vaccine-related injuries and created a federally-funded compensation fund to provide remedies for individuals harmed by the swine flu vaccine.³³⁴ At the time, many lawmakers lamented that “the drug and insurance industry had taken advantage of the influenza crisis to acquire special advantages.”³³⁵ Nonetheless, the bill passed easily and was immediately signed by President Ford.³³⁶ Ford, however, was not warned about several concerns, including side effects of the vaccine and dosage problems for children.³³⁷

The law, which became effective on October 1, 1976, granted legal immunity to swine flu vaccine manufacturers, distributors, and administrators.³³⁸ In cases of vaccine-related injuries, plaintiffs were required to assert a claim against the

³²⁸ Sencer & Millar, *supra* note 293, at 31. For his part, President Ford repeated his demand that Congress solve the liability issue. Baynes, *supra* note 85, at 65.

³²⁹ Sencer & Millar, *supra* note 293, at 31. Sencer’s co-author on the article, Dr. Millar, was the director of the National Influenza Immunization Program, and charged with spearheading the swine flu vaccination efforts. *Id.* at 33.

³³⁰ Baynes, *supra* note 85, at 66.

³³¹ Hilleman, *supra* note 294, at 242.

³³² Greenberger, *supra* note 317, at 12.

³³³ *Id.* at 11-12.

³³⁴ *Id.*

³³⁵ Baynes, *supra* note 85, at 64 n.134 (citing 122 Cong. Rec. S14,108, S14,116, S14,119, H8648 (daily ed. Aug. 10, 1976)).

³³⁶ Reitze, *supra* note 43, at 179.

³³⁷ *Id.* at 173; see also RICHARD E. NEUSTADT & HARVEY V. FINEBERG, *THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY SLOPE* 22 (1978).

³³⁸ National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, § 2, 90 Stat. 1113, 1115 (codified as amended at 42 U.S.C. § 247b (2012)).

federal government under the Federal Tort Claims Act.³³⁹ Claims could proceed “based on any theory of liability . . . including negligence, strict liability in tort, and breach of warranty.”³⁴⁰ Courts interpreted the law to encompass swine-flu-vaccine-related claims where a plaintiff could prove that the vaccine caused their injuries.³⁴¹ Prior to filing a lawsuit, however, claimants were required to file an administrative claim.³⁴² In the event of negligence on the part of manufacturers, distributors, or administrators, the law allowed the United States to seek indemnification from the negligent party.³⁴³ The statute did not place a cap on damages.³⁴⁴

Although public health officials expected swine flu diagnoses to begin in September 1976 (September marks the beginning of flu season), no cases were reported that month.³⁴⁵ Indeed, when vaccinations commenced on October 1, 1976, not one case of swine flu had been diagnosed outside of the earlier cases from Fort Dix.³⁴⁶ This led some experts to question “whether the influenza threat was real or only judged to be real.”³⁴⁷ Indeed, there was “an early and increasing disenchantment in the larger scientific community with the idea that there was a real threat of pandemic influenza.”³⁴⁸ According to one poll, only fifty-three percent of Americans planned to be vaccinated.³⁴⁹ Furthermore, there was a significant vaccine shortage³⁵⁰ and vaccine potency was less than expected.³⁵¹

Notwithstanding these shortcomings, within the first ten weeks of the program about forty-five million Americans were vaccinated—about one-third of the adult population.³⁵² Ten days after vaccinations began, however, three elderly vaccinees in Pittsburgh, Pennsylvania, died.³⁵³ Consequently, the county

³³⁹ Greenberger, *supra* note 317, at 12.

³⁴⁰ § 2, 90 Stat. at 1115.

³⁴¹ Greenberger, *supra* note 317, at 12.

³⁴² *Id.* at 13.

³⁴³ *Id.* at 12.

³⁴⁴ *Id.* at 13.

³⁴⁵ See Hilleman, *supra* note 294, at 242.

³⁴⁶ *Id.*

³⁴⁷ *Id.*

³⁴⁸ *Id.* at 243.

³⁴⁹ Baynes, *supra* note 85, at 69.

³⁵⁰ By December 1, 1976, only 146 million doses were available, far fewer than were necessary to implement the program. Hilleman, *supra* note 294, at 241 tbl.2. The government contracted for the acquisition of two hundred million doses. Greenberger, *supra* note 317, at 11.

³⁵¹ Hilleman, *supra* note 294, at 241 tbl.2.

³⁵² Greenberger, *supra* note 317, at 13; Reitze, *supra* note 43, at 179 (“This was twice the number of inoculations ever given previously for an influenza virus in a single season.”); Sencer & Millar, *supra* note 293, at 31.

³⁵³ Reitze, *supra* note 43, at 179.

and nine states suspended their immunization programs.³⁵⁴ Days later—after President Ford was immunized on public television—the county and five states resumed their respective immunization programs.³⁵⁵ Public health officials then decided that children would be vaccinated and that they would receive two doses of the vaccine.³⁵⁶ Due to vaccine shortages, however, only one in twelve children could be vaccinated.³⁵⁷ Vaccination rates for adults ranged from ten percent in some states to eighty percent in others.³⁵⁸

Meanwhile, by mid-October, dozens of people had died within forty-eight hours of being vaccinated, and “[f]or the first time, the possibility was raised that the vaccine itself might be a killer.”³⁵⁹ Within weeks, cases of Guillain-Barré syndrome surfaced in Alabama, Minnesota, and New Jersey.³⁶⁰ This rare disease results in a potentially fatal form of paralysis.³⁶¹ Treatment for Guillain-Barré syndrome entails “complete nursing care in an intensive hospital setting,” though in some cases the paralysis is reversible.³⁶² One person among the early Guillain-Barré cases died, and the rate of the disease in those who received the swine flu vaccine was seven times higher than those who did not receive it.³⁶³ Moreover, the syndrome can take weeks to develop, so it was not clear how many vaccine-related cases would emerge.³⁶⁴ Vaccine-related cases of Guillain-Barré syndrome were not unexpected, as officials knew that the vaccine could cause the disease and other neurological complications.³⁶⁵ The rate of adverse events, however, was unknown.³⁶⁶

On December 16, 1976, less than three months after immunizations commenced, the federal government halted the program.³⁶⁷ By March 1977, 427 cases of vaccine-related Guillain-Barré syndrome had been reported and at least six individuals died from the disease.³⁶⁸ In the end, the CDC recorded 532 cases

³⁵⁴ *Id.*

³⁵⁵ *Id.*

³⁵⁶ *Id.*

³⁵⁷ *Id.*

³⁵⁸ *Id.*

³⁵⁹ Michael S. Morgenstern, *The Role of the Federal Government in Protecting Citizens from Communicable Diseases*, 47 U. CIN. L. REV. 537, 563 n.133 (1978).

³⁶⁰ Reitze, *supra* note 43, at 179.

³⁶¹ *Id.* at 182; *see also* Greenberger, *supra* note 317, at 13.

³⁶² Greenberger, *supra* note 317, at 13; Reitze, *supra* note 43, at 182.

³⁶³ Hilleman, *supra* note 294, at 242; *see also* Reitze, *supra* note 43, at 179-80 (reporting eleven-fold increase in risk amongst vaccinated (exposed) cohort relative to unvaccinated (unexposed) cohort).

³⁶⁴ Hilleman, *supra* note 294, at 242.

³⁶⁵ NEUSTADT & FINEBERG, *supra* note 337, at 30.

³⁶⁶ *Id.*

³⁶⁷ *Id.* at 61. Because swine flu did not strike the United States that year, the efficacy of the vaccine was not tested. *See* Morgenstern, *supra* note 359, at 539.

³⁶⁸ Hilleman, *supra* note 294, at 242; Morgenstern, *supra* note 359, at 539.

of Guillain-Barré syndrome, resulting in fifty-eight fatalities.³⁶⁹ The estimated risk of the disease was one per one hundred thousand immunizations, a significant increase when compared to the rate of the disease with other vaccines—about one in four hundred million.³⁷⁰ And, notwithstanding the extensive immunization efforts, experts later “discounted” the alleged similarity between the swine flu antibodies from Fort Dix and the 1918 virus.³⁷¹

Where the immunization program ended, litigation began. A wave of swine flu vaccine administrative claims and lawsuits ensued, alleging vaccine-related injuries such as Guillain-Barré syndrome, neurological disorders, and other adverse reactions.³⁷² By April 1985, 4165 administrative claims had been filed.³⁷³ Of these, 2813 (68%) were denied without compensation and 691 (17%) were settled for a total of \$41,923,744, an average of \$60,671 per settled case.³⁷⁴

In total, 1604 swine flu vaccine lawsuits were filed.³⁷⁵ Of the lawsuits, 706 (44%) were dismissed and 372 (23%) cases were settled for a combined amount of \$35,208,225, an average of \$94,646 per settled case.³⁷⁶ In cases where liability was contested, the government won 259 of 307 cases (84%); in the 48 cases (16%) that the government lost, the total award equaled \$24,310,114, an average of \$506,460 per successful case.³⁷⁷ By April 1985, compensation judgments and awards totaled approximately \$90 million, which nearly matched the \$100 million that the government had earmarked for purchase of the vaccine itself.³⁷⁸ As the IOM succinctly concluded in a report published in 1985, the “swine flu program was not a public health success.”³⁷⁹

During the swine flu scare, public health officials faced a “no-win situation.”³⁸⁰ If the government failed to acquire the necessary vaccines and there was a deadly swine flu outbreak, the government would have been accused

³⁶⁹ Reitze, *supra* note 43, at 183-84.

³⁷⁰ *Id.* The rate of Guillain-Barré syndrome shifts with the time window of each study. For example, some studies set a cut off date of six weeks for a case to be deemed vaccine-related, while others set a window of eight weeks. *Id.* at 184.

³⁷¹ Morgenstern, *supra* note 359, at 548 n.72; *see also* Kreston, *supra* note 303.

³⁷² Reitze, *supra* note 43, at 181. The cases were consolidated for purposes of pretrial discovery, and fourteen law firms served on a Swine Flu Litigation Steering Committee. Pursuant to the Swine Flu Act, plaintiffs did not have a right to a jury trial. *Id.* at 184; 1985 IOM REPORT, *supra* note 17, at 111.

³⁷³ Reitze, *supra* note 43, at 184.

³⁷⁴ *Id.*

³⁷⁵ *Id.*

³⁷⁶ *Id.*

³⁷⁷ *Id.* at 184-85.

³⁷⁸ Greenberger, *supra* note 317, at 13; Reitze, *supra* note 43, at 185. This figure does not include other costs of litigation, such as litigation expenses or the opportunity costs of using government attorney time for swine flu cases in lieu of other matters. *Id.*

³⁷⁹ 1985 IOM REPORT, *supra* note 17, at 95.

³⁸⁰ Reitze, *supra* note 43, at 172.

of not doing enough; if the government prepared and there was no outbreak, it might be accused of wasting money.³⁸¹ These are difficult scenarios that public health officials face. At the same time, as public health law expert Wendy Parmet explains, the 1976 swine flu vaccination program “set a precedent and taught a lesson. The precedent was that vaccine manufacturers would demand and receive liability protection in order to maintain an adequate supply of vaccine. The lesson was that the government’s assumption of liability created significant costs for the federal treasury.”³⁸² During the time that Congress was debating the Vaccine Act, the swine flu episode was fresh in the minds of lawmakers, the vaccine industry, and public health officials, and thus had a “substantial influence on the development of public policy concerning vaccination programs.”³⁸³

C. *1980s Public Health Politics: Portraying the FDA as a Bureaucratic Hindrance to Health and Safety*

The reputation and power of the FDA has waxed and waned for decades.³⁸⁴ This oscillation often has aligned with the political will of lawmakers, who have had to balance business interests with public health concerns, and the public’s perception of the proper role of the FDA in regulating access to, and the quality of, medical products. To understand the political climate that enveloped the FDA during the 1980s, however, one must be mindful of the social, medical, and political underpinnings surrounding prior regulatory milestones.

For vaccines, the first regulatory milestone dates back to 1813, shortly after Edward Jenner’s smallpox vaccine became commercially available in the United States.³⁸⁵ The Vaccine Act of 1813 authorized the president “to appoint a federal agent to ‘preserve the genuine vaccine matter, and to furnish the same to any

³⁸¹ *Id.* Because of the resources dedicated to combatting swine flu, sufficient vaccines were not produced to combat the actual flu virus that was present that year. Morgenstern, *supra* note 359, at 555 n.96 (“Two types of vaccine . . . were produced for the 1976 swine flu program. The monovalent protected against swine flu only; the bivalent protected against swine flu and A/Victoria . . . [B]ecause program planners had failed to produce sufficient quantities of A/Victoria monovalent, the population could not be vaccinated against this strain.”).

³⁸² Wendy E. Parmet, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST. LOUIS U. J. HEALTH L. & POL’Y 113, 132-33 (2010).

³⁸³ Reitze, *supra* note 43, at 169.

³⁸⁴ See generally DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (2010) (discussing how FDA has built and retained influence amongst powerful national entities through use of its organizational image and reputation).

³⁸⁵ 1985 IOM REPORT, *supra* note 17, at 15 (“By the middle of the eighteenth century, physicians recognized that persons infected with cowpox appeared to be protected from later exposure to smallpox, resulting in Edward Jenner’s classic experiment in 1796 . . . [T]he vaccine was the subject of the nation’s first law regulating the distribution of drugs, the Vaccine Act of 1813.”).

citizen' who requested it."³⁸⁶ This law was repealed in 1822 "after Congress decided that vaccine regulation should be left to local authorities."³⁸⁷ In many instances, however, local authorities did not issue any regulations for the testing and certification of vaccines, and "substandard, ineffective, or dangerous preparations were sometimes produced and sold."³⁸⁸ Medical experts and public health officials had consistently warned of the potential pitfalls of inadequate regulations, though "profiteering by manufacturers" and legislative inaction continued throughout the nineteenth century.³⁸⁹

In October 1901, thirteen children in St. Louis, Missouri, died after being inoculated with a diphtheria antitoxin vaccine that was contaminated with tetanus.³⁹⁰ That same fall, nine children in Camden, New Jersey, died after being administered a contaminated smallpox vaccine.³⁹¹ Following the tragedies, fear of tainted vaccines swept across the nation.³⁹² An editorial in the *Journal of the American Medical Association* argued that physicians must "demand [from the manufacturers] a guaranteed purity of antitoxin."³⁹³ Months later, lawmakers passed the Biologics Control Act of 1902.³⁹⁴ This law authorized the Hygienic Laboratory of the Public Health and Marine Hospital Service—the precursor to the FDA's Center for Biologics Evaluation and Research, which today is responsible for the regulation of vaccines—to issue regulations governing the production, potency, purity, and safety of immunizations.³⁹⁵ The law granted federal authorities the ability to inspect manufacturing plants and issue or revoke vaccine licenses.³⁹⁶

³⁸⁶ *Id.*

³⁸⁷ *Id.*

³⁸⁸ *Id.* at 16.

³⁸⁹ *Id.*

³⁹⁰ U.S. FOOD & DRUG ADMIN., CTR. FOR BIOLOGICS EVALUATION & RES., SCIENCE AND THE REGULATION OF BIOLOGICAL PRODUCTS 13 (2002).

³⁹¹ OFFIT, *supra* note 51, at 59.

³⁹² ROSS E. DEHOVITZ, *The 1901 St Louis Incident: The First Modern Medical Disaster*, 133 PEDIATRICS 964, 965 (2014).

³⁹³ *Id.*

³⁹⁴ Biologics Control Act of 1902, ch. 1378, 32 Stat. 728, 730 (prohibiting sale of "any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man" unless associated production and distribution facilities are licensed or abide by certain labeling requirements). The United States lagged behind other nations in regulating immunizations. By 1895, countries such as France, Germany, Italy, and Russia had laws governing vaccine production, licensing, and inspection. *See* U.S. FOOD & DRUG ADMIN., *supra* note 390, at 12.

