

# VACCINES IMMUNIZE PEOPLE; LEGISLATION IMMUNIZES VACCINE MANUFACTURERS. LEGISLATION IN THE UNITED STATES REGULATING LIABILITY FOR THE MANUFACTURE, DISTRIBUTION AND ADMINISTRATION OF VACCINES

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Infectious diseases have caused widespread misery, and have wreaked havoc physically, mentally, economically, politically, and socially. Fortunately, in more recent years, scientists have developed vaccines. Vaccines are generally very safe, but cause side effects in a small percentage of cases. The United States Congress has passed two major pieces of legislation that provide sweeping tort immunity to vaccine manufacturers and others. In 1986 Congress passed the National Childhood Vaccine Injury Act (NCVIA) and in 2005 it passed the Public Readiness and Emergency Preparedness Act (PREP ACT). Both Acts were passed to encourage manufacturers to develop vaccines, particularly in times of public emergencies, in exchange for expansive liability protection. Both Acts established no-fault type compensation schemes to compensate those suffering injury or death from vaccines without having to resort to typical litigation. The author discusses both Acts in detail, in the context of the current Covid-19 crisis. The author discusses both Acts in detail, in the context of the current Covid-19 crisis.

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## 1 Introduction

### 1.1 Sooner or Later, Everything Old is New Again.<sup>1</sup> A Brief Timeline of Pandemics

Infectious diseases have plagued mankind for thousands of years. As observed by Huremovic (2019), the “[i]ntermittent outbreaks of infectious diseases have had profound and lasting effects on societies throughout history.” They have caused widespread misery, and have wreaked havoc physically, mentally, economically, politically, and socially. They literally have toppled civilizations and ended wars. When epidemics spread beyond a country’s borders, the disease becomes a pandemic. As civilization has evolved, and more especially in more modern times with the advent of mass transportation, including trains and airplanes, communicable diseases have been able to spread rapidly around the entire globe, impacting very large swathes of the population. Indeed, it is fair to say that in present times, a virus anywhere in the world can cause a problem everywhere.

The first recorded pandemic occurred during the Peloponnesian War, in Athens, in 430 B.C. The disease, thought to have been typhoid fever, passed through Libya, Ethiopia and Egypt and claimed the lives of as much as two-thirds of the population (Finns, 2020, Huremović, 2019; History.com Editors, 2020). This was followed, in turn, by the Antonine Plague (165 A.D.), the Cyprian Plague (250 A.D.), and the Justinian Plague (541 A.D.).<sup>2</sup> Europe suffered a serious outbreak of leprosy (leprosarium) in the 11<sup>th</sup> century (Bassareo et al., 2020). “A slow-developing bacterial disease that causes sores and deformities, leprosy was believed to be a punishment from God that ran in families. This belief led to moral judgments and ostracization

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<sup>1</sup> It is not entirely clear who first coined this expression, whether an ancient author or the composers of the song by the same name. *See*, Peter Allen & Carole Bayer Sager (1974), *Everything Old is New Again*, on Continental American (A & M Records 1974). However, it struck me during this last year, as the world has struggled with this pandemic caused by Covid-19, that we were hardly the first in history to have endured the ravages, death, illness, economic destruction, inconveniences, etc. caused by this infectious process, though often we seem to act as if we are. In point of fact, assuming that the current vaccines work as largely expected by the experts, in terms of world-wide deaths anyway, we will have gotten off “relatively” easily. And, there will be more such pandemics in the future, since it is true that everything old is new again.

<sup>2</sup> The Justinian Plague first appeared in Egypt, and then spread through Palestine and the Byzantine Empire, and later throughout the Mediterranean. This plague is said to be “credited with creating an apocalyptic atmosphere that spurred the rapid spread of Christianity” while squelching Emperor Justinian’s plans to reunite the Roman Empire. This plague, believed to be the first significant appearance of the bubonic plague, carried by rats and spread by fleas and causing enlarged lymphatic glands, recurred over the ensuing two centuries, leading to the deaths of around 50 million people, or 26 percent of the world population (Huremović, 2019; Eisenberg & Mordechai, 2019; History.com Editors, 2020).

of victims. Now known as Hansen's disease, it still afflicts tens of thousands of people a year and can be fatal if not treated with antibiotics." (History.com Editors, 2020). Leprosy spread and grew into a pandemic.

The Black Death, the second large outbreak of the bubonic plague, is believed to have possibly started in Asia and was transported west in caravans, entering the European continent through Sicily in 1347 when plague sufferers arrived in the port of Messina. The disease spread rapidly throughout Europe (Bassareo et al., 2020; History.com Editors, 2020). Responsible for the death of one-third of the world population, "England and France were so incapacitated by the plague that the countries called a truce to their war. The British feudal system collapsed when the plague changed economic circumstances and demographics. Ravaging populations in Greenland, Vikings lost the strength to wage battle against native populations, and their exploration of North America halted." (History.com Editors, 2020; Eisenberg & Modenchai, 2019).

Continuing on with our timeline, the next great event, or perhaps series of events, was the Columbian Exchange of 1492 (Bassareo et al., 2020; History.com Editors, 2020). When the Spanish arrived in the Caribbean, they brought with them and transmitted to native populations diseases including smallpox, measles and bubonic plague. Since people did not have the benefit of immunity from such diseases, they "devastated indigenous people, with as many as 90 percent dying throughout the north and south continents. Upon arrival on the Island of Hispaniola, Christopher Columbus encountered the Taino people, population 60,000. By 1548, the population stood at less than 500. This scenario repeated itself throughout the Americas." (Bassareo et al., 2020; History.com Editors, 2020). Smallpox destroyed the Aztec Empire in 1520, so weakening the population that it was not able to repel Spanish colonizers and left farmers unable to produce needed crops.<sup>3</sup>

The Great (bubonic) Plague of London in 1665 led to the deaths of about twenty percent of London's population. Believed to be the possible cause of the illnesses,

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<sup>3</sup> Id. According to these authors, research from "2019 concluded that the deaths of some 56 million Native Americans in the 16<sup>th</sup> and 17<sup>th</sup> centuries, largely through disease, may have altered Earth's climate as vegetation growth on previously tilled land drew more CO<sub>2</sub> from the atmosphere and caused a cooling event." (History.com Editors, 2020).

cats and dogs were slaughtered *en masse*. The outbreak tapered off at around the same time as the Great Fire of London, which occurred in September 1666.<sup>4</sup> The first of seven cholera pandemics over the next 150 years broke out in Russia in 1817, where one million people died (Azizi & Azizi, 2010; History.com Editors, 2020).<sup>5</sup> Each year, cholera infects 1.3 to 4 million people around the world, killing 21,000 to 143,000 people according to the World Health Organization (History.com Editors, 2017). The Third Plague Pandemic started in China in 1855 before spreading to India and Hong Kong. The bubonic plague this time claimed fifteen million victims.<sup>6</sup> The Fiji Measles Pandemic took the lives of 40,000 people, one-third of Fiji's population, in 1875 (Shanks, 2016; History.com Editors, 2017).

We are all reasonably familiar with “the flu.”<sup>7</sup> Influenza is a virus that attacks the respiratory system. Highly contagious, the flu is easily transmittable when an infected person coughs, sneezes or even talks. Respiratory droplets are generated and transmitted into the air, and can then can be inhaled by anyone nearby. The virus also can be transmitted when it lands on a surface and another touches that surface and the virus, and then touches his or her mouth, eyes or nose (Bassareo et al., 2020; History.com Editors, 2010). Called the Russian Flu of 1889, the first significant flu pandemic occurred in Siberia and Kazakhstan, and then traveled to Moscow, Finland, Poland, and the rest of the European continent. In 1890 the flu had made its way to North America and Africa. 360,000 died by the end of 1890 (Gregg, Hinman & Craven, 1978; History.com Editors, 2010).<sup>8</sup>

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<sup>4</sup> City records show that 68,596 Londoners died as a result of this epidemic, although it is believed that the actual number probably exceeded 100,000 out of a total population of around 460,000. The outbreak was caused by *Yersinia pestis*, the bacterium associated with other plague outbreaks before and since the Great Plague of London (Morrill, 2016).

<sup>5</sup> Cholera is an infectious disease caused by a bacterium called *Vibrio cholerae*. This bacterium lives in waters that are somewhat salty and warm, including estuaries and waters along coastal areas. People contract *V. cholerae* after drinking liquids or eating foods contaminated with the bacteria, such as raw or undercooked shellfish (History.com Editors, 2017).

<sup>6</sup> India faced the most substantial casualties, and the epidemic was used as an excuse for repressive policies that sparked some revolt against the British. This pandemic was considered active until 1960 when cases dropped below a couple hundred (History.com Editors, 2017; see also Bassareo et al., 2020).

<sup>7</sup> Influenza remains a serious problem, despite vaccines developed to combat it. The Centers for Disease Control and Prevention estimates that in the United States, influenza has resulted in between 9 million – 45 million illnesses, between 140,000 – 810,000 hospitalizations and between 12,000 – 61,000 death annually since 2010 (Centers for Disease Control and Prevention, n.d.).

<sup>8</sup> Some researchers now believe “it’s even possible that one of the cold-causing coronaviruses sparked” this serious outbreak “before fading into the litany of mild, commonplace human pathogens. Based on the spread of its family tree, researchers estimated in 2005 that the endemic coronavirus OC43 entered humans sometime in the late 19<sup>th</sup> century, likely the early 1890s. The timing has led some researchers to speculate that the original version of OC43 may have caused the ‘Russian flu’ pandemic of 1890, which was noted for its unusually high rate of neurological symptoms – a noted effect of COVID-19.” (Greshko, 2021; Gregg, Hinman & Craven, 1978).

Dubbed the Spanish flu since the news outlets reported a flu outbreak in Madrid in the spring of 1918, this avian-borne flu, which travelled swiftly around the world at a time when there were no effective drugs or vaccines to treat this deadly strain, resulted in an astounding fifty million deaths worldwide. The flu largely disappeared in the summer of 1919, when most of the infected had either developed immunities or died (Martini et al., 2019; Huremović, 2019; History.com Editors, 2020). In 1957, the Asian flu spread throughout China, the United States and England. A second wave followed in early 1958, causing approximately 1.1 million deaths worldwide. A vaccine was then developed which was effective in containing this pandemic (History.com Editors, 2020).

The HIV/AIDS virus, which destroys a person's immune system, resulting in eventual death by diseases the body otherwise would be able to combat, was initially observed in gay communities in the United States. However, the scientific community believes this devastating virus originated first from a chimpanzee virus from West Africa in the 1920s (History.com Editors, 2020). The virus is believed to have travelled to Haiti in the 1960s, and then to New York and San Francisco in the 1970s. While the scientific community has successfully developed treatments that slow the progress of the disease, the virus nonetheless has claimed the lives of thirty-five million people worldwide and a total cure remains elusive (Huremović, 2019; History.com Editors, 2020).

Severe Acute Respiratory Syndrome (SARS), was first identified in 2003. Symptoms included dry cough, fever and head and body aches. Believed to have possibly originated in bats, and then spread to cats and ultimately humans in China, and then many other countries (e.g., Taiwan), SARS fortunately took the lives of a relatively modest 774 people (Huremović, 2019; Hsieh et al., 2006; History.com Editors, 2020). Quarantine strategies were highly effective in containing SARS and this disease has remained at bay ever since.

Our timeline concludes with the world's current crisis, COVID-19. The first case having been reported in the Hubei Province of China on November 17, 2019, and then spreading around the globe like wildfire, on January 30, 2020, the World Health Organization (WHO) declared COVID-19 a public health emergency of international concern. WHO officially characterized COVID-19 as a pandemic on

March 11, 2020 (WHO - Immunization, Vaccines and Biologicals, 2020). COVID-19 is caused by a novel coronavirus that had not previously been found in people. While many symptoms have been reported, the chief ones include respiratory problems, fever and cough, and pneumonia. As with SARS and influenza, the virus is spread through droplets from sneezes (WHO - Immunization, Vaccines and Biologicals, 2020). As of the finalization of this paper, COVID-19 has claimed 2.13 million lives worldwide and 99.2 million cases have been reported.<sup>9</sup> Fortunately, with scientists around the globe working nonstop and through the scientific community's herculean efforts, several vaccines have been developed that have been approved through various regulatory agencies.

The Amsterdam-based European Medicines Agency (EMA) is responsible for approving all new drugs and vaccines across the 27 EU Members states, Iceland, Liechtenstein and Norway. The EMA is roughly equivalent to the US Food and Drug Administration. The first vaccine the EMA recommended granting a conditional marketing authorization for was Comirnaty, developed by BioNTech and Pfizer. This vaccine was designed to prevent COVID-19 in people from sixteen years of age. Approval occurred just before Christmas 2020. In early January, 2021, the EMA gave the same authorization for COVID-19 vaccine Moderna. According to the EMA web page, "A very large clinical trial showed that COVID-19 Vaccine Moderna was effective at preventing COVID-19 in people from 18 years of age."<sup>10</sup> (European Medicines Agency, 2021).

These have been strategically distributed throughout the world. The hope is that mass injections of these various vaccines (and perhaps others still to be developed) will eventually help contain the virus, although it is believed that, as is true with influenza, COVID-19 will not be eradicated, at least not in the near future.

## 1.2 The Role of Vaccines in Minimizing the Spread of Diseases

A vaccine is "a biological preparation that contains small amount of weak, dead, or modified disease-causing agents known as antigens, which can include viruses, bacteria, fractions of these agents, or the toxins they produce." Vaccines work to prevent illness in the following way: "Once introduced to the body, the antigen elicits

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<sup>9</sup> Johns Hopkins Coronavirus statistics, retrieved from: <https://coronavirus.jhu.edu/map.html> (25 January 2021).