³⁹⁵ U.S. FOOD & DRUG ADMIN., *supra* note 390, at 7, 13.

³⁹⁶ 1985 IOM REPORT, *supra* note 17, at 16.

Congress's response to vaccine safety was more expedient than its response to safety concerns about food, drugs, and cosmetics.³⁹⁷ For decades prior to the Biologics Control Act, Congress debated whether to enact regulations or continue with a *laissez-faire* approach to these important consumer products. All the while, the public lamented at "the use of poisonous [ingredients] in foods, and cure-all claims for worthless and dangerous . . . medicines."³⁹⁸ Congress did not act until after the 1906 publication of Upton Sinclair's *The Jungle*, which revealed grossly unsanitary conditions in meat-packing plants.³⁹⁹ The Pure Food and Drug Act of 1906, though it did not speak directly to vaccines, established federal authority for enacting regulations governing food and drugs.⁴⁰⁰

The limited scope of the Pure Food and Drug Act became apparent in the following decades, though public calls for more stringent federal guidelines were rebuffed by lawmakers who were eager to acquiesce to industry demands.⁴⁰¹ This was notwithstanding public outcry over serious health risks posed by products that included radioactive beverages, drugs that caused blindness, and quack medicines that purported to cure diseases such as diabetes and tuberculosis.⁴⁰² Congressional inaction turned to action after a separate

³⁹⁷ See INST. OF MED., CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY 13 (2007).

³⁹⁸ *Id.*; see generally *Developments in the Law: The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 633 (1954) (noting, as impetus for regulation, such things as mercury-contaminated wheat shipments, "insect-invested" grits, and dubious curatives for various chronic illnesses). Some companies marketed "patent or proprietary medicines" that were lethal potions, or just sugar water. Margaret A. Hamburg, *Innovation, Regulation, and the FDA*, 363 NEW ENG. J. MED. 2228, 2228 (2010).

³⁹⁹ See UPTON SINCLAIR, *THE JUNGLE* (1906); see also INST. OF MED., *supra* note 397, at 13 (drawing connection between Sinclair's reporting and congressional action).

⁴⁰⁰ See Federal Food and Drug Act of 1906, ch. 3915, 34 Stat. 768.

⁴⁰¹ See, e.g., Oscar E. Anderson, Jr., *The Pure-Food Issue: A Republican Dilemma, 1906-1912*, 61 AM. HIST. REV. 550, 569 (1956); Rayburn D. Tousley, *The Federal Food, Drug, and Cosmetic Act of 1938*, 5 J. MARKETING 259, 260 (1941). The 1906 Act was amended seven times between 1906 and 1935. *Id.* at 259. One such amendment, passed in 1912, "declared that a drug was misbranded if its label contained any *false and fraudulent* statement[s] regarding the therapeutic effect[s] of the drug." *Id.* This rendered the provision "virtually unenforceable since legal fraud, which involves an intent to deceive, [was] almost impossible to prove." *Id.* An early draft of the amendment contained the phrase "false or misleading," which would have made enforcement less challenging. *Id.* Further hindering enforcement, the Supreme Court ruled that the 1906 Act did not apply to false claims of efficacy. *United States v. Johnson*, 221 U.S. 488, 495-97 (1911) (construing Act's misbranding provisions to only prohibit false statements as to drug's identity, and not to false curative or therapeutic statements).

⁴⁰² See generally ARTHUR KALLET & F.J. SCHLINK, *100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS* (1933) (discussing health risks posed by food, drug, and cosmetic products nationwide, and how consumers can best defend themselves against these dangers).

public health disaster in 1937 where over one hundred people died from use of elixir sulfanilamide, a syrup administered to children with sore throats.⁴⁰³ In addition to the deaths, countless children suffered “intense and unrelenting pain,” which included stoppage of urine, convulsions, vomiting, and severe abdominal pain.⁴⁰⁴ Had the company conducted basic animal studies or simply reviewed the scientific literature, it would have discovered the lethal characteristics of the concoction.⁴⁰⁵

In the aftermath of the elixir sulfanilamide tragedy, public health officials and media outlets pointed to pre-market review for vaccines, as afforded under the Biologics Control Act, as an appropriate model for regulating pharmaceuticals.⁴⁰⁶ The following year, Congress enacted the Food, Drug, and Cosmetic Act of 1938 (“FDCA”).⁴⁰⁷ Although the FDCA did not amend or supersede the Biologics Control Act, it mandated pre-market safety review for drugs, authorized factory inspections, and established new powers to regulate food and cosmetics.⁴⁰⁸ At the time, the pharmaceutical industry opposed what it deemed to be “an extensive revision of existing legislation” while consumers argued that the FDCA did not sufficiently address public health concerns.⁴⁰⁹ In the years following the FDCA’s enactment, Congress worked to narrow the scope of the statute so as not to disrupt industry practice “while at the same time establishing in the public mind the belief that an acceptable law had been adopted.”⁴¹⁰

The Biologics Control Act was later incorporated into the Public Health Service Act of 1944.⁴¹¹ In part, the new law was passed in response to polio vaccine research, during which several children died or were paralyzed.⁴¹² After

⁴⁰³ Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER (June 1981), <https://www.fda.gov/aboutfda/whatwedo/history/productregulation/sulfanilamidedisaster/> [<https://perma.cc/258P-KWPX>]. The drug was created by combining sulfanilamide (a powder) with diethylene glycol (a toxic chemical that often is used as an antifreeze), and then adding a raspberry sweetener. *Id.*

⁴⁰⁴ *Id.*

⁴⁰⁵ *Id.* The owner of the pharmaceutical company denied any error in the manufacture of the product and passed responsibility on to the public for desiring a sweet-tasting, liquid form of sulfanilamide. *Id.* The chemist who created the medicine did not share this sentiment, and committed suicide shortly after the catastrophe. *Id.*

⁴⁰⁶ CARPENTER, *supra* note 384, at 102.

⁴⁰⁷ Food, Drug, and Cosmetic Act of 1938, ch. 675, § 505(a), 52 Stat. 1040, 1052 (codified as amended at 21 U.S.C.A. §§ 301-399g (2017)).

⁴⁰⁸ U.S. FOOD & DRUG ADMIN., *supra* note 390, at 13; Tousley, *supra* note 401, at 262-63.

⁴⁰⁹ Tousley, *supra* note 401, at 267.

⁴¹⁰ David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 4-5 (1939). One congressional tactic was to grossly underfund the FDA. *See, e.g.*, Parasidis, *supra* note 72, at 941.

⁴¹¹ 1985 IOM REPORT, *supra* note 17, at 17.

⁴¹² Chen et al., *supra* note 27, at 545 (“Although concerns were expressed about the lack of regulations to protect against fraudulent or impure antitoxins on the market, it was only

the Public Health Service Act, authority for vaccine oversight was transferred from the Hygienic Laboratory of the Public Health Service to the NIH.⁴¹³

A public health crisis in the late 1950s contributed to another round of public outcry—approximately eight thousand children were born with birth defects to mothers who had taken thalidomide, a widely-used medication for morning sickness during pregnancy.⁴¹⁴ Thereafter, Congress responded with the 1962 Kefauver-Harris Amendments to the FDCA.⁴¹⁵ The Kefauver-Harris Amendments were substantial, and their key contribution was a new requirement that pharmaceutical companies demonstrate that their product was not only safe (as was required under the FDCA), but also effective. Thus, it was not until 1962 that the FDA began requiring evidence of safety and efficacy for all new pharmaceuticals.⁴¹⁶ Following enactment of the Kefauver-Harris Amendments, the agency also established the randomized control study as the gold standard for demonstrating efficacy.⁴¹⁷ Although then-FDA Commissioner George Larrick praised the new legislation as necessary to promote the public health, he also warned that “even the most extensive clinical investigation will reveal only a fraction of the information that emerges during the course of a drug’s general marketing and use.”⁴¹⁸

Business groups and the pharmaceutical industry opposed the new efficacy laws, as did the American Medical Association, the country’s largest association

after 13 children died from administration of tetanus-contaminated diphtheria antitoxin that the first Biologics Control Act . . . was adopted.”). Another motivating factor likely was the yellow fever vaccine tragedy during World War II. Approximately fifty thousand service members contracted liver disease after receiving a vaccine contaminated with hepatitis B; about one hundred fifty died. Wadman, *supra* note 104.

⁴¹³ 1985 IOM REPORT, *supra* note 17, at 17.

⁴¹⁴ *The Thalidomide Disaster*, TIME, Aug. 10, 1962, at 34. This public health crisis occurred in Europe, and marketing of thalidomide had been held up in the United States thanks to the work of one FDA employee, Dr. Frances Kelsey, who pressed the drug sponsor for additional tests in order to ensure that the product was safe. *Id.*

⁴¹⁵ Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781-82 (codified as amended at 21 U.S.C.A. § 355(d) (2017)).

⁴¹⁶ The Kefauver-Harris Amendments also granted the FDA the authority to evaluate the efficacy of all drugs approved between 1938 and 1962, as well as the power to withdraw inefficacious drugs from the market. *Id.* (allowing FDA to refuse approval of drug if “there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have”).

⁴¹⁷ INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 49 (2011).

⁴¹⁸ David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 486 n.111 (2008) (internal quotation marks omitted) (quoting Charles Steenburg, *The Food and Drug Administration’s Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 FOOD & DRUG L.J. 295, 297 (2006)).

of physicians.⁴¹⁹ One of the pharmaceutical industry's principal lobbying groups—the Pharmaceutical Research and Manufacturers' Association (“PhRMA”)—created a “rumor campaign . . . that was designed to discredit the FDA among practicing physicians.”⁴²⁰ Regulation of vaccines transferred to the FDA in 1972, where it currently remains.⁴²¹ In large part, this transfer was motivated by the NIH's failure to institute a framework for evaluating vaccine efficacy that was on par with the system established by the FDA for pharmaceuticals.⁴²²

The Kefauver-Harris Amendments placed significant new responsibilities on the FDA, yet Congress did not appropriate adequate funds to permit the agency the ability to fulfill its mandate.⁴²³ This phenomenon is something that Peter Hutt has termed “hollow government syndrome,” which applies to an agency that has “expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.”⁴²⁴

Along with granting the FDA increased regulatory power, the Kefauver-Harris Amendments increased the time required to bring a new drug to market.⁴²⁵ Notwithstanding the increase in review time, from the FDA's inception through the mid-1970s the agency never received congressional criticism for a delay in approving a new medical product.⁴²⁶ Rather, countless investigations were launched into drugs that were approved but later turned out to be dangerous.⁴²⁷ As FDA Commissioner Alexander Schmidt testified in 1974: “The message to FDA staff could not be clearer. Whenever a controversy over a new drug is resolved by its approval, the Agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made.”⁴²⁸

This would change abruptly. By the late 1970s, both Republicans and Democrats supported anti-regulatory positions, and an anti-regulatory zenith

⁴¹⁹ CARPENTER, *supra* note 384, at 300.

⁴²⁰ *Id.* at 365.

⁴²¹ U.S. FOOD & DRUG ADMIN., *supra* note 390, at 22.

⁴²² *Id.*

⁴²³ Daniel P. Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy*, 23 HEALTH AFF. 52, 58 (2004) (“One important reason that FDA drug approval times slowed in the 1970s, engendering complaints of a ‘drug lag,’ is that the 1962 Amendments to the 1938 Food, Drug, and Cosmetic Act piled many new responsibilities onto the FDA without a proportionate increase in personnel.”).

⁴²⁴ Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 432 (2008). Mr. Hutt was FDA Chief Counsel from 1971 to 1975. *Id.* at 431.

⁴²⁵ Carpenter, *supra* note 423, at 58.

⁴²⁶ *Id.* at 54.

⁴²⁷ *See id.*

⁴²⁸ *Id.* As Carpenter explains, “[b]efore the 1980s it was rare for anyone outside of clinical or academic circles to criticize the FDA for delay.” *Id.* at 56.

came during the Reagan Administration.⁴²⁹ The FDA emerged as a primary target. Throughout the 1980s, several influential publications—including the *Wall Street Journal*, *Washington Post*, and *Science*—published editorials that characterized the FDA as an agency with “blood on its hands” due to unnecessarily high standards and slow review times.⁴³⁰ One respected media outlet, *Barron’s*, characterized FDA officials as “angels of death” who worked for a government enterprise that was “a clear and present danger to the nation’s health and welfare.”⁴³¹ While some articles in the mainstream media focused on specific decisions of products under FDA review, others targeted the “entire regulatory structure.”⁴³²

In particular, the *Wall Street Journal* tackled head-on the public’s high regard for the FDA, lamenting that “[t]he public has been given to believe that the Food and Drug Administration is, of its nature, a social good.”⁴³³ In one editorial, the *Wall Street Journal* claimed that the FDA’s delay in approving one drug “had killed 100,000 Americans;” the authors then argued that this “raised the question of ‘whether we should even have an FDA.’”⁴³⁴ In lieu of a federal agency with expertise in analyzing the safety and efficacy of medical products, the journalists suggested that “responsibility for safety could be merely returned to the drug makers and doctors.”⁴³⁵ The pages of the *Wall Street Journal* had significant influence, and the opinions of the newspaper’s editors “seemed quickly to spill over into the journalism of industry-focused trade reporters, and before long it would influence the internal structure of the [Reagan] Administration itself.”⁴³⁶

A cascade of congressional committee and subcommittee meetings contributed to the war on the FDA; while some praised the agency, others sought to “tarnish” or “influence” its reputation.⁴³⁷ The anti-regulatory voices gained particular prominence during the 1980s, as attacks on regulation “won allies and seized political and cultural momentum.”⁴³⁸ This framing was, in many respects, “irrevocably altered by the AIDS crisis” of the 1980s, which pitched a clash between “dying protestors and white-coated bureaucrats.”⁴³⁹ Pharmaceutical

⁴²⁹ CARPENTER, *supra* note 384, at 364.

⁴³⁰ *Id.* at 4.

⁴³¹ *Id.* at 367 (citing *Angels of Death*, BARRON’S NAT’L BUS. & FIN. WKLY., Nov. 14, 1966, at 1).

⁴³² *Id.* at 4.

⁴³³ *Id.* at 8.

⁴³⁴ *Id.* at 368.

⁴³⁵ *Id.* (internal quotation marks omitted).

⁴³⁶ *Id.*

⁴³⁷ *Id.* at 302.

⁴³⁸ *Id.* at 366.

⁴³⁹ *Id.* at 394.

companies and patient advocacy groups joined forces to petition against what they viewed as long delays in the approval of new medicines.⁴⁴⁰

Yet, advocates for early access to AIDS medicines altered much more than their specific cause. Rather, the national media widely portrayed the moral claims of AIDS activists as something that challenged the “modus operandi” of the FDA itself.⁴⁴¹ As political scientist and FDA expert Daniel Carpenter succinctly explains, “[i]n the anti-regulatory moment of the late 1970s and 1980s, national politicians began to single out the FDA as overly intrusive in the doctor-patient relationship and in the entrepreneurial process of drug development.”⁴⁴² These perspectives are embedded in the Vaccine Act.