<sup>10</sup> <https://www.ema.europa.eu/en> (4 February 2021)

a response by the immune system creating antibodies and immune memory cells that prevent future infection from the same disease. The immune response from a vaccine is similar to the immune response from acquiring an infectious disease naturally; however, since the antigen in the vaccine is weakened or dead, the vaccine usually does not cause disease. In the case of vaccines made with weakened live attenuated viruses or bacteria, the vaccine may cause a form of the disease that is usually much milder than the actual disease. In addition, the immune response triggered by any vaccine may cause some symptoms in some patients.”<sup>11</sup>

Public health can rightly claim that vaccines have been a huge success.<sup>12</sup> Vaccines have completely eradicated smallpox and nearly eliminated the polio virus. Furthermore, vaccines have dramatically decreased the number of people who experience preventable, infectious diseases such as measles, diphtheria, and whooping cough. However, it is crucially important, given that vaccines are administered so widely, that they are safe for public use. If they are not safe, then public confidence in them erodes and the public will become skeptical of the vaccines, and will not take them.<sup>13</sup> For example, a study in France showed that one-in-three respondents disagreed that vaccines are safe (Vanderslott, 2019). This in turn diminishes their efficacy to the public and also leads to litigation. Indeed, while the WHO and other health agencies recommend vaccinations in many instances, there is also a scientific consensus that vaccines cause illness and even death in some (limited number of) individuals, even when these vaccines are both properly manufactured and administered (WHO - Immunization, Vaccines and Biologicals, 2020). The balance that must be struck, then, from a public policy standpoint, is how best to promote the widespread use of vaccinations, that have been proven effective in, if not eradicating diseases, at least largely keeping them at bay, while at the same time ensuring that those unfortunate persons that have adverse reactions to the vaccines receive fair compensation.

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<sup>11</sup> Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines, Congressional Research Service, 2020: 3, citing CDC, “Principles of Vaccination,” in *Epidemiology and Prevention of Vaccine-Preventable Diseases*, ed. Jennifer Hamborsky, Andres Kroger, and Charles Wolfe, 13<sup>th</sup> ed. (Washington, DC: Public Health Foundation, 2015). (can be accessed at <https://crsreports.congress.gov/R46593>).

<sup>12</sup> See Centers for Disease Control and Prevention, 2011. Indeed, the death rates in the United States as a result of infectious disease are very low (Shemin, 2008).

<sup>13</sup> Much has been written and discussed on the issue of vaccine skepticism. For a short introduction to this topic Vanderslott, 2019.

This Article will address the legislation that has been enacted in the United States by the Congress to deal with these complicated issues, namely the 1986 National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. §300aa-1 to 34 (2012)); the 2005 Public Readiness and Emergency Preparedness Act (the PREP Act) (42 U.S.C. §247d-6d (2012)); as well as one of the key legal cases that has interpreted the legislation, in particular, the Supreme Court's ruling in *Bruesewitz v. Wyeth LLC* (131 S.Ct. 1068; 562 U.S. 223; 179 L.Ed.2d 1 (2011)) that interpreted the NCVIA. As we shall see, this legislation, when coupled with the judicial gloss to the NCVIA provided by the Court in *Wyeth*, affords vaccine manufacturers with broad tort immunity while creating administrative mechanisms for those injured or dying as a consequence of the side effects of vaccines to secure certain compensation through no-fault, worker's compensation type of mechanisms, long employed in the injured-worker setting. The Article will conclude with some general observations.

## 2 History of Federal Safety Regulations and Programs

### 2.1 Biologics Control Act of 1902

In the United States, the seminal federal law requiring premarket review of pharmaceutical products, including vaccines, was the Biologics Control Act of 1902 (P.L. 57-244, enacted July 1, 1902; see also Dudzinski, 2005: 147). This Act was passed in response to the many deaths stemming from the contamination of tetanus of the smallpox vaccine and diphtheria. This Act set forth requirements concerning the manufacturing and labeling of biological products ("biologics") and further mandated the inspection of manufacturing facilities as a condition for the issuance of a federal license for marketing such products. In 1944, the Public Health Service Act (PHSA) was enacted, leading to revisions and recodification of the Act. Currently, biologics are subject to regulation by the U.S. Food and Drug Administration (FDA) under the PHSA and the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>14</sup> Since the 1902 Act was enacted, the federal government has passed additional legislation dealing with vaccine safety, in an attempt to try to minimize

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<sup>14</sup> Prior to 1972, biologics, including vaccines, were regulated by the National Institutes of Health (NIH, or its precursors) under the Biologics Control Act of 1902. In 1972, however, regulatory responsibility over biologics was transferred from NIH to the U.S. Food and Drug Administration (FDA). With the development of biotechnology, the FDA's Center for Biologics Evaluation and Research (CBER) has taken on an expanded role in reviewing and approving new biological products intended for medical purposes, including probiotics, xenotransplantation and gene therapy. See, about the FDA, 2021 - Center for Biologics Evaluation and Research (CBER) ([www.fda.gov](http://www.fda.gov)).



the adverse events that sometimes accompany the administration of vaccines. This additional legislation will be discussed next.

## **2.2 The National Childhood Vaccine Injury Act**

Congress enacted the National Childhood Vaccine Injury Act (NCVIA) in November 1986 (42 U.S.C.A. §300aa-10 to -33 (West Supp. 1987)). The NCVIA, passed following four years of deliberations, and as a compromise effort to balance the tripartite goals of victim injury compensation; a more stable vaccine supply; and, the creation of safer vaccines,<sup>15</sup> was adopted in response to a vaccine liability crisis described in Section 2.2.1 of this Article, and which had threatened the nation's supply of childhood vaccines. The NCVIA established a National Vaccine Injury Compensation Program (NVICP) which was designed to protect the nation's vaccine supply from the market instability that had occurred as a consequence of a high number of lawsuits filed due to injuries stemming from vaccines.<sup>16</sup> A co-founder of a group known as Dissatisfied Parents Together wrote: "Parents supported the concept that a federal compensation system would result in official recognition of the reality of vaccine deaths and injuries and would help make vaccine safety a priority in United States Health." (Coulter & Fisher, 1991: 213-214).

NCVIA is a federal, mandatory no-fault compensation scheme available for persons injured by vaccines routinely administered to prevent childhood illnesses: diphtheria, tetanus, pertussis (aka whooping cough), measles, mumps, rubella (so-called "German measles"),<sup>17</sup> and polio. It requires persons that received such a vaccine and who claim injury to fully adjudicate their claims through the federal compensation program as a condition precedent to fling a civil action in the courts (42 U.S.C.A. §300aa-II(2)(A) (West Supp. 1987)). Families must file a claim in the NVICP within

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<sup>15</sup> See, H.R. Rep. 99-908, at 1 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344.

<sup>16</sup> See, H.R. Rep. No. 908, 99<sup>th</sup> Cong., 2d Sess. 4-5 (1986) [hereinafter VACCINE HOUSE REPORT] reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6344.