At the time the Vaccine Act was enacted, the FDA did not maintain a robust system for collecting and reviewing vaccine-related adverse events. This was notwithstanding the fact that, during the 1976 swine flu immunization program, the government created an adverse event surveillance system that utilized the latest technologies in data collection and analysis.⁴⁴³ Indeed, it is not unreasonable to conclude that because of the success of the swine flu vaccine adverse event analysis (e.g., the discovery that the vaccine caused Guillain-Barré syndrome at a rate far higher than other vaccines), the government was reluctant to structure a comprehensive national program that closely monitored all vaccine related adverse events.⁴⁴⁴ The CDC Director, along with the director of the swine flu vaccination program, candidly wrote that the swine flu vaccination program’s “innovative surveillance system would prove to be [the program’s] Trojan horse.”⁴⁴⁵

Thus, rather than acknowledge that robust data collection and analysis serve important public health goals, leading public health officials characterized diligent adverse event surveillance as something that appears beneficial but in reality can undermine immunization efforts. The extent to which the swine flu vaccine program influenced lawmakers not to incorporate into the Vaccine Act provisions that require robust data collection and analysis is unknown, though no one can seriously doubt that the swine flu vaccine program and litigation were fresh in the minds of lawmakers and public health officials at the time of the Vaccine Act’s enactment.

⁴⁴⁰ See Carpenter, *supra* note 423, at 56 (explaining that pharmaceutical firms regularly seek alliances with patient advocates in pressing cases for priority status and FDA approval). This marked “the beginning of a much larger story of disease-based political mobilization in the United States.” *Id.* at 57.

⁴⁴¹ CARPENTER, *supra* note 384, at 394.

⁴⁴² *Id.* at 380.

⁴⁴³ Sencer & Millar, *supra* note 293, at 30-31 (detailing 1976 “proactive system of surveillance for possible adverse effects of the influenza vaccine”).

⁴⁴⁴ Greenberger, *supra* note 317, at 13.

⁴⁴⁵ Sencer & Millar, *supra* note 293, at 31.

II. THE VACCINE ACT FRAMEWORK

A review of the landscape leading up to the enactment of the Vaccine Act reveals a potpourri of legal, political, economic, and public health factors that influenced the structure of the law. Health officials sought to maximize the public health benefits of immunization, but the public increasingly grew wary of official statements given the prevalence of vaccine-related side effects and haphazard disclosures of vaccine risks.⁴⁴⁶ The public's concerns were exacerbated by significant legal challenges that injured plaintiffs faced in litigating claims against vaccine manufacturers.⁴⁴⁷ Litigation risks—particularly when coupled with unpredictable manufacturing costs and revenues—led manufacturers and investors to question whether vaccines were financially worthwhile, while challenges in assessing risk caused insurance companies to increase premiums or refuse coverage for certain vaccines.

Government indemnification of the swine flu vaccine underscored the immense costs that might arise from a comprehensive compensation program for vaccine-related injuries.⁴⁴⁸ The swine flu vaccine litigation also confirmed that the economic concerns of manufacturers and insurance companies were not unreasonable.⁴⁴⁹ At the same time, state and local public health officials were tasked with convincing the public that immunizations serve essential individual and public health goals.⁴⁵⁰

Meanwhile, judges, lawmakers, and commentators questioned the costs and benefits of allowing market share liability or products liability claims for vaccine-related injuries. A parallel, though not entirely unrelated, movement portrayed government agencies (including the FDA) as superfluous, if not harmful to the health and welfare of society. It was not just politicians and

⁴⁴⁶ As to the latter, social scientists have characterized this phenomenon as a “struggle or competition between actors and institutions, vying to valorize their own capital, control the distribution and exchange rate of capital in the field, and thus control what counts as legitimate scientific inquiry and research.” Decoteau & Underman, *supra* note 14, at 474-75. Along these lines, one must distinguish knowledge, unknown risks, and insufficiently explored risk theories. *See id.* at 475-76 (explaining that when scientific community or public advocates disagree, “the boundaries of the field are nonetheless at stake” and those involved try to “impose the definition of science that best conforms to their specific interest”).

⁴⁴⁷ *See* Greenberger, *supra* note 317, at 15.

⁴⁴⁸ *Id.* at 11-14.

⁴⁴⁹ *Id.* at 13-14 (explaining that increase in vaccine tort litigation meant that “vaccine manufacturers faced grave difficulty in obtaining liability insurance, which caused one vaccine manufacturer to stop producing vaccines temporarily in 1984”).

⁴⁵⁰ Cold War-era fears of attacks with biological weapons compounded the public health concerns, as an undervaccinated population would be particularly susceptible to weaponized infectious diseases. *See generally* Susan Wright, *Evolution of Biological Warfare Policy, 1945-1990*, in PREVENTING A BIOLOGICAL ARMS RACE (Susan Wright ed., 1990) (surveying post-war evolution of United States’ biological warfare policy and use of biological sciences for military purposes).

industry executives who shared these views—to the contrary, a significant and growing proportion of Americans adhered to core principles of libertarianism and conservatism,⁴⁵¹ both of which highly value individual choice, including the choice of whether to be vaccinated.

In terms of legislative history, the Vaccine Act was “put together at the last minute from pieces of legislation discussed in both Houses.”⁴⁵² The Senate passed the bill on voice vote and House members did not even receive a copy of the bill prior to voting.⁴⁵³ The Vaccine Act was not enacted as standalone legislation; rather, it was a component of an omnibus health measure, the central feature of which was a law that allowed for the export of American medical products that had not earned FDA approval.⁴⁵⁴ President Reagan signed the omnibus health bill “with mixed feelings.”⁴⁵⁵ He strongly supported the export provision and a separate law that eliminated federal health planning authorities, but noted his “serious reservations” with the Vaccine Act.⁴⁵⁶ Specifically, Reagan raised concerns that “there continues to be the opportunity for very substantial and inequitable differences in liability judgments awarded similarly situated plaintiffs.”⁴⁵⁷ The Department of Justice—which was responsible for representing the government in vaccine injury cases—lobbied for a presidential veto of the bill on the grounds that the Vaccine Act would be “the first step toward no-fault compensation” for other claims, such as Agent Orange and the military’s radiation experiments.⁴⁵⁸ It was in this complex cloud of public policy that the Vaccine Act was launched.

A. *National Vaccine Program: Goals, Funding, and Administration*

The Vaccine Act established the National Vaccine Program with two specific goals: “to achieve optimal prevention of human infectious diseases through

⁴⁵¹ See, e.g., Conor Friedersdorf, *Libertarians Can Be a Significant Force for Good in U.S. Politics*, ATLANTIC (Aug. 14, 2014), <https://www.theatlantic.com/politics/archive/2014/08/an-opening-for-libertarians-to-be-a-significant-force-in-us-politics/375972/> [<https://perma.cc/65NN-FQDA>] (providing an overview of the history and growth of libertarianism and conservatism); see also, e.g., Brian Doherty, *Libertarianism: Past and Prospects*, CATO UNBOUND (Mar. 7, 2007), <https://www.cato-unbound.org/2007/03/07/brian-doherty/libertarianism-past-prospects> [<https://perma.cc/5EN2-2GNV>] (same); Ryan Lizza, *Flying High*, NEW YORKER, July 25, 2016, at 28 (same).

⁴⁵² Leah R. Young, *Justice Urges Veto of Vaccine Bill*, J. COM., Oct. 23, 1986, at 14A.

⁴⁵³ Reitze, *supra* note 43, at 179.

⁴⁵⁴ Act of Nov. 14, 1986, Pub. L. No. 99-660, 100 Stat. 3743.

⁴⁵⁵ Statement on Signing the State Comprehensive Mental Health Plan Bill, 1986 PUB. PAPERS 1553, 1553 (Nov. 14, 1986).

⁴⁵⁶ *Id.*

⁴⁵⁷ *Id.* Reagan also took issue with the fact that the compensation program was to be administered by the federal judiciary, not the executive branch, and he did not want compensation funds to come from federal taxpayers. *Id.*

⁴⁵⁸ See Young, *supra* note 452, at 14A.

immunization and to achieve optimal prevention against adverse reactions to vaccines.”⁴⁵⁹ The Director of the National Vaccine Program is responsible for coordinating with, and providing direction to, several governmental agencies, including the Agency for International Development, CDC, Department of Defense, FDA, and NIH.⁴⁶⁰ This work includes: (1) research and development related to producing new vaccines and minimizing adverse reactions to vaccines; (2) safety and efficacy testing of vaccines; (3) licensing, production, procurement, and distribution of vaccines; (4) evaluating and monitoring immunizations and adverse reactions to vaccines, and determining the need for specific vaccines; and (5) encouraging investment in vaccines from industry and other non-governmental entities.⁴⁶¹

The Vaccine Act mandated that the government create a national vaccine adverse event database.⁴⁶² Prior to enactment of the Act, health-care providers did not have an obligation to report adverse events to regulators,⁴⁶³ despite the success of the adverse event reporting system implemented during the 1976 swine flu vaccine program.⁴⁶⁴ Rather, between 1978 and 1990, the CDC and FDA maintained separate, voluntary adverse event reporting systems.⁴⁶⁵ Meaningful post-market analysis was hindered significantly by a lack of interoperability and insufficient reporting requirements.⁴⁶⁶ In 1990, the Vaccine Adverse Event Reporting System (“VAERS”) became operational (though it too relied, as it still does, largely on voluntary reporting).⁴⁶⁷

The cornerstone of the Vaccine Act is the National Vaccine Injury Compensation Program, “under which compensation may be paid for a vaccine-related injury or death.”⁴⁶⁸ The compensation program is funded entirely from an excise tax of \$0.75 per vaccine dose.⁴⁶⁹ Vaccinees pay the tax, and vaccine

⁴⁵⁹ 42 U.S.C. § 300aa-1 (2012).

⁴⁶⁰ *Id.* § 300aa-2. The HHS Secretary is responsible for selecting the Director of the National Vaccine Program. *Id.* § 300aa-1. The Vaccine Act also establishes a National Vaccine Advisory Committee, whose members are appointed by the Director in consultation with the National Academy of Sciences. *Id.* § 300aa-5. The advisory committee assists in identifying research priorities and in the implementation of the National Vaccine Program. *Id.*

⁴⁶¹ 42 U.S.C. § 300aa-2.

⁴⁶² *Id.* § 300aa-2(a)(7).

⁴⁶³ Chen et al., *supra* note 27, at 542.

⁴⁶⁴ *Id.* at 545.

⁴⁶⁵ *Id.*

⁴⁶⁶ *Id.*

⁴⁶⁷ *Id.*

⁴⁶⁸ 42 U.S.C. § 300aa-10 (2012).

⁴⁶⁹ Evans, *supra* note 4, at S132. For inoculations that combine vaccines, the tax applies to each component. For example, the MMR vaccine tax is \$2.25. *Id.* The excise tax covers compensation for vaccine-related injury or death for vaccines administered after October 1,

manufacturers transfer the payment into the Trust Fund.⁴⁷⁰ Compensation for vaccine-related injuries or deaths, and the costs of administering the compensation program, are drawn entirely from the fund. The amount of the excise tax was based on anticipated compensation awards and related administrative costs,⁴⁷¹ but the Trust Fund has a net balance of over \$3.6 billion.⁴⁷²

B. *The National Vaccine Injury Compensation Program*

The rules and procedures governing claims for compensation under the Vaccine Act stem from four sources: (1) the statute; (2) Vaccine Rules of the United States Court of Federal Claims; (3) Guidelines for Practice Under the National Vaccine Injury Compensation Program; and (4) decisions of the Court of Federal Claims, Court of Appeals for the Federal Circuit, and Supreme Court. To commence a claim under the compensation program, a claimant must file a petition with the Court of Federal Claims and pay a \$400 filing fee.⁴⁷³ Petitions eligible for compensation are those where the vaccine-related injury: “[1] lasted for more than 6 months after the vaccine was given; or [2] resulted in a hospital stay and surgery; or [3] resulted in death.”⁴⁷⁴ These threshold requirements limit the realm of vaccine-related injuries that are eligible for compensation.

The petition must outline the vaccine that allegedly caused the injury, where it was administered, and the nature of the petitioner’s injuries.⁴⁷⁵ The court then forwards the petition to a special master, who reviews the petition, admits and considers evidence, and issues a ruling on the merits of the claim.⁴⁷⁶ The Vaccine Act allows for no more than eight special masters for the entire compensation program.⁴⁷⁷ Initially, the Vaccine Act afforded special masters a “limited role of only making proposed findings of fact, proposed conclusions of law, and [a] recommended decision to a judge of the Court of Federal Claims.”⁴⁷⁸ Within a few years, however, amendments to the Vaccine Act granted special masters

1988. 42 U.S.C. § 300aa-15(i)(2). For vaccine-related injury or death stemming from vaccines administered prior to that date, additional funds were appropriated. *Id.* § 300aa-15(i), -15(j).

⁴⁷⁰ See Meyers, *supra* note 21, at 793.

⁴⁷¹ Evans, *supra* note 4, at S132.

⁴⁷² TRUST FUND STATEMENT, *supra* note 37. The Trust Fund has grown steadily; for example, in 2005 the balance was approximately \$2.1 billion. Evans, *supra* note 4, at S132. Total annual costs to administer the compensation fund are about \$19 million. 2014 GAO REPORT, *supra* note 12, at 27.

⁴⁷³ 42 U.S.C. § 300aa-11(a)(1); HRSA: WHAT YOU NEED TO KNOW, *supra* note 73, at 4.

⁴⁷⁴ HRSA: WHAT YOU NEED TO KNOW, *supra* note 73, at 5 (emphasis omitted).

⁴⁷⁵ OFFICE OF SPECIAL MASTERS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 5 (2016) [hereinafter NVICP GUIDELINES].

⁴⁷⁶ 42 U.S.C. §§ 300aa-11(a)(1), -12; U.S. CT. FED. CLAIMS VACCINE R. 3(b).

⁴⁷⁷ 42 U.S.C. § 300aa-12(c)(1).

⁴⁷⁸ Meyers, *supra* note 21, at 807.

“full authority, like any trial judge or administrative law judge, to issue decisions.”⁴⁷⁹

Each vaccine claim is bifurcated; the first phase investigates “entitlement to compensation” (i.e., causation) while the second phase considers damages.⁴⁸⁰ Unlike with civil actions brought before a state or federal court, in vaccine petitions there is no discovery as a matter of right.⁴⁸¹ Rather, the rules indicate that an “informal and cooperative exchange of information is the ordinary and preferred practice.”⁴⁸² Formal discovery can be requested by either party, but the special master has wide discretion in considering whether to grant such requests.⁴⁸³ The government maintains a staff of physicians and nurses who review the petitions and issue recommendations on whether compensation should be awarded.⁴⁸⁴

Petitioners must submit all relevant medical records, and may submit an expert report that substantiates their claim for a vaccine-related injury. Respondent—the government, which is represented by attorneys from the Torts Branch of the Department of Justice⁴⁸⁵—then must file a “Rule 4 Report,” wherein the government summarizes the facts, provides a medical analysis of the petitioner’s claim, and identifies any legal issues.⁴⁸⁶ In essence, the Rule 4 Report is the government’s “evaluation of the medical and legal basis for petitioner’s claim.”⁴⁸⁷ Along with its Rule 4 Report, the government may file a motion to dismiss or motion for summary judgment, though if it elects not to do so the government is not precluded from filing such motions later.⁴⁸⁸

The Vaccine Act establishes several time limitations for claims. Petitions must be filed within three years after the first symptoms of an alleged vaccine-related injury.⁴⁸⁹ For vaccine-related deaths, the limitations period expires two years from the date of death or four years from the first symptoms of a vaccine-

⁴⁷⁹ *Id.*

⁴⁸⁰ NVICP GUIDELINES, *supra* note 475, at 5.

⁴⁸¹ U.S. CT. FED. CLAIMS VACCINE R. 7(a).

⁴⁸² *Id.*

⁴⁸³ *Id.* R. 7(b).

⁴⁸⁴ Evans, *supra* note 4, at S131.

⁴⁸⁵ Engstrom, *supra* note 8, at 1671.

⁴⁸⁶ U.S. CT. FED. CLAIMS VACCINE R. 4(c) (explaining that report must set forth “full and complete statement of its position as to why an award should or should not be granted” and “must contain respondent’s medical analysis of petitioner’s claims and must present any legal arguments that respondent may have in opposition”); NVICP GUIDELINES, *supra* note 475, at 5 (noting that “respondent files a ‘Rule 4 report’ summarizing the evidence and addressing any legal issues the case presents”). In cases where a petitioner has filed an expert report, the government must respond with an expert report along with its Rule 4 Report. *Id.* at 25.

⁴⁸⁷ NVICP GUIDELINES, *supra* note 475, at 24.

⁴⁸⁸ *Id.*

⁴⁸⁹ 42 U.S.C. § 300aa-16(a) (2012).

related disease that led to death, whichever is sooner.⁴⁹⁰ In instances where the Vaccine Injury Table is revised to include additional vaccine-related injuries, a petitioner alleging a newly added injury must file their claim within two years of the revision; in such cases, however, the Vaccine Act prohibits claims where the vaccine-related injury or death occurred more than eight years prior to the revision.⁴⁹¹

Special masters have “wide latitude” in adjudicating petitions under the compensation program.⁴⁹² Some special masters look for “magic words” in expert reports regarding causation, while others place “less emphasis on these reports.”⁴⁹³ The special masters also determine what evidence may be “reasonable and necessary” to the petition, and may require “the testimony of any person and the production of any documents as may be reasonable and necessary.”⁴⁹⁴ Special masters can mandate that a petitioner undergo additional medical testing, and may, on occasion, order that the parties hire a “neutral medical expert to render an opinion on a medical dispute.”⁴⁹⁵

Special masters also have a voice in the procedural rules governing petitions. For example, special masters can recommend amendments to the rules regarding the admissibility of evidence and summary judgment, and the Court of Federal Claims must take these recommendations into account when issuing rules governing the compensation program.⁴⁹⁶ These rules may include “limitations on discovery” that need not align with “the usual rules of discovery in civil actions in the United States Court of Federal Claims.”⁴⁹⁷ Moreover, special masters “may, in specific cases or in all cases assigned to them,” deviate from established rules and guidelines.⁴⁹⁸ The compensation program guidelines encourage alternative dispute resolution, and cases that are more likely than not to be eligible for compensation may be referred to a special processing unit.⁴⁹⁹

⁴⁹⁰ *Id.* § 300aa-16(a)(3).

⁴⁹¹ *Id.* § 300aa-16(b).

⁴⁹² NVICP GUIDELINES, *supra* note 475, at 4; *see* U.S. CT. FED. CLAIMS VACCINE R. 8.

⁴⁹³ JOHNSON ET AL., *supra* note 33, at 28 (discussing use and supplementation of petitioners’ expert reports in typical proceedings).

⁴⁹⁴ 42 U.S.C. § 300aa-12(d).

⁴⁹⁵ NVICP GUIDELINES, *supra* note 475, at 26 (detailing examples of high level of flexibility afforded to special masters in tackling evidentiary issues arising in petitions).

⁴⁹⁶ 42 U.S.C. § 300aa-12(d)(2).

⁴⁹⁷ *Id.*

⁴⁹⁸ NVICP GUIDELINES, *supra* note 475, at 4 (expressing that special masters and practitioners are encouraged to use “creative” procedures to efficiently resolve petitions, as long as they still “ensure fairness”).

⁴⁹⁹ *Id.* at 32-41 (describing use and structure of alternative dispute resolution and settlement negotiation to process petitions efficiently); HEALTH RES. & SERVS. ADMIN., ADVISORY COMM. ON CHILDHOOD VACCINES, TRANSCRIPT OF QUARTERLY MEETING: SEPT. 3, 2015, at 22-23 (2015), <https://www.hrsa.gov/sites/default/files/vaccinecompensation/>

In all cases, the petitioner has the burden of demonstrating a compensable vaccine-related injury by “a preponderance of the evidence.”⁵⁰⁰ If the petitioner can satisfy this burden, the special master or court also must find that “there is *not* a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine.”⁵⁰¹ Petitioner’s claims must be substantiated “by medical records or by medical opinion.”⁵⁰² As the program guidelines further explain, each petition “must be supported by all medical and related records potentially relevant” to the claim.⁵⁰³ Such records may include prenatal medical care, vaccination records, medical records before and after the vaccination, records from any emergency care treatment, day care and school records, affidavits, expert reports, and “entries in various social media or email messages made at or near the time of the injury claimed.”⁵⁰⁴

The Vaccine Act establishes the Vaccine Injury Table that lists each vaccine for which compensation may be available.⁵⁰⁵ The compensation program distinguishes between on-table and off-table vaccine-related injuries.⁵⁰⁶ With respect to vaccine-related injuries listed on the Vaccine Injury Table, a petitioner’s injury “must manifest within the time frame specified on the Table for that vaccine and injury, and the nature of the injury must track the description, if any,” that has been specified in the textual provisions that accompany the table.⁵⁰⁷

All other injuries are deemed to be off-table injuries, including injuries that may be listed on the table but occur outside the specified time period identified

recording09032015.pdf [https://perma.cc/U7NM-DB9F] (outlining parameters of special processing unit).

⁵⁰⁰ 42 U.S.C. § 300aa-13(a)(1)(A).

⁵⁰¹ *Id.* § 300aa-13(a)(1)(B) (emphasis added). The statute defines “factors unrelated to the administration of the vaccine” to “not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.” *Id.* § 300aa-13(a)(2). Moreover, the statute indicates that the term may “include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner’s illness, disability, injury, condition, or death.” *Id.*

⁵⁰² *Id.* § 300aa-13(a).

⁵⁰³ NVICP GUIDELINES, *supra* note 475, at 14.

⁵⁰⁴ *Id.* at 13-17.

⁵⁰⁵ 42 U.S.C. § 300aa-14 (listing Vaccine Injury Table, qualifications to aid in interpreting Table, and standards for revision). The current version of the table was last updated on March 21, 2017. *See* Vaccine Injury Table, *supra* note 20.

⁵⁰⁶ Vaccine Injury Table, *supra* note 20.

⁵⁰⁷ NVICP GUIDELINES, *supra* note 475, at 43.

on the table.⁵⁰⁸ The Vaccine Act allows for revisions to the Vaccine Injury Table, either to add or remove a vaccine-related injury.⁵⁰⁹ Although any person may petition for a revision, the ultimate decision on whether to revise the table lies with the HHS Secretary.⁵¹⁰ Given the large number of off-table petitions, several omnibus proceedings have been established whereby similar cases are consolidated into one proceeding.⁵¹¹ The largest, and arguably the most controversial, was the autism omnibus proceeding,⁵¹² though several others have been created.⁵¹³

The distinction between on- and off-table injuries has immense legal significance. Specifically, causation is presumed for on-table injuries, and the government has the burden of disproving causation.⁵¹⁴ For off-table injuries, however, the petitioner is responsible for proving that a vaccine caused their injury.⁵¹⁵ This includes general causation—a medical theory linking the vaccine

⁵⁰⁸ *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228-29 (2011) (“A claimant may also recover . . . for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation [as in off-table cases].”).

⁵⁰⁹ 42 U.S.C. § 300aa-14(c).

⁵¹⁰ *Id.* (noting that “any person” may submit petition to amend table, and requiring Secretary to either “conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding”). The law contemplates a role for advisory commissions to assist the Secretary. *Id.* §§ 300aa-14(d), -19 (describing composition and role of Advisory Commission on Childhood Vaccines in advising Secretary on “implementation of the Program”).

⁵¹¹ Meyers, *supra* note 21, at 802.

⁵¹² More than 5600 petitions were filed alleging that vaccines cause autism. Decoteau & Underman, *supra* note 14, at 473. In particular, petitioners argued that the preservative thimerosal, which was a vaccine component, had toxic properties that could contribute to the development of autism. *Id.* at 472, 489. Among the thousands of petitions that were filed, test cases were selected for adjudication, and all were denied compensation because of the inability of the petitioners to prove that thimerosal, or the immunizations, were responsible, in whole or in part, for the manifestation of autism. *Id.* at 473, 484. Nevertheless, the CDC and American Academy of Pediatrics concluded that thimerosal should not be used in vaccines, given the dangers of the preservative as noted by the Environmental Protection Agency (“EPA”). *Id.* at 472. The level of thimerosal in the vaccines exceeded EPA guidelines, *see* OFFIT, *supra* note 51, at 185, though public health officials denied that thimerosal was responsible for any harm, Decoteau & Underman, *supra* note 14, at 472.

⁵¹³ Meyers, *supra* note 21, at 802.

⁵¹⁴ *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011) (“Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation.”).

⁵¹⁵ NVICP GUIDELINES, *supra* note 475, at 45.

with an adverse health consequence—and specific causation, which is whether the vaccine caused the petitioner’s injuries.⁵¹⁶

As the Federal Circuit has clarified, “a persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,] the logical sequence being supported by reputable medical or scientific explanation.”⁵¹⁷ As with a classic tort claim of negligence, the causation inquiry includes a demonstration that the vaccine was a but-for cause and a substantial factor that led to injury.⁵¹⁸ A petitioner must prove more than “a proximate temporal relationship between vaccination and injury,” and cannot rely on “a simplistic elimination of other potential causes of the injury.”⁵¹⁹

There are four general categories of damages that may be available to successful petitioners: (1) compensation for past medical expenses, (2) compensation for anticipated future medical expenses, (3) lost earnings, and (4) pain and suffering.⁵²⁰ The Vaccine Act contains damages caps; these were enacted partly in response to damage awards from the swine flu litigation experience.⁵²¹ As to the first two categories of damages, compensation for successful petitioners may include actual unreimbursable expenses and reasonable projected unreimbursable expenses that result from the vaccine-related injuries.⁵²² The amount of compensation for anticipated future expenses may be reduced to account for costs that have been reimbursed, or “can reasonably be expected to be reimbursed,” by others.⁵²³

⁵¹⁶ *Id.* (citing *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)) (indicating that to prove causation, petitioners must address all factors identified in *Althen*, including general, specific, and temporal causation).

⁵¹⁷ *Althen*, 418 F.3d at 1278 (internal quotation marks omitted) (alteration in original) (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). Over the years, however, the Federal Circuit has not applied a consistent legal standard. *See, e.g.*, *Grey*, *supra* note 30, at 379–401 (detailing history and development of Federal Circuit’s inconsistent application of varying legal standards for sufficiency of causal proof in off-table cases); *Meyers*, *supra* note 21, at 802–03 (describing divergent legal standards applied by Federal Circuit in off-table cases, and arguing that this has created “substantial uncertainty”).

⁵¹⁸ *Althen*, 418 F.3d at 1278.

⁵¹⁹ *Id.*

⁵²⁰ NVICP GUIDELINES, *supra* note 475, at 54. In cases of death, compensation is capped at \$250,000. *Id.*

⁵²¹ *Greenberger*, *supra* note 317, at 13–14 (proposing that structure of National Childhood Vaccine Injury Act, including capping certain awards, was shaped by government’s “increasing [reluctance] to assume the financial risks associated with vaccination initiatives” after large payouts during swine flu vaccine litigation).

⁵²² Such expenses may include medical care, rehabilitation, special education, vocational training and placement, counseling, emotional or behavioral therapy, and residential or custodial care. 42 U.S.C. § 300aa-15(a) (2012).

⁵²³ NVICP GUIDELINES, *supra* note 475, at 59 (explaining that vaccine injury compensation program is “intended to be a secondary payer for expenses arising out of

The compensation program guidelines contemplate using “life care planners” to help assess the care that an injured party may need over the course of their life, and these planners assist special masters in determining appropriate remedies for successful petitioners.⁵²⁴ Compensation for anticipated future medical care is typically structured as an annuity, most of which are “government purchased and government owned.”⁵²⁵ The amount of compensation for future care is reduced to account for care that is provided by a third party, such as a public school.⁵²⁶ The compensation program guidelines place the responsibility on the petitioner to provide “particularly accurate information on the questions of what health insurance benefits have been and will likely be available to petitioner, what school system services (e.g., speech therapy) have been and will be available, and what state and federal program benefits (e.g., state ‘crippled children’s funds,’ federal Medicare, or similar benefits programs) have been and will be available.”⁵²⁷

Lost earnings are available, but if the vaccine-related injury occurs before an individual turns eighteen years of age, lost earnings are calculated “on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy.”⁵²⁸ A petitioner may be awarded up to \$250,000 for “actual and projected pain and suffering and emotional distress.”⁵²⁹

For a vaccine-related death, the decedent’s estate shall be awarded \$250,000.⁵³⁰ Reasonable attorneys’ fees and costs are awarded for successful petitions, and for unsuccessful petitions reasonable attorneys’ fees and costs may be awarded “if the special master or court determines that the petition was

vaccine injuries” and describing examples of what programs may “reasonably” be expected to reimburse petitioner).

⁵²⁴ *Id.* at 6.

⁵²⁵ *Id.* at 58 (explaining and advocating for use of annuities in providing compensation awards for life-care plans, particularly for minors or mentally disabled persons).

⁵²⁶ *Id.* at 59.

⁵²⁷ *Id.*

⁵²⁸ 42 U.S.C. § 300aa-15(a)(3) (2012). As of September 2017, this annual income equals less than \$29,000. This figure is based on estimates as follows: (1) Department of Labor statistics, which identify the relevant income as \$47,493, *see Table B-3. Average Hourly and Weekly Earnings of All Employees on Private Nonfarm Payrolls by Industry Sector, Seasonally Adjusted*, BUREAU OF LABOR STATISTICS (Nov. 3, 2017), <https://www.bls.gov/news.release/empst.t19.htm> [<https://perma.cc/ACK5-FF7K>]; (2) on this income, federal taxes, social security, and Medicare taxes equal about \$9000 (note that this does not include state income tax or other applicable taxes); and (3) according to CMS, in 2016 the average person paid \$10,345 for health care, *see Ester Bloom, Here’s How Much the Average American Spends on Health Care*, CNBC MONEY (June 23, 2017, 10:52 AM), <https://www.cnbc.com/2017/06/23/heres-how-much-the-average-american-spends-on-health-care.html> [<https://perma.cc/7F2N-AJVD>].

⁵²⁹ 42 U.S.C. § 300aa-15(a)(4).

⁵³⁰ *Id.* § 300aa-15(a)(2).

brought in good faith and there was a reasonable basis for the claim.”⁵³¹ Under this standard, “good faith is subjective,” but whether there was a reasonable basis for a claim is objective.⁵³² To receive attorneys’ fees in an unsuccessful case, the objective standard of reasonable basis “must exist at each stage of the case,” and no fees shall be awarded for attorney time after the special master determines that a reasonable basis for a claim no longer existed.⁵³³ The compensation program also prohibits any punitive or exemplary damages.⁵³⁴

Either party may appeal the special master’s decision.⁵³⁵ Jurisdiction for the appeal lies in the Court of Federal Claims.⁵³⁶ The court may set aside findings of fact or legal conclusions only if the court concludes that the special master’s determination was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”⁵³⁷ Specifically, the Court of Federal Claims reviews special master decisions using “three distinct standards” that “vary in application as well as degree of deference”: (1) findings of fact are reviewed under an “arbitrary and capricious” standard, (2) conclusions of law are reviewed under a “not in accordance with law” standard, and (3) all discretionary rulings are reviewed under an “abuse of discretion” standard.⁵³⁸ For example, the abuse of discretion standard applies when a special master “excludes evidence or otherwise limits the record upon which he relies,” as well as to all evidentiary rulings, including rulings regarding the qualification of experts.⁵³⁹ Under the abuse of discretion standard, a determination “must be sustained unless ‘manifestly erroneous.’”⁵⁴⁰ Upon applying these standards, the court may issue its own findings of fact or conclusions of law, or may remand the case back to the special master.⁵⁴¹

⁵³¹ *Id.* § 300aa-15(e).

⁵³² NVICP GUIDELINES, *supra* note 475, at 65.