<sup>17</sup> Rubella, sometimes called "German measles" because it was first described as a separate disease by German physicians in 1814, is caused by a virus. The infection is usually mild with fever and rash, but if a pregnant woman gets infected, the virus can cause serious birth defects. The measles-mumps-rubella (MMR) vaccine is the best way to help protect against rubella. During the last major rubella epidemic in the US from 1964-1965: 12.5 million people contracted rubella; 11,000 pregnant women lost their babies; 2,100 newborns died; and, 20,000 babies were born with congenital rubella syndrome (CRS). Since the rubella vaccine became available in the US, the number of people infected with rubella dropped dramatically and currently less than 10 people in the US contract rubella each year. This is a true testament to the value of vaccines (National Foundation for Infectious Diseases (2021) Rubella (German Measles), retrieved from: <https://www.nfid.org/infectious-diseases/rubella/> (28 January 2021)).

three years of the first manifestation of injury (42 U.S.C. §300aa-16(a)(2) (2012)).<sup>18</sup> Respondent in the NVICP is the Secretary of the U.S. Department of Health and Human Services and attorneys from the U.S. Department of Justice represent respondent. Vaccine manufacturers are not parties to this litigation and of course bear no liability (42 U.S.C.A. § 300aa-11(a)(3)). The NCVIA also restricts the kinds of actions that may be brought against the vaccine manufacturers in the event the claimant decides to reject the statutory compensation and chooses instead to pursue a tort claim through the courts.<sup>19</sup> Most significantly, the NCVIA eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects. Awards are paid out of a fund created by an excise tax on each vaccine dose.

The NVICP has two parts. Part A creates a mandatory forum for the administration of claims by requiring individuals who seek compensation, including the injured party's legal representative, to file a petition in the United States Court of Federal Claims – i.e., the Vaccine Court (42 U.S.C.A. at §300aa-12). The U.S. Court of Federal Claims is tasked with overseeing the NVICP (42 U.S.C.A. at §300aa-12(c)). In line with this oversight obligation, this Court both appoints and removes the chief and associate special masters, who serve four-year terms (42 U.S.C.A. at §300aa-12(c)). Special masters manage and decide individual cases (42 U.S.C.A. at §300aa-12(d)). In general, special masters are lawyers and most of them have backgrounds in representing the U.S. government in various capacities.<sup>20</sup> Procedural and evidentiary rules are more relaxed in Vaccine Court as compared to the district courts (Colgrove, 2006: 215). Indeed, special masters have considerable discretion concerning how to hold hearings. For example, they can ask questions of witnesses, can hold hearings telephonically (or other means), and may permit prehearing discovery.<sup>21</sup>

A petitioner is entitled to recover if the affected person (1) received a vaccine covered by the Vaccine Act; (2) suffered a “covered” injury as set forth in the

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<sup>18</sup> In *Cloer v. Secretary of Health & Human Services* (654 F.3d 1322, 1344-45 (Fed. Cir. 2011)), the U.S. Court of Federal Claims held that the three-year statute of limitations from the first manifestation of injury was not tolled when subsequent science demonstrated that injury was vaccine-related after the three-year window.

<sup>19</sup> Interestingly, the NCVIA also requires attorneys to advise clients that compensation may be available under the NVICP when consulted by a client regarding a vaccine-related injury or death (42 U.S.C.A. §300aa-10(b)).

<sup>20</sup> See generally Office of Special Masters, U.S. Court of Fed. Claims, Guidelines for Practice Under the National Vaccine Injury Compensation Program (2004).

<sup>21</sup> See 42 U.S.C. §300aa-12(c)(1), (d)(2)(A) (2012). Section 300aa-12(d)(2)(A) states the guidelines for the VICP are to: “Provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions.”

Vaccine Injury Table;<sup>22</sup> and (3) 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 described in the petition (42 U.S.C.A. §§300aa-11, 300aa-13). While in the usual tort case the burden of proof is met by expert testimony, in the Vaccine Court the burden is met utilizing a three-prong test: (1) the petitioner must present a biological theory of harm; (2) must demonstrate a logical sequence of events connecting the vaccine to the injury; and (3) must establish an appropriate time frame in which the injury occurred. The petitioner must also show that there is not another biologically plausible explanation for the injury (*Althen v. Secretary of Health and Human Services* (Fed. Cir. 2005)). Essentially, the NVICP relieves claimants from the burden of providing causation by creating statutory presumptions of causation for the various injuries and adverse events as set forth in the Vaccine Injury Table. Some of these adverse events include anaphylaxis, paralytic polio, encephalopathy,<sup>23</sup> and death. Accordingly, if a claimant meets the Table's requirements for a specified injury, then he/she is entitled to compensation and is not required to prove causation. A petitioner that suffers an off-Table, or non-covered, injury may still recover compensation by establishing affirmatively that the vaccine administered caused the injury complained of (*Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)).<sup>24</sup> According to Engstrom (2015: 1702-1703), when the NVICP was in its infancy, around 74 percent of claims presented were resolved as on-Table injuries whereas presently 98 percent of cases are resolved off-Table meaning, a vast increase in litigation. The special masters review injury claims in two phases: the causation phase and the compensation phase.

Part B permits a petitioner to decline the result of the Vaccine Court and pursue a civil suit in state or federal district court, but only after a final judgment has been issued by the Vaccine Court (42 U.S.C.A. §300aa-21). Upon issuance of a Special Master's decision, each party has 30 days to file a motion to have the United States

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<sup>22</sup> The NCVIA created the "Vaccine Injury Table," which sets forth the "vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration" of vaccines for which individuals may seek compensation. *Id.* at §300aa-14. For a complete list of covered vaccines and injuries (Human Resources and Services Administration, 2021).

<sup>23</sup> Anaphylaxis is a severe, potentially life-threatening reaction. Common triggers include certain foods, some medications, insect venom and latex (retrieved from: <https://www.mayoclinic.org/diseases-conditions/anaphylaxis/symptoms-causes/syc-20351468> (23 January 2021)).

<sup>24</sup> Petitioners whose claims do not fall within the Table have the burden of proving that a given vaccine's administration caused a specific injury by a preponderance of the evidence (§300aa-13(a)(1)).

Court of Federal Claims review the decision.<sup>25</sup> If there is no such motion, the clerk of the United States Court of Federal Claims shall immediately enter a judgment in accordance with the Special Master's decision. The parties may further obtain review of the judgment in the United States Court of Appeals for the Federal Circuit (§§300aa-12(e)-(f)). Once judgment has been entered by the United States Court of Federal Claims or by the Court of Appeals for the Federal Circuit, a petitioner may give notice to the court that it will file a civil action in a state or federal district court (§300aa-21(a)). Any such subsequent civil action is governed by state law, including the applicable statute of limitations, which is stayed pending the outcome of the suit filed in the Vaccine Court (§§300aa-22(a), 21(c), 16(c)). Even prior to the Supreme Court's ruling in *Bruesewitz*, which as we shall see in the next section foreclosed vaccine design defects as an available remedy in tort, it was extremely rare for claimants to reject awards issued by the NVICP, with fewer than 0.5 percent of successful claimants who received an award in the compensation program rejecting it. The reality therefore is, that while Congress perhaps did not intend this outcome, in reality the NVICP is nearly an exclusive remedy (Engstrom, 2015: 1673).