⁵³³ *Id.*

⁵³⁴ 42 U.S.C. § 300aa-15(d).

⁵³⁵ *Id.* § 300aa-12(e). A party may file a motion for reconsideration with the special master, but such motions are “disfavored and are rarely granted.” NVICP GUIDELINES, *supra* note 475, at 72.

⁵³⁶ 42 U.S.C. § 300aa-12(e).

⁵³⁷ *Id.* § 300aa-12(e)(2)(B).

⁵³⁸ *Contreras v. Sec’y of Health & Human Servs.*, 121 Fed. Cl. 230, 234 (2015) (citing *Munn v. Sec’y of Health & Human Servs.*, 121 Fed. Cl. 230, 240 (2015)). This is despite the fact that, as a general matter, the role of special masters “is to aid judges in the performance of specific judicial duties, as they may arise in the progress of a cause, and not to displace the court.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005) (quoting *La Buy v. Howes Leather Co.*, 352 U.S. 249, 256 (1957)).

⁵³⁹ *Contreras*, 121 Fed. Cl. at 234.

⁵⁴⁰ *Id.* at 235 (citing *Jarvis v. Sec’y of the Dep’t of Health and Human Servs.*, 99 Fed. Cl. 47, 59 (2011)).

⁵⁴¹ 42 U.S.C. § 300aa-12(e)(2).

A party aggrieved by the court's decision may file an appeal with the Court of Appeals for the Federal Circuit.⁵⁴² For questions of law, the Federal Circuit reviews the decisions of the lower court and special master *de novo*.⁵⁴³ For issues of fact, however, the Federal Circuit must apply the same level of deference to the special master as the Court of Federal Claims must apply.⁵⁴⁴ Moreover, scientific studies or other evidence not considered by the special master cannot be considered on appeal.⁵⁴⁵ The Federal Circuit's decision can be appealed to the Supreme Court, and in the thirty years since the enactment of the Vaccine Act the Supreme Court has granted three petitions for writ of certiorari.⁵⁴⁶

C. *The Vaccine Act's Limits on Tort Claims Against Vaccine Manufacturers*

After the issuance of a judgment that either awards or denies compensation, a petitioner may elect to reject the judgment and pursue a civil action for damages for a vaccine-related injury or death.⁵⁴⁷ However, the Vaccine Act places "significant" limits on civil claims against vaccine administrators and manufacturers.⁵⁴⁸ Any claim alleging unspecified damages or damages more than \$1000 must be filed via the administrative process of the compensation program.⁵⁴⁹ Vaccine manufacturers are immune from punitive or exemplary damages, and from liability for claims alleging that the manufacturer failed "to provide direct warnings" to vaccinees or their legal representatives.⁵⁵⁰ The

⁵⁴² *Id.* § 300aa-12(f).

⁵⁴³ *Althen*, 418 F.3d at 1277-78 ("[W]e review the trial court's legal determination that the special master acted in a manner not in accordance with law *de novo* [W]e owe no deference to either the special master or the trial court on questions of law").

⁵⁴⁴ *LaLonde v. Sec'y of Health and Human Servs.*, 746 F.3d 1334, 1338-39 (Fed. Cir. 2014).

⁵⁴⁵ *Whitecotton v. Sec'y of Health and Human Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996) ("We cannot incorporate scientific studies cited for the first time on this appeal into our review because doing so would amount to retrying petitioner's case before this appellate tribunal.").

⁵⁴⁶ *See Sebelius v. Cloer*, 133 S. Ct. 1886, 1888-89 (2013) (finding untimely petition for compensation brought in good faith eligible for an award of attorneys' fees); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 224 (2011) (denying compensation and ruling that Vaccine Act preempts design defect claims); *Shalala v. Whitecotton*, 514 U.S. 268, 272-73 (1995) (denying compensation on grounds that claimant who demonstrates that they experienced injury symptoms after receiving vaccine does not establish prima facie case for compensation in instances where sole causation evidence is that claimant had no symptoms before vaccine administration).

⁵⁴⁷ 42 U.S.C. § 300aa-21.

⁵⁴⁸ *Bruesewitz*, 562 U.S. at 229-30 (detailing "significant tort-liability protections" included in Vaccine Act, including limitations on liability for vaccine manufacturers).

⁵⁴⁹ 42 U.S.C. § 300aa-11(a)(2).

⁵⁵⁰ *Id.* § 300aa-22(c). At the same time, the Vaccine Act requires that the government "develop and disseminate vaccine information materials" that health-care providers must distribute to patients and their families. *Id.* § 300aa-26. These materials must include, inter alia, "a concise description" of risks and benefits and the availability of the compensation

statute also excludes from the definition of “vaccine-related injury or death,” any “illness, injury, condition or death associated with an adulterant or contaminant intentionally added” to the vaccine.⁵⁵¹

The statute further states that a manufacturer shall be presumed to have complied with proper directions and warnings if it demonstrates “that it complied in all material respects” with the FDCA and the regulations governing biologics.⁵⁵² A plaintiff may rebut this presumption by demonstrating that the vaccine manufacturer engaged in fraud or the intentional and wrongful withholding of information regarding vaccine approval, safety, or efficacy, regardless of whether the information relates to pre-market approval or post-market surveillance of the vaccine.⁵⁵³

The legislative history of the Vaccine Act reveals that the limitations on tort claims adopted the principles set forth in Comment k from section 402A of the Restatement (Second) of Torts,⁵⁵⁴ which purport to elucidate how drugs and vaccines should be evaluated under the unavoidably unsafe exception to products liability claims.⁵⁵⁵ By the mid-1980s, however, the broad exceptions to liability outlined in Comment k had been widely criticized, and courts began to hold drug and vaccine manufacturers accountable for failing to incorporate safer alternative designs.⁵⁵⁶

Nevertheless, the Vaccine Act preempts civil claims against vaccine manufacturers for unavoidable adverse side effects, which the statute defines as “side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”⁵⁵⁷ In 2011,

program for vaccine-related injuries. *Id.* § 300aa-26(c). Health-care providers must provide this information prior to administering any vaccine identified in the Vaccine Injury Table. *Id.* § 300aa-21.

⁵⁵¹ *Id.* § 300aa-33(5).

⁵⁵² *Id.* § 300aa-22(b)(2).

⁵⁵³ *Id.*

⁵⁵⁴ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965) (“Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous”); Victor E. Schwartz & Liberty Mahshigian, *National Childhood Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 392 (1987) (discussing legislative history of Vaccine Act). For a discussion of the history of Comment k, see generally James A. Henderson & Aaron D. Twerski, *Drug Design Liability: Farewell to Comment k*, 67 BAYLOR L. REV. 521 (2015).

⁵⁵⁵ Henderson & Twerski, *supra* note 554, at 525-30. The confusion caused by Comment k is evidenced by the various interpretations offered by the majority, concurring, and dissenting opinions in *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 231-76 (2011).

⁵⁵⁶ See Henderson & Twerski, *supra* note 554, at 544-49 (discussing shift and summarizing cases).

⁵⁵⁷ 42 U.S.C. § 300aa-22(b)(1).

the Supreme Court ruled that the term “unavoidable” includes design defect claims.⁵⁵⁸ Thus, vaccine manufacturers are not liable for vaccine-related injuries even if a safer, alternative vaccine formula would have caused fewer adverse effects without compromising efficacy.

III. MODERNIZING THE VACCINE ACT

Three decades of experience have provided a wealth of data from which to analyze the Vaccine Act and consider the extent to which the Act addresses modern-day vaccine policy concerns. Insofar as it is unwise or unrealistic to call for a reframing of the entire regime, it is essential to structure reforms that can work within the system. For any reform proposal to have a realistic chance of implementation, it also must account for the current economic and political climate. While the Trump Administration and Republicans in Congress have taken a strong deregulatory stance, they also have called for inquiries into vaccine safety.⁵⁵⁹ Additionally, many Democrats have questioned the need for broad legal immunities for the pharmaceutical industry.⁵⁶⁰

As such, it is not unreasonable to think that amending the Vaccine Act can be achieved, particularly if the amendments address safety concerns without unduly burdening industry. The proposals outlined herein aim to achieve this balance. There are three guiding principles: (1) using law as a tool to promote public health by encouraging vaccine research and incorporating scientific innovations into vaccine design, (2) ensuring that an appropriate safety net exists for individuals who suffer vaccine-related injuries, and (3) instituting legal levers that can help build and maintain public trust in immunizations.

While this Article focuses on five reforms, they are by no means an exhaustive list of areas that need recalibration.⁵⁶¹ Rather, I selected the five reforms because

⁵⁵⁸ *Bruesewitz*, 562 U.S. at 231-32 (“[P]rovided that there was proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable.”).

⁵⁵⁹ *See, e.g., Hotez, supra* note 54. As such, there is reason to think that the Trump Administration may call for the creation of a vaccine commission. *Id.*

⁵⁶⁰ *Cf. Joanna B. Apolinsky & Jeffrey A. VanDetta, Rethinking Liability for Vaccine Injury*, 19 CORNELL J.L. PUB. POL’Y 537, 559-62 (2010).

⁵⁶¹ Additional areas for reform include: (1) increasing damages caps (at the very least, to account for inflation); (2) allowing courts de novo review of special masters’ factual findings; (3) updating the Vaccine Injury Table automatically to include injuries where a special master or court has determined an injury is vaccine-related; (4) increasing the number of special masters so as to help expedite adjudication of petitions; (5) eliminating the \$400 filing fee for petitions; (6) increasing the incentives for attorneys to take cases where there is credible evidence that a vaccine caused an injury; (7) extending statutes of limitations; (8) allowing parents or guardians to right to sue for their children’s injuries; (9) clarifying evidentiary admissibility standards in vaccine-injury petitions; (10) including all vaccines in the compensation program, and not just those routinely recommended for children; and (11) allowing petitions to be brought for injuries caused to unborn children when a pregnant woman is vaccinated. Of these, issues (1) and (2) are discussed in Parasidis, *supra* note 68, at

they are politically palatable and are areas where statutory tweaks can address serious shortcomings of the Vaccine Act. The proposals—which aim to harmonize the interests of patients, physicians, public health officials, and the vaccine industry—include: (1) adjusting the requirements for adverse event reporting and post-market analysis of vaccine safety and efficacy, (2) predicating limited liability for vaccine manufacturers on compliance with post-market analysis requirements, (3) exempting design defect claims from the preemption provision of the Vaccine Act in cases of negligent failure to utilize a safer alternative design, (4) restructuring the burden of proof for claims alleging off-table vaccine-related injuries, and (5) mandating a minimum investment of Trust Fund proceeds for vaccine research and development. For each proposal, this Article provides draft legislation that may serve as a foundation from which to amend the Vaccine Act.

A. *Adjusting the Requirements for Adverse Event Reporting and Post-Market Analysis of Vaccine Safety and Efficacy*

The Vaccine Act contains a mandate for creating safer childhood vaccines. The HHS Secretary must “promote the development of childhood vaccines that result in fewer and less serious adverse reactions” and the “refinement of such vaccines.”⁵⁶² The mandate also requires the Secretary to “make or assure improvements” in “licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.”⁵⁶³

To help achieve these goals, the Act places recording and reporting requirements on physicians and vaccine manufacturers. Each patient’s medical records must identify all vaccine doses,⁵⁶⁴ and providers are obligated to report all on-table vaccine-related injuries, any contraindicating reaction to a vaccine that is identified in the vaccine package insert, and “such other matters” as the HHS Secretary may require.⁵⁶⁵ According to a study by CDC officials, however, 63.1% of pediatric healthcare providers indicated that they were unlikely to report a minor vaccine-related adverse event, and 3.6% indicated that they were

1141-50; issues (1), (6), (7), and (8) are discussed in Meyers, *supra* note 21, at 847-50; issue (9) is discussed in Grey, *supra* note 30, at 412-13; and issues (10) and (11) are discussed in OFFIT, *supra* note 51, at 187-88. I thank Marc Spindelman for suggesting issue (3).

⁵⁶² 42 U.S.C. § 300aa-27(a).

⁵⁶³ *Id.* The statute establishes a task force to assist the Secretary in these endeavors, and places reporting requirements on the Secretary. *Id.* § 300aa-27(b), (c).

⁵⁶⁴ *Id.* § 300aa-25. This includes the date of administration, vaccine manufacturer, and lot number. *Id.*

⁵⁶⁵ *Id.*

unlikely to report a serious symptom known to be an adverse event.⁵⁶⁶ The study also found that one in four health-care providers “did not have any knowledge about VAERS,” and that eighty-two percent of providers who identified an adverse event following vaccination failed to report the adverse event to VAERS.⁵⁶⁷

While pediatricians often are overburdened and undercompensated,⁵⁶⁸ they are the first line of defense in identifying vaccine-related injuries and adverse events. Underreporting masks the actual rate of vaccine-related side effects and can have serious public health implications, such as hindering health-care decision-making and impeding redesign innovation.⁵⁶⁹ Underreporting also hinders injured parties’ ability to prove causation in cases alleging vaccine-related injuries.⁵⁷⁰

To address these concerns, lawmakers should incorporate penalties into the Vaccine Act for failure to comply with the reporting requirements of 42 U.S.C. § 300aa-25(b). Such penalties could be fines or reductions in reimbursements for failure to report. The former is the paradigm that the Vaccine Act applies if a manufacturer fails to comply with recordkeeping and reporting requirements,⁵⁷¹ while the latter is the model used in other health-care settings, such as failure to comply with meaningful use requirements.⁵⁷²

Although physicians likely will challenge this proposal, incentivizing compliance with reporting requirements is necessary to address physicians’ well-documented underreporting of vaccine-related adverse events.⁵⁷³ Electronic health records (“EHRs”) and health information technology systems simplify a physician’s ability to comply with the reporting requirements; for example, a program could be structured to automatically report any adverse event that is identified in a patient’s medical records. Insofar as such a system requires a financial investment on the part of physicians, lawmakers can allocate

⁵⁶⁶ Michael M. McNeil et al., *Who is Unlikely to Report Adverse Events After Vaccinations to the Vaccine Adverse Event Reporting System (VAERS)*, 31 *VACCINE* 2673, 2676 (2013). In addition, the study found that slightly more than eighteen percent of pediatric health-care providers were unlikely to report to VAERS an adverse event following a vaccine that was reported by a patient or parent. *Id.*

⁵⁶⁷ *Id.* at 2677.

⁵⁶⁸ Rosenthal, *supra* note 44, at 2.

⁵⁶⁹ Chen et al., *supra* note 27, at 548 (outlining inability to find causal relationships between vaccine and adverse event as greatest limitation of VAERS).

⁵⁷⁰ *Id.*

⁵⁷¹ 42 U.S.C. § 300aa-28(b) (2012).

⁵⁷² See David Pittman, *209,000 Doctors Hit with Meaningful Use Penalty This Year*, POLITICO (Jan. 12, 2016, 10:00 AM), <http://www.politico.com/tipsheets/morning-ehealth/2016/01/politicos-morning-ehealth-209-000-doctors-hit-with-meaningful-use-penalty-this-year-212129> [<https://perma.cc/Q86N-L73Z>].

⁵⁷³ Chen et al., *supra* note 27, at 548.

funding from the Trust Fund to accommodate the costs.⁵⁷⁴ Decades of experience have demonstrated that a voluntary reporting structure fails to adequately incentivize physician compliance with the Vaccine Act,⁵⁷⁵ and lawmakers should respond by instituting penalties for failure to comply with the statutorily-mandated reporting requirements.