Section 300aa-22 places highly restrictive limitations on subsequent civil actions. 42 U.S.C.A. Section 300aa-22 (§22) provides:

- (a) General Rule. Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for vaccine-related injury or death.
- (b) Unavoidable adverse side effects; warnings
  - (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, *if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.* (emphasis added)
  - (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine

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<sup>25</sup> However, reviewing tribunals give special masters' decisions a high level of deference. The reviewing courts may only reverse and remand a special master's decisions if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." For a person seeking review, this is an exceedingly high burden to meet (§300aa-12(e)(2)(B), (f)).

and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

- (A) That the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or
  - (B) By clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).
- (c) Direct Warnings. No vaccine manufacturer shall be liable for civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.
- (d) Construction. —[omitted]
- (e) Preemption. No state may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

### **2.2.1 Discussion of *Bruesewitz v. Wyeth LLC***

In *Bruesewitz v. Wyeth, Inc.* (131 S.Ct. 1068; 562 U.S. 223; 179 L.Ed.2d 1 (2011)), the Supreme Court was faced with the issue whether Section 300aa-22(b)(1) provides a blanket immunity to vaccine manufacturers from tort actions filed in state or federal court by injured victims seeking compensation for injuries allegedly arising from defectively designed vaccines.<sup>26</sup> The unfortunate facts of the case are as follows. When Hannah Bruesewitz was six months old, on April 1, 1992, she received her third scheduled injection of the vaccine TRI-IMMUNOL (“DTP”), which had been manufactured by Wyeth. Shortly after this injection, Hannah began experiencing seizures, which persisted over a sixteen-day period over which her parents observed

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<sup>26</sup> As a comparison of the majority and dissenting opinions in the case confirms, the language Congress used in the statute, as quoted in the text of this Article, is murky at best. Congress could have simply said that the statute bars any design defect claims. There is legislative history suggesting Congress did not intend to do so. The bill's sponsor, when presenting the bill to the full House of Representatives for vote, stated that civil claims for “inadequately researched” vaccines would be preserved. This is suggestive that design defect claims were to be preserved, not preempted (see generally H.R. Rep. No. 100-391(1), at 691 (1987), as reprinted in 1987 U.S.C.A.N. 2313-1, 2313-365).

some 126 seizures. These seizures resulted in Hannah being lethargic, developmentally stunted, and displaying autistic-like symptoms. Approximately eleven years later, one of Hannah's doctors diagnosed her with a residual seizure disorder and encephalopathy.<sup>27</sup> Consequently, Hannah's medical team testified that she likely would require lifelong medical care. Hannah had no pre-vaccine history of seizures. At the age of twenty months, Hannah was non-verbal and understood only simple commands (*Bruesewitz*, 562 U.S. 223).

Over the years, DTP had been very successful in reducing pertussis (or “whooping cough”) infections. Hannah's parents contended, however, that Wyeth and other medical professionals and organizations knew of several adverse effects associated with the vaccine. Hannah's injection, in fact, had been drawn from a vaccine lot that had over sixty-five complaints of adverse reactions filed with the FDA and the Centers for Disease Control and Prevention (“CDC”). Of that total, thirty-nine resulted in emergency room visits, six in hospitalizations, and two in deaths. Hannah's parents contended that her injuries could have been avoided had Wyeth used an alternate design called ACEL-IMUNE (“DTaP”). Although the FDA did approve DTaP in 1991, the approval extended to only the fourth and fifth injections following three scheduled injections of the DTP formula. It was not until 1996 that the FDA licensed DTaP for all five injections. Wyeth ceased distribution of DTP in 1998.

As required by the NCVIA, petitioners submitted their case to the Vaccine Court. After the hearing held in that forum, the Vaccine Court found that Hannah's residual seizure disorder and encephalopathy were not listed on the NCVIA Vaccine Injury Table entry for DTP, and that causation was not proven. As permitted under the NCVIA, petitioners then brought their case in Pennsylvania state court, contending that Wyeth was subject to strict liability and liability for negligent design under Pennsylvania common law. Wyeth then removed the matter to federal district court based on diversity of citizenship.<sup>28</sup> Wyeth subsequently moved for and was granted

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<sup>27</sup> Encephalopathy means damage or disease that affects the brain. This occurs when there has been a change in the way the brain functions, or a change in the body that affects the brain. These changes lead to an altered mental state, and leaves the person confused and disoriented. It is not a single disease, but rather a group of disorders that can have several causes (Erkkinen & Berkowitz, 2019).

<sup>28</sup> Diversity jurisdiction is one of two methods for a federal court to acquire federal subject matter jurisdiction over a case – the other being federal question jurisdiction. Diversity jurisdiction is codified in 28 U.S.C.A. §1332(a). To have diversity jurisdiction, there are two requirements: (1) the jurisdictional amount exceeds \$75,000

summary judgment on all counts, the district judge holding that the relevant Pennsylvania law was preempted by 42 U.S.C. §300aa-22(b)(1), which is quoted in full above. On appeal (561 F.3d 233 (3<sup>rd</sup> Cir. 2009)), the Third Circuit affirmed the district judge's grant of summary judgment, holding that Congress intended to preempt all design-defect claims in passing Section 22(b)(1) of the NCVIA. Petitioners subsequently appealed to the Supreme Court, which in turn granted a writ of certiorari.<sup>29</sup>

Writing for the majority of the Court,<sup>30</sup> Justice Scalia framed the issue as whether the preemption provision of the NCVIA set forth in 42 U.S.C. §300aa-22(b)(1) "bars state-law design-defect claims against vaccine manufacturers." (*Bruesewitz*, 562 U.S. at 226). The Court began its opinion by discussing the history of vaccines in the United States and noting that, in particular, while at the same time being "one of the greatest achievements" "of public health in the 20<sup>th</sup> century"<sup>31</sup> in the 1970's and 1980's the DTP vaccine (although overwhelmingly successful in preventing diseases) nevertheless was being blamed for causing disabilities and developmental delays in some of the children to whom the vaccine was administered, thus leading "to a massive increase in vaccine-related tort litigation" which in turn "destabilized the DTP vaccine market, causing two of the three domestic manufacturers to withdraw; and the remaining manufacturer, Lederle Laboratories, estimated that its potential tort liability exceeded its annual sales by a factor of 2000. Vaccine shortages arose when Lederle had production problems in 1984." (562 U.S. at 227 and fn. 7-8).

Destabilization of the vaccine market<sup>32</sup> was only one problem. The Court pointed out that many complained that efforts to obtain compensation for legitimate

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and (2) there must be complete diversity, that is, no plaintiff shares a state of citizenship with any defendant. Both prongs were met in the instant case.

<sup>29</sup> A case cannot, as a matter of right, be appealed to the U.S. Supreme Court. A party seeking to appeal to the Supreme Court from a lower court decision must file a writ of certiorari. In the Supreme Court, if four Justices agree to review the case, then the Court will hear the case. This is referred to as granting certiorari. The Court entertains many thousands of requests to grant certiorari in a given year but grants writs in approximately 125 cases or less. The Court grants cert in cases involving significant public interest or to resolve conflicts of decisions from the 13 Courts of Appeals (there are 12 courts whose jurisdictions are geographically apportioned and the United States Court of Appeals for the Federal Circuit, whose jurisdiction is subject-oriented and nationwide).

<sup>30</sup> The Supreme Court affirmed the Third Circuit, 6-2. Justices Sotomayor and Ginsburg dissented. Justice Kagan took no part in the consideration or decision of the case.

<sup>31</sup> 562 U.S. at 226 *quoting* Centers for Disease Control & Prevention, 1999).

<sup>32</sup> Between 1980 and 1984, injured plaintiffs sought \$3.5 billion in damages from vaccine manufacturers, causing six manufacturers to pull out of the market (Cantor, 1995: 1853, 1858; citing Subcomm. On Health and the Env't of the House Comm. On Energy and Commerce, 99<sup>th</sup> Cong., 2d Sess, Childhood Immunizations 72 (Comm. Print 1986) (presenting results of vaccine manufacturer survey)).

vaccine-inflicted injuries through the traditional tort litigation system was both “too costly and difficult.”<sup>33</sup> Additionally, a significant segment of society was becoming skeptical or fearful of the side-effects of the vaccine, and thus decided to decline vaccinating their children.<sup>34</sup> The Court also observed that public health officials became concerned about these troubling trends “since vaccines are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated.”<sup>35</sup> It was against this backdrop that the U.S. Congress in 1986 decided to enact the NCVIA for the purpose of both stabilizing the vaccine market and making it easier for victims to secure compensation. In discussing how the no-fault system works,<sup>36</sup> the Court noted that when applying for benefits under the Act, the claimant who can show that one of the injuries listed in the Vaccine Injury Table first manifested itself at the appropriate time is “prima facie entitled to compensation. No showing of causation is necessary; the Secretary [of Health and Human Services/Respondent] bears the burden of disproving causation. A claimant may also recover for unlisted side effects, and for those specified in the Table, but for those the claimant must prove causation. Unlike in tort suits, claimants under the Act are not required to show that the administered vaccine was defectively manufactured, labeled, or designed.”<sup>37</sup>

The compensation scheme established under the NCVIA was fairly generous and reasonably comprehensive. As the Court indicated, “Successful claimants receive compensation for medical, rehabilitation, counseling, special education, and vocational training expenses; diminished earning capacity; pain and suffering [up to \$250,000]; and \$250,000 for vaccine-related deaths. Attorney’s fees are provided, not only for successful cases, but even unsuccessful claims that are not frivolous.”<sup>38</sup>

The *quid pro quo* for this scheme, said the Court, designed to stabilize the vaccine market, was the Act’s “significant tort-liability protections for vaccine manufacturers.” (562 U.S. at 229). First, pursuant to Section 300aa-11(a)(2), a

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<sup>33</sup> 562 U.S. at 227 *citing* Apolinsky & Van Detta, 2010: 550-551; Burke, 2002.

<sup>34</sup> 562 U.S. at 227 *citing* Mortimer, 1978: 902, 906.

<sup>35</sup> 562 U.S. at 227 *citing* Hagan, 1990: 477, 479.

<sup>36</sup> This already has been discussed to some extent earlier in the paper.

<sup>37</sup> 562 U.S. at 228-229 and fns. 18-20, citing to appropriate provisions of the NCVIA.

<sup>38</sup> 562 U.S. at 229 and fns. 21-22, citing to appropriate provisions of the NCVIA. A serious shortcoming of the Vaccine Act is that the Congress has failed to step in to increase these limits. Government data shows that due to inflation, \$250,000 in 1986 is equal to approximately \$112,000 in 2017 dollars (*see* U.S. Bureau of Labor Statistics (2021) CPI Inflation Calculator, retrieved from: [http://www.bis.gov/data/inflation\\_calculator.htm](http://www.bis.gov/data/inflation_calculator.htm). (21. January 2021).



claimant must seek relief through this no-fault compensation program as a condition precedent for filing suit for more than \$1,000. Furthermore, the vaccine manufacturers are generally immune from liability for the failure to warn, so long as they have complied with all regulatory requirements, including but not limited to warning requirements, and so long as they have given the warning either to the claimant directly or to the claimant's physician (42 U.S.C. § 300aa-22(b)(2), (c)).<sup>39</sup> Additionally, manufacturers are immune from liability for punitive damages<sup>40</sup> absent failure to comply with regulatory requirements, fraud, intentional and wrongful withholding of information, or other criminal or illegal activity (42 U.S.C. § 300aa-23(d)(2)). And, as already discussed, and at the heart of the Court's decision, Section 300aa-22(b)(1) "eliminates liability for a vaccine's unavoidable, adverse side effects." (562 U.S. at 230).

Fundamentally, the parties disagreed on the meaning of the verbiage Congress used in Section 300aa-22(b)(1). Petitioners argued this section shields manufacturers against design-defect claims only when a vaccine's harmful side effects could not have been prevented through a safer design. Wyeth, on the other hand, contended that the section extends far broader protection, guarding vaccine manufacturers in absolute terms against all possible design-defect claims. Ultimately, the Supreme Court's majority sided with Wyeth, holding that the NCVIA preempts all design-defect claims against vaccine manufacturers. The Court ruled that the text of this section compels such a conclusion. According to the Court's analysis, if a manufacturer could be held liable for failure to use a different design, the phrase "even though" would have no purpose. Furthermore, the Court reasoned, a vaccine's side effects could always have been avoidable by use of a different vaccine not containing the harmful element. Therefore, the language of the provision suggests the design is not subject to debate in a tort action. Assuming that the manufacturer manufactures the vaccine safely and gives the proper warning, the statute establishes unavoidability as a complete defense with respect to the particular design. The Court supported its conclusion by noting that while product-liability theory provides for three well-established grounds for proving liability: defective

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<sup>39</sup> However, the immunity does not apply in cases where the claimant can establish by clear and convincing evidence that the manufacturer was negligent, or was guilty of fraud, intentional and wrongful withholding of information, or other unlawful activity (*See*, §§300aa-22(b)(2), 300aa-23(d)(2)).

<sup>40</sup> The vast majority of states allow for an award of punitive damages, although a handful do not. For those that do, the standard of proof is typically clear and convincing evidence, although some require only a preponderance of the evidence (Wilson Elser, 2018).

manufacture; inadequate directions for use or warnings; and, defective design<sup>41</sup> – the NCVIA mentions only manufacture and warnings. Thus, the Act’s failure to mention design-defect liability is “by deliberate choice, not inadvertence.”<sup>42</sup>

Furthermore, the majority rejected petitioners’ argument that the word “unavoidable” contained in Section 300aa-22(b)(1) was meant by Congress to be a term of art incorporating Restatement (Second) or Torts §402A,<sup>43</sup> Comment *k*, which exempts from strict liability rules “unavoidably unsafe products.” Further parsing the language, and continuing its strictly textual analysis, the majority noted that “unavoidable” is a commonly used word and that legal authority interpreting comment *k* attach special significance only to the phrase “unavoidably unsafe products” and not to the singular word “unavoidable.” Continuing its grammatical lesson, the Court stated that reading the phrase “side effects that were unavoidable” to exempt injuries caused by a flawed design would require treating the phrase “even though” as a coordinating conjunction linking independent ideas when it is a concessive, subordinating conjunction conveying that one clause weakens or qualifies the other.

The Court also observed that the structure of the NCVIA specifically, and of vaccine regulation in general, “reinforces” what the text of Section 300aa-22(b)(1) suggests: that design defects do not merit a single mention in either the Act itself or in Food and Drug Administration regulations that pervasively regulate the drug manufacturing process. According to the Court, this lack of guidance for design defects, when combined with the extensive guidance for the two other liability grounds specifically mentioned in the Act (i.e., failure to warn/direct and manufacturing defects), strongly suggests that design defects were not mentioned because they are not a basis for liability (562 U.S. at 237-238).