In addition to adjusting physicians' reporting incentives, lawmakers should amend the Vaccine Act to incentivize manufacturers to analyze post-market data on vaccine safety and efficacy. Manufacturers currently are responsible for documenting "the history of the manufacturing, processing, testing, repooling, and reworking" of vaccines, "including the identification of any significant problems encountered in the production, testing, or handling."⁵⁷⁶ If safety testing reveals "a potential imminent or substantial public health hazard," manufacturers must notify the government within twenty-four hours of the test.⁵⁷⁷ Failing to comply with these recording and reporting requirements may result in civil penalties, fines, and jail time.⁵⁷⁸

While these recording and reporting requirements are important, a key element is missing. Specifically, the Vaccine Act does not mandate that vaccine manufacturers collect or analyze safety and efficacy data from patients in which their vaccines are administered. Rather, the bulk of this work is left to regulators. As detailed, however, VAERS—the FDA's primary mechanism for post-market review—is a "passive" surveillance system and "no active effort is made to search for, identify and collect information."⁵⁷⁹ As public health experts have detailed, the "greatest limitation of VAERS . . . is its general inability to determine whether a vaccine actually caused the reported adverse event."⁵⁸⁰

Other post-market adverse event tools include (1) Phase 4 studies (often required for newly licensed vaccines), (2) the Vaccine Safety Datalink ("VSD") and Clinical Immunization Safety Assessment, which are collaborations between the CDC and various health-care organizations, and (3) the FDA's Sentinel Post-Licensure Rapid Immunization Safety Monitoring System.⁵⁸¹

⁵⁷⁴ See *infra* Section III.E.

⁵⁷⁵ See McNeil et al., *supra* note 566, at 2677.

⁵⁷⁶ 42 U.S.C. § 300aa-28(a).

⁵⁷⁷ *Id.*

⁵⁷⁸ *Id.* § 300aa-28(b).

⁵⁷⁹ Shimabukuro et al., *supra* note 29, at 4398. While VAERS has limitations, its strengths include a nationwide reach and an ability to generate safety signals that can be evaluated further. However, for VAERS data to be meaningful, follow-up studies are essential. Chen et al., *supra* note 27, at 548.

⁵⁸⁰ Chen et al., *supra* note 27, at 548.

⁵⁸¹ Meghan A. Baker et al., *Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM) Data Characterization*, 31 VACCINE K98, K98 (2013); Edwards & Hackell, *supra* note 53, at e3; Michael M. McNeil et al., *The Vaccine Safety Datalink: Successes and Challenges Monitoring Vaccine Safety*, 32 VACCINE 5390, 5391 (2014). As of 2014, VSD contained information on more than twenty-one million individuals, and the

Although this system of post-market review has had some successes (such as detecting the association between the rotavirus vaccine and intussusception), it has produced very few safety signals over the past twenty-five-plus years.⁵⁸² Moreover, as CDC and FDA officials explain, using existing post-market data, “it is not possible to calculate and compare rates of adverse events in vaccinated versus unvaccinated individuals and determine if vaccination is associated with an increased risk of an adverse event.”⁵⁸³ The current, passive system results in significant underreporting of adverse events and may lead to spurious associations between vaccines and injuries.⁵⁸⁴ Furthermore, it is difficult to draw conclusions about risks of individual vaccines because many children receive multiple vaccinations at one time.⁵⁸⁵

database “has the unique ability to conduct timely vaccine safety studies, including assessments of rare adverse events and longitudinal studies involving prolonged follow-up of individual patients.” *Id.* For additional details on the benefits and limitations of existing systems for vaccine adverse event reporting, see INST. OF MED., *THE CHILDHOOD IMMUNIZATION SCHEDULE AND SAFETY: STAKEHOLDER CONCERNS, SCIENTIFIC EVIDENCE, AND FUTURE STUDIES* 39-54 (2013) [hereinafter 2013 IOM REPORT].

⁵⁸² Shimabukuro et al., *supra* note 29, at 4401-03.

⁵⁸³ *Id.* at 4402.

⁵⁸⁴ *Id.* For example, VAERS data typically does not contain laboratory or clinical findings specific to vaccine administration. Chen et al., *supra* note 27, at 548. The value of VAERS data is further weakened by “[b]iases in reporting, inadequate denominator data, and lack of background rates.” David Banks et al., *Comparing Data Mining Methods on the VAERS Database*, 14 *PHARMACOEPIDEMOLOGY & DRUG SAFETY* 601, 608 (2005). In addition to underreporting, these biases include “stimulated reporting, which is elevated reporting that might occur in response to intense media attention.” Shimabukuro et al., *supra* note 29, at 4402. Because reporting to VAERS is voluntary and anyone can submit a report, VAERS also “may be manipulated inappropriately to influence litigation and public policy.” Michael J. Goodman & James Nordin, *Vaccine Adverse Event Reporting System Reporting Bias: A Possible Source of Bias in Longitudinal Studies*, 117 *PEDIATRICS* 387, 388 (2006). As CDC and FDA officials candidly acknowledge, “[t]he background rates of many adverse events, particularly rare adverse events and their distribution in either vaccinated or unvaccinated populations are unknown, which makes the assessment of representativeness difficult.” James A. Singleton et al., *An Overview of the Vaccine Adverse Event Reporting System (VAERS) as a Surveillance System*, 17 *VACCINE* 2908, 2914 (1999). Moreover, “VAERS usually cannot be used to determine whether an adverse event is caused by a vaccine or is simply coincidental.” McNeil et al., *supra* note 581, at 5391. Nor can VAERS identify “[r]ates or relative risks of vaccine adverse events.” *Id.* Notwithstanding these significant limitations, VAERS is “the nation’s frontline post-licensure vaccine safety monitoring system.” Shimabukuro et al., *supra* note 29, at 4403. At the same time, innovations in health-information technology have led to advanced signal-generating mechanisms. For example, the CDC’s VSD has tested “rapid cycle analysis, which may flag safety signals requiring further study very soon after vaccine introduction.” John Iskander et al., *Data Mining in the US Using the Vaccine Adverse Event Reporting System*, 29 *DRUG SAFETY* 375, 381 (2006) (internal quotation marks omitted).

⁵⁸⁵ 2017 CDC VACCINE SCHEDULE, *supra* note 1, at 2.

Anecdotally, I called the FDA with a handful of vaccine lots (from vaccines that were administered to my children) to see what the reported adverse events were for the lots. The FDA agent with whom I spoke was able to quickly locate the vaccine lots in the FDA database, but unable to say with any confidence whether the reported adverse events were linked to vaccines from the lots. As the FDA agent explained to me, because children often receive multiple vaccines during a single office visit (in accordance with the CDC-recommended vaccine schedule), even when adverse events are reported, the FDA is unable to determine which vaccine is associated with the adverse event, let alone whether a given vaccine may be causally related to the adverse event.

Although regulators have expanded their efforts to collect and analyze vaccine-related adverse events, the government's heavy reliance on passive post-market surveillance fails to capitalize on the state of the art in health information technology. A twenty-first century post-market framework must leverage recent and emerging advancements in health information technology, and should place a legal burden of diligent post-market analysis on vaccine manufacturers.

As an additional component to the existing post-market regime, all vaccine manufacturers should be required to actively monitor their products to evaluate safety and efficacy. Given the proliferation of EHRs and the established need to document vaccine doses (to provide to educational institutions), manufacturers (in conjunction with physicians and public health officials) could create vaccine registries that are linked to the medical records of children. Regulators could mandate that manufacturers monitor and analyze the registries, and subsequently impose penalties for failure to conduct timely and diligent analysis.⁵⁸⁶

⁵⁸⁶ Insofar as many children receive multiple vaccines during a doctor's visit, causation issues are likely to remain. To a certain extent, increased use of alternative vaccine schedules may help address causation hurdles, particularly since many parents limit vaccines for their child to one per visit. See, e.g., Kiera Butler, *My Interview with a Pediatrician Who Thinks Vaccines Are "Messing with Nature,"* MOTHER JONES (Mar. 31, 2014), <http://www.motherjones.com/environment/2014/03/pediatrician-believes-vaccines-are-messing-nature/> [https://perma.cc/6CL2-VLXZ]; Alice Park, *Many Doctors Give in When Parents Want to Space out Vaccines,* TIME (Mar. 2, 2015), <http://time.com/3726887/doctors-space-out-vaccines/> [https://perma.cc/KE7U-5WKU].

Instituting a requirement for manufacturer-sponsored, active post-market analysis of vaccine safety and efficacy can be accomplished by adding a subsection (d) to 42 U.S.C. § 300aa-25. The new subsection could be based on the following:

§ 300aa-25. Recording and reporting of information

. . . .

(d) Analysis of vaccine safety and efficacy

(1) In consultation with the Secretary, a vaccine manufacturer shall conduct analysis of vaccine safety and efficacy for each of the manufacturer's licensed vaccines.

(2) The analysis shall be based, in part, on reported information as referred to in subsection (b).

(3) If a vaccine manufacturer fails to comply with this subsection, the limited liability provisions of section 300aa-22(b) of this title shall not apply.⁵⁸⁷

In turn, the Secretary, via the FDA and U.S. Preventive Services Task Force, which is a collaboration between the CDC, FDA, and NIH,⁵⁸⁸ should issue guidance on best practices for active post-market analysis. The actual studies to be conducted for each vaccine should be created via collaborative efforts between the manufacturer and the FDA, and should incorporate information from EHRs, patient registries, the Sentinel network, VAERS, VSD, and other data sources. The Advisory Commission on Childhood Vaccines also should play a role in advising the Secretary on appropriate post-market research. The Advisory Commission is composed of a diverse group of nine members, and includes health professionals, pediatricians, experts in epidemiology and infectious diseases, attorneys, and legal representatives of children who have suffered vaccine-related injuries or death.⁵⁸⁹ A component of the Advisory Commission's mandate is to "advise the Secretary . . . regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions."⁵⁹⁰

Insofar as the vaccine market is strong,⁵⁹¹ the costs of a manufacturer-led active post-market analysis system are unlikely to have a substantial financial impact on manufacturers. While total costs per vaccine will vary, a typical observational study that relies on primary and secondary data costs between \$100,000 and \$250,000 for small studies lasting less than two years, and \$1.5

⁵⁸⁷ The rationale underlying proposed subsection (d)(3) is discussed *infra* Section III.B.

⁵⁸⁸ See 42 U.S.C. § 300aa-27(b) (2012).

⁵⁸⁹ *Id.* § 300aa-19(a).

⁵⁹⁰ *Id.* § 300aa-19(f)(3).

⁵⁹¹ PHARM. RESEARCH & MFRS. OF AM., *supra* note 28, at 45 (reporting that global vaccine market was valued at \$27.3 billion in 2012, and projected to grow significantly).

million to \$3 million for larger and lengthier studies.⁵⁹² Industry representatives estimate annual costs of observational studies based on registry data at \$1.5 million.⁵⁹³ Though not insignificant amounts, these figures represent a fraction of the total cost for vaccine development, which typically runs in the hundreds of millions of dollars.⁵⁹⁴

At one extreme, these costs may be passed entirely on to patients. At the other, the vaccine industry would fully absorb the costs and decrease its return on investment. As discussed in the fifth proposal of this Article, proceeds from the Trust Fund may be allocated to help defray the research costs.⁵⁹⁵ Furthermore, insofar as manufacturers are conducting analogous post-market studies in accordance with regulatory requirements outside the United States,⁵⁹⁶ it may be the case that the costs of the increase in responsibilities in the United States are less than the projected costs outlined herein.

Taken together, adjusting the requirements for vaccine-related adverse event reporting and analysis: (1) helps address significant underreporting of adverse events, (2) shifts part of the costs of post-market analysis from regulators to the entity that gains financially from vaccine sales, (3) helps address challenges that arise from the fact that the FDA has long been plagued by limited resources to address its expansive mandate, and (4) furthers the Vaccine Act's mandate for creating safer childhood vaccines. A twenty-first century post-market framework also can help facilitate independent research on vaccine safety and efficacy, which might help alleviate the fears of vaccine-hesitant parents, and thus increase immunization rates and the public health benefits that follow.

B. Predicating Limited Liability for Vaccine Manufacturers on Compliance with Post-Market Analysis Requirements

Subsection (d)(3) of the proposed amendment to 42 U.S.C. § 300aa-25 promotes the Vaccine Act's mandate to encourage safer childhood vaccines by predicating the limited liability provisions of the Vaccine Act on a manufacturer's compliance with post-market analysis responsibilities. As detailed, the Vaccine Act provides vaccine manufacturers with valuable legal and economic benefits via its limited liability provisions: a manufacturer is

⁵⁹² ERIN HOLVE & PATRICIA PITTMAN, ACADEMYHEALTH, A FIRST LOOK AT THE VOLUME AND COST OF COMPARATIVE EFFECTIVENESS RESEARCH IN THE UNITED STATES 7 fig.3 (2009).

⁵⁹³ *Id.*

⁵⁹⁴ PHARM. RESEARCH & MFRS. OF AM., *supra* note 28, at 48.

⁵⁹⁵ *See infra* Section III.E.

⁵⁹⁶ For example, Denmark and New Zealand maintain more robust systems for collecting and analyzing vaccine-related adverse events. *See* 2013 IOM REPORT, *supra* note 581, at 52-53 (explaining use of registries in Denmark, each containing individual identification numbers to allow access to demographic and health information at individual level); Sumit Kumar et al., *Vaccine Adverse Events Reporting System Globally*, 7 INT'L J. BIOMED. RES. 89, 92 (2016) (describing adverse event surveillance system that utilizes spontaneous reporting of "all suspected reactions (including minor reactions)").

immune from liability for failure to warn of adverse effects if the manufacturer has complied with regulatory requirements, though the manufacturer has no duty to provide warnings directly to patients.⁵⁹⁷ Punitive damages are precluded so long as the manufacturer complied with regulatory requirements, did not act fraudulently, did not engage in criminal or illegal activity, and did not wrongfully or intentionally withhold information.⁵⁹⁸ Furthermore, the Vaccine Act precludes legal liability for unavoidable adverse events.⁵⁹⁹ The Supreme Court has interpreted this provision broadly to preclude claims where: (1) the injury results from a properly manufactured vaccine that carries known safety risks, or (2) the injury could have been avoided if the manufacturer had used an alternative design.⁶⁰⁰ As to the latter, if a company fails to manufacture a vaccine using a safer, but equally effective, formula, that company is nonetheless shielded from liability.⁶⁰¹

As Justices Ruth Bader Ginsburg and Sonia Sotomayor have argued, the Vaccine Act's wholesale elimination of design defect claims creates "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."⁶⁰² The Act's expansive legal immunities, enacted amidst the deregulation days of the Reagan Administration, served as an incentive for companies to stay in the business of creating vaccines.⁶⁰³ In today's market, however, the legal immunities do little to promote the public health goals of immunizations. The economic uncertainty from the 1980s is no longer present, and manufacturers consistently yield robust earnings; in addition, the vaccine market is predicted to expand significantly over the next five years, from \$24 billion to \$61 billion.⁶⁰⁴ Furthermore, the Vaccine Act contains a "mandate for safer childhood vaccines" that requires promoting "the development of childhood vaccines that result in fewer and less serious adverse reactions."⁶⁰⁵ This mandate includes efforts to refine existing vaccines.⁶⁰⁶

Accordingly, Congress should realign the incentives of the Vaccine Act to reflect contemporary concerns in the vaccine market, such as ensuring that

⁵⁹⁷ 42 U.S.C. § 300aa-22 (2012).

⁵⁹⁸ *Id.* § 300aa-23(d).

⁵⁹⁹ *Id.* § 300aa-22(b).

⁶⁰⁰ *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 231-32 (2011).

⁶⁰¹ *Id.* at 237-39.

⁶⁰² *Id.* at 250.

⁶⁰³ *Id.* at 227-28.

⁶⁰⁴ Timothy Guzman, *Big Pharma and Big Profits: The Multibillion Dollar Vaccine Market*, GLOBAL RES. CTR. FOR RES. ON GLOBALIZATION (Jan. 27, 2016), <https://www.globalresearch.ca/big-pharma-and-big-profits-the-multibillion-dollar-vaccine-market/5503945> [<https://perma.cc/DC27-B6C7>].