As further support for its conclusion, the Court reasoned that the Act’s mandate provides for federal agency improvement of vaccine design and for federally prescribed compensation, which are other means for achieving the two beneficial

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<sup>41</sup> Claims of design defect implicate an entire product line based on the theory that the risks the product poses to the consumer outweigh any utility the consumer would derive from using it (the so-called “risk utility” test). This is in contrast with construction or manufacturing defects, which usually involve aberrational departures from the product’s intended design (see Geistfeld, 2006).

<sup>42</sup> 562 U.S. at 233 quoting *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003).

<sup>43</sup> The various Restatements of the Law (whether of torts, property, contract etc.) are scholarly works generated by leading professors and other experts. While not binding on courts, they are highly persuasive and are often relied upon by the Courts, including the Supreme Court.

effects of design-defect based torts – prompting the development of improved designs, and providing compensation for inflicted injuries (562 U.S. at 238). Additionally, the Act’s structural *quid pro quo* compels the same conclusion (562 U.S. at 239). The vaccine manufacturers fund an informal, efficient compensation program for vaccine-related injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict. Taxing their product to fund the compensation program, while leaving their liability for design defect virtually unaltered, the Court reasoned, would hardly coax them back into the market (562 U.S. at 240).

Justice Sotomayor wrote a dissenting opinion that was extremely critical of the reasoning employed by the majority. She essentially accused the majority of merely adopting the policy preferences advanced by Wyeth instead of engaging in reasoned legal analysis. She wrote: “[T]he Court imposes its own bare policy preference over the considered judgment of Congress. In doing so, the Court excises 13 words from the statutory text, misconstrues the [Vaccine] Act’s legislative history, and disturbs the careful balance Congress struck between compensating vaccine-injured children and stabilizing the childhood vaccine market. Its decision leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products.” (562 U.S. at 250 (Sotomayor, dissenting)). She also wrote that the majority failed to carry out the Congressional intent “to leave the courthouse doors open for children who have suffered severe injuries from defectively designed vaccines. The majority’s policy-driven decision to the contrary usurps Congress’ role and deprives such vaccine-injured children of a key remedy that Congress intended them to have.” (562 U.S. 275, n. 25).

### **2.2.2 Further Discussion of the National Vaccine Injury Compensation Program**

The MMR vaccine is a vaccine against measles, mumps, and rubella (German measles). The first dose is generally given to children around nine months to fifteen months of age, with a second dose at fifteen months to six years of age, with at least four months between doses. Many petitioners filed claims in the Vaccine Court claiming autism was caused by MMR. In 2002, the Court instituted the Omnibus

Autism Proceeding in which plaintiffs were allowed to proceed with the three cases they considered to be the strongest before a panel of special masters. In each of the cases, the panel found that the plaintiffs had failed to demonstrate a causal effect between the MMR vaccine and autism (Abramson, Thomas & Safir, 2018: 9-23). Following this determination, the Vaccine Court has regularly dismissed such suits, finding no causal relationship between the MMR vaccine and autism (Maugh & Zajac, 2010).

As of November 2020, over \$4.4 billion in compensation (not including attorney's fees and costs) have been awarded pursuant to the VICP.<sup>44</sup> Between the years 2006-2017 there were 3,454,305,356 vaccinations administered (the most for influenza: 1,518,400,000) and compensation was awarded in only 4,153 cases (the highest for influenza: 2,833) translating into on average 1.2 awards per million applications for vaccines.<sup>45</sup> Through 2020, there have been a total of 5,646 awards with the average award being approximately \$456,113 (Health Resources and Services Administration, 2019).

The NCVIA, together with the Act's interpretation in *Breusewitz*, has been the subject of great debate, some lauding the legislation and the Court's endorsement of it, others decrying that the legislation struck an unfair balance in favor of vaccine manufacturers. Proponents point out that the twin goals of the NVICP – to protect the nation's vaccine supply (including stabilizing prices for same) while at the same time providing an easier non-litigation path to compensation for victims have largely been achieved. These advocates highlight that “Claimants going through the program receive many breaks compared to litigants in civil courts: 1) They do not have to provide evidence of design defect – or any defect; 2) Causation standards are less demanding than in civil courts 3) The rules of evidence are relaxed – claimants can use experts and bring in materials that would not be allowed in regular courts; 4) Fees and costs are covered even if people lose. No contingency fee: the whole award goes to the claimant.” (Reiss, 2019). These advocates also point out that while claimants give things up, such as full discovery; a shortened statute of

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<sup>44</sup> National Vaccine Injury Compensation Program Monthly Statistics Report. Health Resources and Services Administration (HRSA). U.S. Department of Health and Human Services, October 2019.

<sup>45</sup> Data and Statistics. Health Resources & Services Administration. Retrieved February 18, 2019.

limitations; and, the possibility of huge jury verdicts, “all in all, it’s a favorable system.”(Reiss, 2019).<sup>46</sup>

## **2.3 Public Readiness and Emergency Preparedness Act (PREP ACT)**

### **2.3.1 Introduction**

The most recent, and perhaps the most important, legislative enactment providing nearly blanket immunity to manufacturers, distributors and others of vaccines is the Public Readiness and Emergency Preparedness Act (42 U.S.C. §247d-6d) (hereinafter PREP Act). The PREP Act was passed by the United States Congress and signed into law by then President George W. Bush in December 2005. Vaccine manufacturers lobbied strongly for this legislation, asserting that they would not produce new vaccines unless this legislation was enacted. As we shall see, the Act preempts state vaccine safety laws in situations where the Secretary of Health and Human Services (HHS) issues an emergency declaration. During the legislative process, the proponents of the PREP legislation added it to the final version of a lengthy Department of Defense appropriations bill<sup>47</sup> while the bill was being negotiated between the Senate and the House of Representatives. The principal purpose of the PREP Act was to encourage the rapid and expeditious development and deployment of medical countermeasures (i.e., vaccines) to protect American citizens in the case of potential public health threats, such as viruses. The *quid pro quo* to the manufacturers (and others) is that they have secured nearly complete legal immunity (in both contract and tort) from any and all actions related to the manufacture, testing, development, distribution, administration and use of “medical countermeasures (i.e., vaccines) employed against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics.” The legislation protects drug manufacturer companies (and others) by removing financial risk barriers for any new vaccines that urgently need to be placed into the market to stem emergencies. The sole exception to PREP Act immunity is for death or serious physical injury caused by “willful misconduct.” However, individuals who die or suffer serious injuries directly caused by the administration of covered

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<sup>46</sup> For an insightful book on this topic Kirkland, 2016. Dr. Kirkland is an attorney and Associate Professor at the University of Michigan, in the Department of Women’s and Gender Studies.