⁶⁰⁵ 42 U.S.C. § 300aa-27 (2012).

⁶⁰⁶ *Id.*

vaccines are manufactured using the most current science. This can be accomplished by predicating legal immunities on a vaccine manufacturer's compliance with active and continuous post-market analysis requirements. As courts have recognized, "[t]he manufacturer is in the best position to discover and guard against defects in its products and to warn of harmful effects."⁶⁰⁷ Moreover, "recent advances in immunology are beginning to shed new light on the mechanisms of vaccine-mediated protection and development of long-term immunity."⁶⁰⁸ Realigning the quid pro quo of preemption laws will maintain legal protections while encouraging timely integration of the latest immunological findings into vaccine design.

C. *Exempting Design Defect Claims from the Preemption Provision of the Vaccine Act in Cases of Negligent Failure to Utilize a Safer Alternative Design*

Another statutory lever to promote the Vaccine Act's mandate is exempting design defect claims in cases where a vaccine manufacturer was negligent in failing to utilize a safer vaccine design. This exemption should apply in cases where there is a preponderance of the evidence that the increased safety is more than de minimis, any decrease in vaccine efficacy is de minimis, and the vaccine manufacturer could have manufactured the vaccine with the alternative design. The third component relates to manufacturing process, and aims to ensure that manufacturers have a reasonable time period during which to obtain the necessary vaccine ingredients or alter their manufacturing processes in order to accommodate a new design.⁶⁰⁹ This would include any necessary FDA clearances on altering the vaccine formula.⁶¹⁰ In cases where a safer alternative design exists and the manufacturer has made good faith efforts to transition to the new design, the manufacturer should not be liable.

The Supreme Court's decision in *Bruesewitz v. Wyeth LLC*⁶¹¹ was grounded in a false dilemma—that allowing design defect claims would eviscerate the Vaccine Act's preemption provision because a "side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element."⁶¹² However, the Court's rationale presumes

⁶⁰⁷ *E.g.*, *Sindell v. Abbott Labs.*, 607 P.2d 924, 936 (Cal. 1980).

⁶⁰⁸ Mark K. Slifka & Ian Amanna, *How Advances in Immunology Provide Insight into Improving Vaccine Safety*, 32 *VACCINE* 2948, 2948 (2014) (outlining potential to "elicit more effective and long-lived immunity with fewer vaccinations").

⁶⁰⁹ For example, building and validating a new manufacturing facility takes, on average, five years. PHARM. RESEARCH & MFRS. OF AM., *supra* note 28, at 51.

⁶¹⁰ Vaccine manufacture is a complicated and highly regulated process, and non-trivial changes in manufacture or design must be discussed with regulatory authorities. *See, e.g.*, Jon Smith et al., *Vaccine Production, Distribution, Access and Uptake*, 378 *LANCET* 428, 435 (2011).

⁶¹¹ 562 U.S. 223 (2011).

⁶¹² *Id.* at 232 (emphasis added).

that such an alternative design actually exists and that the alternative design does not compromise vaccine efficacy. Rather than eliminate design defect claims entirely, the Court should have incorporated legal and scientific nuance into its holding—along the lines of that provided by the First Circuit in *Brochu v. Ortho Pharmaceutical Corp.*,⁶¹³ the Idaho Supreme Court in *Toner v. Lederle Laboratories*,⁶¹⁴ and the California appellate court in *Kearl v. Lederle Laboratories*⁶¹⁵—whereby design defect claims would be permitted for a negligent failure to incorporate a safer alternative design.⁶¹⁶

Incorporating an exemption to design defect claims could be accomplished by adding a paragraph (3) to 42 U.S.C. § 300aa-22(b). The new paragraph could be based on the following:

§ 300aa-22. Standards of responsibility

.....

(b) Unavoidable adverse side effects; warnings

.....

(3) For purposes of paragraph (1), a side effect shall not be unavoidable if the plaintiff shows that a vaccine could have been manufactured using an alternative design, where

(A) the increased safety of the vaccine due to the alternative design is more than de minimis,

(B) any decrease in the efficacy of the vaccine due to the alternative design is de minimis, and

(C) the vaccine manufacturer had, or reasonably could have been expected to have, the ability to produce the vaccine with the alternative design.

This provision accounts for the regulatory gap that Justices Ginsburg and Sotomayor highlighted—specifically, that the Vaccine Act’s broad preemption provision fails to ensure that manufacturers incorporate scientific advancements into vaccine design. It permits design defect claims in very limited circumstances—namely, in cases where the manufacturer has failed to take reasonable steps to update their vaccine formula in light of scientific evidence that a safer design exists that would not compromise vaccine efficacy.

Notably, this carve-out for allowing design defect claims was contemplated by courts prior to the Vaccine Act’s enactment. Recall *Kearl*, where the plaintiff alleged that the polio vaccine was defectively designed. There, a California appellate court indicated that design defect claims for vaccines may be appropriate if a manufacturer were negligent in failing to incorporate a safer

⁶¹³ 642 F.2d 652 (1st Cir. 1981).

⁶¹⁴ 732 P.2d 297 (Idaho 1987).

⁶¹⁵ 218 Cal. Rptr. 453 (Cal. Ct. App. 1985).

⁶¹⁶ See *supra* Section I.A.3 (discussing various judicial approaches to design defect claims).

alternative design.⁶¹⁷ Similarly, the First Circuit held that prescription drugs “should not be exempt from strict liability design defect analysis if the evidence shows inter alia availability, at the time of distribution, of an alternative product that would have *as effectively* accomplished the *full intended purpose* of the subject product.”⁶¹⁸ And, in *Toner*, the Idaho Supreme Court held that a claim for negligent failure to utilize a safer alternative design was actionable, indicating that such claims are necessary to incentivize manufacturers to create and market safe and effective vaccines.⁶¹⁹

The proposed paragraph (3) to 42 U.S.C. § 300aa-22(b) reflects these principles. Specifically, it precludes design defect claims in instances where the adverse effect was unavoidable and permits design defect claims in cases where the adverse effect was avoidable. Allowing for manufacturer liability in instances of negligence is also in line with the government’s indemnification agreement during the swine flu vaccine program, where the vaccine industry agreed to assume liability in instances of “any negligent conduct.”⁶²⁰

It is important to note that design defect claims were not the primary cause of litigation fears during the 1980s. Indeed, cases finding manufacturers liable for selling defective vaccines were “very rare.”⁶²¹ To the contrary, it was the legal uncertainty surrounding warning defects, in large part due to the decisions in *Davis* and *Reyes*, that caused industry executives to worry.⁶²² As such, the provision of the Vaccine Act that broadly preempts design defect claims addressed a non-issue (in terms of litigation-influenced market destabilization), and can be seen as a political handout to manufacturers who lobbied for “greater insulation from liability.”⁶²³

To be sure, satisfying the level of proof necessary to bring a claim under the proposed new model would be challenging. Moreover, the foregoing amendment is not aligned with Section 6(c) of the Restatement (Third) of Torts,

⁶¹⁷ *Kearl*, 218 Cal. Rptr. at 460. As the *Kearl* court suggested, a de minimis safety concern is one that results in a “mere temporary or insignificant inconvenience.” *Id.* at 464. In terms of efficacy, *Kearl* indicated that the alternative design must have been able to “effectively accomplish[] the full intended purpose of the subject product.” *Id.*

⁶¹⁸ *Id.* at 462.

⁶¹⁹ *Toner*, 732 P.2d at 309-11.

⁶²⁰ 1985 IOM REPORT, *supra* note 17, at 94.

⁶²¹ *Id.* at 86.

⁶²² *Id.* at 86-93 (discussing impact of *Reyes* and *Davis* on failure-to-warn litigation); Baynes, *supra* note 85, at 66 (characterizing manufacturers’ concerns as “understandable”); Greenberger, *supra* note 317, at 15 (noting that Congress “legislatively altered the rule established in *Reyes*” to assuage industry concerns in its aftermath).

⁶²³ Engstrom, *supra* note 8, at 1659. Although some commentators have argued that the availability of tort claims hinders innovation, several empirical studies cast serious doubt on the contention, and “[t]he more persuasive voices in the academic debates express skepticism.” James A. Henderson, *Tort v. Technology: Accommodating Disruptive Innovation*, 47 ARIZ. ST. L.J. 1145, 1180 (2015).

which states that design defects for medical products should be permitted only if a safer alternative product is on the market.⁶²⁴ Section 6(c), however, has been criticized as providing too much protection for industry.⁶²⁵ Section 6(c) also is inconsistent with Section 2(b) of the Restatement (Third) of Torts, which allows design defect claims even if a safer alternative design is not on the market.⁶²⁶ The co-reporters of the Restatement (Third) of Torts candidly indicated that they “did not restate existing case law” in drafting Section 6(c), but rather argued that divergent standards are necessary because “drug designs are different.”⁶²⁷ In the context of vaccines, however, the totality of the evidence does not support their conclusion. The vaccine market is highly consolidated, there is little-to-no competition for individual vaccines, pre-market FDA review is limited in scope, post-market analysis is lackluster, and the Vaccine Act largely insulates manufacturers from legal or financial liability in the event of vaccine-related injuries. Indeed, seventeen years after publication of the Restatement (Third) of Torts, the co-reporters identified more states rejecting Section 6(c) than those adopting it.⁶²⁸

In short, market and regulatory imperfections do not provide adequate incentives for vaccine manufacturers to update their products. Legal levers—including the availability of design defect claims—can help fill this void. Although updating vaccine design may impact vaccine pricing, safer and more effective vaccines will result in fewer adverse events and better protection against disease.⁶²⁹ Incentivizing manufacturers to update their vaccines in light of new scientific developments is particularly important given the fact that, as the IOM explains, “the need for a vaccine to deliver lifelong or long-lasting immunity is at odds with the prospect of multiple or repeat sales.”⁶³⁰ As such,

⁶²⁴ See, e.g., James A. Henderson & Aaron D. Twerski, Essay, *Drug Designs Are Different*, 111 YALE L.J. 151, 158 (2001) (summarizing various interpretations of meaning of Section 6(c)).

⁶²⁵ See *id.* at 151-55.

⁶²⁶ See *id.* at 158 (citing RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §§ 2(b), 6(c) (AM. LAW INST. 1998)) (describing the differences between the Sections 2(b) and 6(c)).

⁶²⁷ *Id.* at 180 (emphasis omitted).

⁶²⁸ Henderson & Twerski, *supra* note 554, at 554-56, 554 n.179 (indicating that four states had adopted Section 6(c) or a similar rule, while five states had rejected it). By contrast, the co-reporters note that the principles outlined in Section 2(b) have been widely adopted by courts. See generally Aaron D. Twerski & James A. Henderson Jr., *Manufacturers' Liability for Defective Designs: The Triumph of Risk-Utility*, 74 BROOK. L. REV. 1061 (2009) (noting that “virtually all American courts use . . . section 2(b)”).

⁶²⁹ Production-related efficiencies and advancements may decrease the cost of production, and thus it is not necessarily the case that the manufacturing costs of a new vaccine design will be higher than the old design. Nonetheless, subparagraph (C) of the proposed amendment to 42 U.S.C. § 300aa-22(b) should be interpreted to incorporate the cost of production. Specifically, if the cost of producing a safer vaccine is unreasonably high, then a manufacturer should not be reasonably expected to have produced the new vaccine.

⁶³⁰ 1985 IOM REPORT, *supra* note 17, at 7.

lawmakers should amend the Vaccine Act to permit design defect claims for the negligent failure to incorporate a safer alternative design.

D. *Restructuring the Burden of Proof for Claims Alleging Off-Table Vaccine-Related Injuries*

When the Vaccine Act was enacted, “the expectation was that most cases would involve [on-table] injuries.”⁶³¹ During the “early days” of the compensation program, “that expectation was borne out.”⁶³² In recent years, however, the majority of vaccine compensation cases have involved off-table injuries.⁶³³ For example, as of April 2016, off-table injuries accounted for more than ninety-eight percent of the average caseload of a special master.⁶³⁴

Under current law, the petitioner’s burden in claims alleging an off-table injury is to demonstrate, by a preponderance of the evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.”⁶³⁵ Even if a petitioner can meet this high burden, compensation is not available if the government can demonstrate, by a preponderance of the evidence, “that the injury was in fact caused by factors unrelated to the vaccine.”⁶³⁶

Challenges in demonstrating vaccine-injury causation were well-documented prior to the enactment of the Vaccine Act. The IOM noted that the “difficulty of proving or disproving a causal relationship between a given vaccine and a particular injury suggest[] that . . . outcomes will depend on who is required to carry the burden of proof.”⁶³⁷ As the IOM further explained, efforts to prove causation “will be time-consuming, expensive, and probably inconclusive.”⁶³⁸ Thereafter, the Federal Circuit observed that demonstrating causation for off-table injuries requires “heavy lifting” on the petitioner’s part, and “it is not surprising that petitioners have a difficult time proving off-table cases,”⁶³⁹ while the Chief Special Master “chastised the government for ‘alter[ing] the game so that it’s clearly in their favor.’”⁶⁴⁰ Moreover, between 1999 and 2002, several

⁶³¹ NVICP GUIDELINES, *supra* note 475, at 43; Grey, *supra* note 30, at 357-64 (detailing legislative history and concluding that “[t]he legislative history of the Vaccine Act suggests that the off-Table claims mechanism was an afterthought”).

⁶³² NVICP GUIDELINES, *supra* note 475, at 43.

⁶³³ *Id.* at 45.

⁶³⁴ *Id.* at 43. In part, this is due to expedited adjudication of on-table cases. *See id.*

⁶³⁵ *Althen v. Sec’y of Health and Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

⁶³⁶ *Id.*

⁶³⁷ 1985 IOM REPORT, *supra* note 17, at 155.

⁶³⁸ *Id.*

⁶³⁹ *Althen*, 418 F.3d at 1280 (quoting *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000)).

⁶⁴⁰ Engstrom, *supra* note 8, at 1704 (alteration in original).

congressional hearings examined the Vaccine Act, and Democrat and Republican lawmakers alike criticized the stringent legal bar for off-table injuries and called for more lenient burdens for petitioners.⁶⁴¹

In terms of vaccine policy, the crucial question is whether maintaining a high, if not insurmountable, bar for injured parties is reasonable and necessary to fulfill the Vaccine Act's mandates of stabilizing the vaccine market, incentivizing innovation, and providing adequate compensation for vaccine-related injuries. Arguably, the high bar for off-table injuries can be traced to the government's experience with compensation claims following the 1976 swine flu immunization program, where "the government became increasingly reluctant to assume the financial risks associated with vaccination initiatives."⁶⁴² Causation was a controversial issue in the swine flu cases.⁶⁴³ For example, the government was willing to settle most cases if Guillain-Barré syndrome manifested within ten weeks of vaccination, though some plaintiffs were successful when they were diagnosed with the disease after twelve weeks.⁶⁴⁴ On the other hand, many plaintiffs experienced causation problems because Guillain-Barré symptoms are amorphous and difficult to diagnose.⁶⁴⁵

Lawmakers established a causation bar in the Vaccine Act that reasonably could have been predicted to result in few off-table compensation awards. A petitioner's ability to prove an off-table injury is further compromised by the lackluster system of adverse event reporting and analysis. One study found that, based on VAERS data alone, only three percent of VAERS reports could be identified as "definitely causally related to vaccine received."⁶⁴⁶ As CDC and FDA officials acknowledge, with rare exceptions, "it generally cannot be determined if a vaccine caused an adverse event using VAERS data."⁶⁴⁷ A recent IOM report underscored this conclusion, finding that, in many cases, "the evidence is inadequate to accept or reject a causal relationship" between a vaccine and an injury.⁶⁴⁸ If the CDC, FDA, and IOM acknowledge that the data often are insufficient to make meaningful conclusions about vaccine-related adverse events, how can injured parties be expected to meet the high legal standard for compensation?

⁶⁴¹ See Grey, *supra* note 30, at 363-65.

⁶⁴² Greenberger, *supra* note 317, at 13.

⁶⁴³ Reitze, *supra* note 43, at 186.

⁶⁴⁴ *Id.* at 185-86.

⁶⁴⁵ *Id.* at 186.

⁶⁴⁶ Anita M. Loughlin et al., *Causality Assessment of Adverse Events Reported to the Vaccine Adverse Event Reporting System (VAERS)*, 30 VACCINE 7253, 7253 (2012).

⁶⁴⁷ Shimabukuro et al., *supra* note 29, at 4402.

⁶⁴⁸ 2012 IOM REPORT, *supra* note 24, at 629-33.

One alternative is to amend the legal standard to implement a burden-shifting paradigm. This may be accomplished by adding a paragraph (3) to 42 U.S.C. § 300aa-13(a). The new paragraph could be based on the following:

§ 300aa-13. Determination of eligibility and compensation

(a) General rule

. . . .

(3) In a petition for compensation wherein it is alleged that a person sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to under section 300aa-11(c)(1)(A) of this title, compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has provided credible evidence linking the alleged illness, disability, injury, or condition with the vaccine, unless

(B) the respondent has demonstrated by a preponderance of the evidence that the alleged illness, disability, injury, or condition is not caused by the vaccine.

Under this burden-shifting approach, the petitioner would have the initial burden of providing credible scientific evidence linking their injury with vaccination, but would not be required to prove causation by a preponderance of the evidence. If the petitioner provides credible evidence, the government would be responsible for demonstrating that the injury is not linked to the vaccine.

In essence, this proposed revision to the Vaccine Act expands the safety net for vaccine-related injuries where there is credible evidence of a causal link. At the same time, it incentivizes research on vaccine-related adverse events—at least on the part of the government—by providing the government with an ability to deny compensation if the government can produce evidence to refute a causal link. Insofar as the legal tools that can require collecting and analysis of vaccine-related adverse events are in the hands of government agencies (i.e., the CDC and FDA), this burden-shifting framework also encourages robust data collection and analysis.

Burden-shifting in a compensation fund is appropriate where, as is the case with immunizations, there are important public health goals, there are significant challenges to proving causation, and a majority of the population benefits while the costs of injury fall on the few. Furthermore, unlike requiring that a party prove a null hypothesis, the aforementioned proposal would force the government to respond to credible scientific evidence or pay the claim.

A burden-shifting paradigm also accounts for the immense challenges that petitioners face in terms of finding expert witnesses. In some cases, highly-qualified physicians who have opined that the data strongly suggest a causal relationship between a vaccine and an injury have experienced intimidation and

shaming.⁶⁴⁹ For example, one Harvard physician who was an expert for a petitioner was told that his testimony would ruin his reputation and jeopardize his ability to receive government funding for research.⁶⁵⁰ Although the physician initially opted to continue with the case, once the expert witness for the government reached out to the physician's supervisor at Harvard, the physician dropped out of the case.⁶⁵¹ While the extent of such practices is unknown, the roadblocks faced by challengers to vaccine orthodoxy are well-documented.⁶⁵²

Furthermore, the compensation program guidelines contemplate a relaxed burden of causation in cases involving off-table injuries. For example, the guidelines indicate that a special master may evaluate "new or novel theories of causation, particularly those involving new vaccines or rare conditions, [which] may lack any support in current medical literature."⁶⁵³ In such cases the guidelines indicate that compensation may be appropriate even if "the available epidemiological evidence suggests that the alleged injury is not one casually connected to a vaccine," so long as the petitioner can demonstrate that "such studies, pre- or post-licensure for the vaccine in question, should not be relied upon in the case."⁶⁵⁴

Shifting the legal burden of demonstrating causation also makes sense in light of the significant increase in the number of vaccines, and the increase in the number of doctor visits during which children receive multiple vaccines. As CDC officials succinctly explain, not only has the number of vaccines increased, the number of combination vaccines has increased, as has "the number of potential vaccine permutations that may be given simultaneously."⁶⁵⁵ For example, in 1989, children received no more than two vaccines per visit, and no more than six vaccines in the first two years of life.⁶⁵⁶ Today, children receive up to five vaccines in a single visit and twenty-seven vaccines by age two.⁶⁵⁷

An adjusted standard of causation is unlikely to place a significant strain on the vaccine-injury compensation fund, as the fund has a net balance of over \$3.6 billion.⁶⁵⁸ From fiscal years 2014 to 2016, there were 247 petitions dismissed as non-compensable, 189 of which were non-autism claims.⁶⁵⁹ Even if all of the

⁶⁴⁹ Myron Levin, *Witnesses for Petitioners Are Often Tough to Find*, L.A. TIMES, Nov. 29, 2004, at A21.

⁶⁵⁰ *Id.*

⁶⁵¹ *Id.*

⁶⁵² See generally Martin, *supra* note 65.

⁶⁵³ NVICP GUIDELINES, *supra* note 475, at 47.

⁶⁵⁴ *Id.*

⁶⁵⁵ Iskander et al., *supra* note 584, at 376.

⁶⁵⁶ *Id.*

⁶⁵⁷ See 2017 CDC VACCINE SCHEDULE, *supra* note 1.

⁶⁵⁸ TRUST FUND STATEMENT, *supra* note 37, at 2.

⁶⁵⁹ NARAYAN NAIR, U.S. DEP'T OF HEALTH & HUMAN SERVS., THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP): DIVISION OF INJURY COMPENSATION PROGRAMS UPDATE 4-5 (2016).

189 claims were paid at the average award rate per petition, the total would equal approximately 2.4% of the Trust Fund balance.⁶⁶⁰ Although a relaxed standard runs the risk that significantly more petitions will be filed and awarded, if the \$0.75 excise tax proves to be insufficient, the tax may be raised. The excise tax has not been adjusted in over thirty years.⁶⁶¹ In the alternative, manufacturers could add resources to the Trust Fund, whereby funding could be linked to the incidence of vaccine adverse events for that manufacturer's vaccines.⁶⁶²

The filing of frivolous claims is unlikely to be a serious issue. Because of stringent guidelines surrounding the availability of attorneys' fees for vaccine petitions, vaccine court attorneys serve as gatekeepers against frivolous claims. Attorneys are legally precluded from taking vaccine petition cases on a contingency basis, and thus rely entirely on the attorney fee provision of the Vaccine Act.⁶⁶³ However, the statute only allows for attorneys' fees if there existed an objectively reasonable basis for bringing the claim.⁶⁶⁴ Thus, there are strong incentives for attorneys to take only those cases for which there is substantial evidence that a vaccine caused an injury. A burden-shifting framework that is grounded on the petitioner's ability to provide credible evidence of causation is unlikely to lead to frivolous claims, as attorneys' fees would be available only if credible evidence of causation existed at the time the petition was filed.

According to Dr. Geoffrey Evans, the Director of the National Vaccine Injury Compensation Program from 1989-2012, Congress created the program "to compensate individuals quickly, easily, and generously," and "it is only simple justice that individuals" receive compensation for vaccine-related injuries.⁶⁶⁵ Instituting a burden-shifting framework for off-table vaccine-related injuries will help further these fundamental goals by expanding the safety net for

⁶⁶⁰ *Id.* at 5-7.

⁶⁶¹ I.R.C. § 4131 (2012) (containing excise tax enacted in 1987).

⁶⁶² Indeed, the Vaccine Act does not punish manufacturers, in a legal or economic sense, when a vaccine-injury petition is successful, but rather provides compensation to injured parties from the Trust Fund, which is funded entirely from an excise tax paid by vaccinees or their health insurers. The notion of linking funding from vaccine manufacturers to the incidence of adverse events is discussed in Schwartz & Mahshigian, *supra* note 554, at 396-97.

⁶⁶³ 42 U.S.C. § 300aa-15(e) (2012); NVICP GUIDELINES, *supra* note 475, at 65.

⁶⁶⁴ 42 U.S.C. § 300aa-15(e); NVICP GUIDELINES, *supra* note 475, at 65.

⁶⁶⁵ Evans, *supra* note 4, at S130-31. As one comprehensive report concluded, it is imperative that the Vaccine Act provides "equitable treatment, transparency, and justice to those children who have the grave misfortune to be injured by the very vaccines intended to keep them healthy." Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480, 481 (2011).

vaccine-related injuries, which in turn might help build public trust in immunization programs.⁶⁶⁶

E. *Mandatory Minimum Investment of Trust Fund Proceeds for Vaccine Research and Development*

Consider again that the Vaccine Act's Trust Fund has a net balance of over \$3.6 billion.⁶⁶⁷ Although the Vaccine Act indicates that one of the responsibilities of the National Vaccine Program is to "coordinate and provide direction" for vaccine research and development,⁶⁶⁸ there is no statutory obligation to use Trust Fund revenues for vaccine research. In part, this may be because Congress anticipated that the tax revenue would be needed entirely to account for compensation awards and administrative costs of the program.⁶⁶⁹

To further the Vaccine Act's mandate "to achieve optimal prevention against adverse reactions to vaccines,"⁶⁷⁰ lawmakers should establish a mandatory minimum of Trust Fund proceeds that are allocated annually for vaccine research. This may be accomplished by adding a subparagraph (C) to 26 U.S.C. § 9510(c)(1).⁶⁷¹ The new subparagraph could be based on the following:

§ 9510. Vaccine Injury Compensation Trust Fund

....

(c) Expenditures from Trust Fund

(1) In general

....

(C) payment for vaccine research and development as may be recommended by the Director of the National Vaccine Program under section 300aa-2 of title 42, provided that annual payments under this subparagraph shall be no less than one percent of the Trust Fund.

In turn, the Director of the National Vaccine Program, in consultation with the U.S. Preventive Services Task Force (comprising officials from CDC, FDA, and NIH), can determine which vaccine projects to fund. The research program could be administered through the NIH, which has extensive experience and expertise in reviewing and funding research. Funding priorities also may be suggested by vaccine innovation reports mandated by the 21st Century Cures

⁶⁶⁶ Apart from the burden-shifting approach outlined in this Article, some commentators have called for other methods of relaxing the petitioner's burden of proof. *See, e.g.*, Grey, *supra* note 30, at 410-13; Meyers, *supra* note 21, at 845-47.

⁶⁶⁷ TRUST FUND STATEMENT, *supra* note 37, at 2.

⁶⁶⁸ 42 U.S.C. § 300aa-2(a)(1).

⁶⁶⁹ Evans, *supra* note 4, at S132.

⁶⁷⁰ 42 U.S.C. § 300aa-1.

⁶⁷¹ In addition to the new subparagraph (C), the period at the end of 26 U.S.C. § 9510(c)(1)(B) should be deleted and replaced with: " , or".

Act; these reports establish vaccine innovation priorities and consider vaccine information dissemination to key stakeholders.⁶⁷²

If implemented, the first year under this proposal would lead to an injection of at least \$36 million in funding for vaccine research and development. In years where the total value of fund-worthy research proposals do not meet the mandatory minimum in funding allocations from the Trust Fund, the NIH can carry forward the remaining balance. Insofar as the mandatory minimum is a small percentage of the Trust Fund, the funding amount is unlikely to cause economic disruption to compensation program funds. That said, the one-percent mandatory minimum can be revisited should the funding amount become unsustainable.

To align Trust Fund investments in vaccine research with the Vaccine Act's mandate, the Director should work to ensure that funding projects include research related to vaccine development, safety and efficacy evaluations, refinement of existing vaccines, improvements in vaccine production, public health outreach, and ethical issues in immunizations and immunization policy. This research also might include inquiries into alternative vaccine schedules.⁶⁷³ Although research into alternative vaccine schedules is not risk free and may serve to challenge established precedent (and perhaps exacerbate lack of public trust), using science to directly address the concerns of vaccine-hesitant parents is, in the long run, likely to help answer questions and alleviate fear.⁶⁷⁴ As the IOM concluded, assessments of safety and efficacy concerns regarding "global assessments of [the] entire sequence of immunizations" is "fragmentary and inconclusive on many issues."⁶⁷⁵

Physicians and vaccine manufacturers should not be precluded from receiving funding pursuant to this program. In fact, providing physicians and manufacturers with funding may be a fruitful means of offsetting part of the costs of increased post-market reporting and analysis, as proposed in Section III.A of this Article. In a sense, this would underscore the symbiotic relationship and shared goals amongst physicians, industry, government, and the public.

⁶⁷² 21st Century Cures Act, Pub. L. No. 114-255, § 3093, 130 Stat. 1151 (2016) (to be codified in scattered sections of 21, 34, 38, and 42 U.S.C.).

⁶⁷³ For example, one recent report noted the dearth of studies examining the safety and efficacy of alternative vaccine schedules, notwithstanding public support for such schedules. 2013 IOM REPORT, *supra* note 12, at 5-6, 10-11.

⁶⁷⁴ Jason M. Glanz et al., *A Population-Based Cohort Study of Undervaccination in 8 Managed Care Organizations Across the United States*, 167 JAMA PEDIATRICS 274, 280 (2013) (concluding that study of alternative vaccination schedules is "in [the] national interest"); Douglas J. Opel & Edgar K. Marcuse, *The Enigma of Alternative Childhood Immunization Schedules*, 167 JAMA PEDIATRICS 304, 305 (2013) (reviewing Glanz et al., *supra*, and concurring).

⁶⁷⁵ 2013 IOM REPORT, *supra* note 581, at 94. The IOM provided several recommendations on how to conduct research on alternative vaccine schedules. *Id.* at 99-122, 161-99.

CONCLUSION

Vaccines provide excellent protection for most individuals and society, but “they are not . . . universally effective or completely safe.”⁶⁷⁶ Rather, immunizations involve “a high-stakes scenario in which some individuals will suffer catastrophic losses and in which no one can know who will be injured.”⁶⁷⁷ Because “the burdens associated with vaccination requirements are special: they go beyond dignitary harms and economic losses to actual physical injury; severe consequences will occur with statistical certainty; and the victims are often children,”⁶⁷⁸ principles of justice and fairness dictate that stakeholders work responsibly towards minimizing harm, and that adequate compensation be afforded to the unfortunate few who suffer vaccine-related injuries.

Building and maintaining public trust is a fundamental principle of public health ethics.⁶⁷⁹ The proposals outlined in this Article leverage the “amazing array of new techniques for vaccine design and delivery”⁶⁸⁰ to address the government’s failure to institute and enforce robust reporting and analysis of vaccine safety and efficacy. Three decades of experience have provided a wealth of information that should be used to analyze which parts of the Vaccine Act work well and which do not. Recalibrating vaccination laws to account for twenty-first century innovations will help build public trust and further the public health goals of immunization policy.

⁶⁷⁶ 1985 IOM REPORT, *supra* note 17, at 8, 80. As with vaccine manufacturers, “individuals should have their risks protected.” Parmet, *supra* note 382, at 153.

⁶⁷⁷ Mello, *supra* note 7, at 41. As such, “[v]accinees are . . . behind a Rawlsian veil of ignorance.” *Id.*

⁶⁷⁸ *Id.* at 37.

⁶⁷⁹ James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J.L. MED. & ETHICS 170, 171-72 (2002) (outlining ten ethical principles that characterize health policy decisions, including respecting personal choice and nurturing trust); Parmet, *supra* note 382, at 143 (“[I]n order to protect public health, laws must promote, rather than erode, the public’s trust in the public health system.”); Reitze, *supra* note 43, at 207 (“The pressure is on the public health profession to improve the public’s perception of their performance.”).

⁶⁸⁰ Baker & Katz, *supra* note 27, at 355.