<sup>47</sup> H.R. 2863. Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006. United State Congress, December 30, 2005.

countermeasures may be eligible to receive compensation through the Countermeasures Injury Compensation Program (CICP). Under the PREP Act, the HHS Secretary has the primary responsibility for making decisions on whether or not to declare an emergency. The liability protections are triggered once such a declaration is issued.<sup>48</sup>

### 2.3.2 March 10, 2020 Emergency Declaration Under PREP Act and General Counsel's Office Omnibus Advisory Opinion of May 19, 2020

The NVICP, it will be recalled, applies only to the specific vaccines set forth in the Vaccine Injury Table (42 U.S.C. §300aa-11(b)(1)(A) (2012)). Accordingly, it does not apply to vaccines that are employed for use in declared public health emergencies<sup>49</sup> or to many vaccines used by adults, such as the shingles vaccine. The PREP Act provides for a much more exclusive and limited administrative remedy than does the NVICP. In addition to covering vaccines, the Prep Act also applies to antidotes, medications, medical devices, and other products used to respond to pandemics and biological chemical threats.<sup>50</sup> The PREP Act authorized the HHS Secretary to issue a Declaration to provide liability immunity to certain individuals and entities (“*Covered Persons*”) against any claim for loss cause by, arising out of, relating to, or resulting from the manufacture distribution, administration, or use of certain medical countermeasures (“*Covered Countermeasures*”), except for claims involving “*willful misconduct*.” In cases where the HHS Secretary declares a public health emergency, liability protection extends not only to manufacturers, but to all medical administrators of the covered countermeasures used to prevent, treat or mitigate an epidemic (U.S.C. §247d-6d(a)(2)(B)). The Secretary has absolute authority to declare a public health emergency, and the declaration is not reviewable by any court.<sup>51</sup> On

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<sup>48</sup> The PREP Act was strongly opposed by consumers and various members of the U.S. Congress. The now late Senator Kennedy, long a progressive Democrat, joined by twenty of his Congressional colleagues, wrote a letter to the house Speaker and majority leader to repeal the PREP Act. *Sen. Kennedy, Colleagues Call on Majority Leader Frist, Speaker Hastert to Repeal ‘Dead of Night’ Vaccine Liability Provision, Enact Real Protections*, U.S. Fed. News, Feb. 15, 2006, 2006 WLNR 2705752. In their letter, they characterized the PREP Act as a “travesty of the legislative process,” and stated that it could be “used to allow manufacturers of virtually any drug or vaccine to escape responsibility for gross negligence or even criminal acts.” Furthermore, they accused the law’s sponsors of creating “an empty shell of a compensation program for injured patients with none of the funding needed to make compensation a reality.”

<sup>49</sup> Public Readiness and Emergency Preparedness Act, 42 U.S.C. §247d-6d (2012).

<sup>50</sup> See *Countermeasures Injury Compensation Program*, Health Resources & Servs. Admin. (Oct. 2017), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicpfactsheet.pdf>

<sup>51</sup> *Id.* §247d-6d(b)(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.”).

March 10, 2020, the Secretary issued such a declaration, effective retroactively to February 4, 2020, for certain medical products to be used against COVID-19.<sup>52</sup>

On May 19, 2020, General Counsel Robert P. Charrow issued an Omnibus Advisory Opinion (hereinafter OAO) intended to “address most questions and concerns about the scope of PREP Act immunity during the Coronavirus disease 2019 (COVID-19) pandemic.”<sup>53</sup> The OAO was written in response to various requests the General Counsel’s office had received “from those donating goods and services, on whether various activities qualify for PREP Act immunity.” (Advisory Opinion). In particular, General Counsel’s office has had to respond to many questions about “whether a medical product is a covered countermeasure, whether a person is a covered person, and whether a specific activity qualifies as use or administration of a covered countermeasure.” In view of the current pandemic, which is covered by the PREP Act in light of the Secretary’s March 10, 2020 Declaration, and given further the thorough nature of the OAO, a significant portion of the balance of this Article will draw heavily upon the OAO in order to explain how the PREP Act works.<sup>54</sup>

### **2.3.2.1 Covered Countermeasures**

Pursuant to the Secretary’s March 10, 2020 declaration, covered countermeasures include any: “antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.” (85 Fed. Reg. 15,198, 15,202 (March 17, 2020); *see also*, Advisory Opinion, p. 3). Furthermore, “[a]ny drug, device, or biological product that is approved, cleared, or licensed by the FDA and is used to diagnose,

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<sup>52</sup> See 85 Fed. Reg. 15,198,15,202 (March 17, 2020); *see also* Pub. L. No. 109-148, Public Health Service Act §319F-3, 42 U.S.C. §247d-6d and 42 U.S.C. §247d-6e. The HHS Secretary has declared numerous other public health emergencies under the PREP Act, including declarations for H1N1 pandemic flu vaccines, Ebola virus vaccines, and Zika virus vaccines. See U.S. Dep’t of Health & Human Servs., *Public Readiness and Emergency Preparedness Act*, Pub. Health Emergency (May 10, 2017), <https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx>.

<sup>53</sup> Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act April 17, 2020, as modified on May 19, 2020 at p. 1. (hereinafter Advisory Opinion).

<sup>54</sup> Advisory Opinions authored by the General Counsel of HHA are just that: advisory opinions. These are nonbinding and lack the force of law. However, they are significant and may inform the judicial interpretation of the PREP Act if courts find their reasoning persuasive.

mitigate, prevent, treat, cure, or limit the harm of COVID-19 is a covered countermeasure.” (Advisory Opinion, p. 3). The Coronavirus Aid, Relief, and Economic Security (CARES) Act amended the PREP Act to add respiratory protective devices to the list of covered countermeasures, assuming they are approved by the National Institute for Occupational Safety and Health and are also determined by the Secretary to be a priority for use during a public health emergency. Covered countermeasures expansively include, among other things, a “qualified pandemic or epidemic product.” (42 U.S.C. §247d-6d(i)(1)(A)). The term “qualified pandemic or epidemic product” means: “a drug ... biological product ... or device [as]defined ... [in] the Federal Food, Drug, and Cosmetic Act ... that is (A) (i) a product manufactured, used, designed, developed, modified, licensed, or procured \_ (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or (II) to limit the harm such pandemic or epidemic might otherwise cause; (ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or (iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and (B) (i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act...” (Advisory Opinion, pp. 3-4).

According to the OAO, “in order to meet the definition of a qualified pandemic or epidemic product, a product (1) must be used for COVID-19; and (2) must be (a) approved, licensed, or cleared by the FDA; (b) authorized under an EUA; (c) described in Emergency Use Instruction; or (d) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).” (*See* Advisory Opinion, p. 4). The OAO goes on to state that currently the number of products that have been approved, licensed, or cleared to deal with COVID-19 are very numerous (Advisory Opinion, p. 4).<sup>55</sup>

In light of the expansive definition of covered countermeasures and “Given the broad scope of PREP Act immunity, Congress did not intend to impose a strict-liability standard<sup>56</sup> on covered persons for determining whether a product is a covered countermeasure. Instead, we believe that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity – even

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<sup>55</sup> Footnote 2 of the Advisory Opinion provides a link where the list of approved products may be accessed.

<sup>56</sup> Strict-liability meaning liability without fault.



if the product is *not* a covered countermeasure – if that person or entity reasonably could have believed that the product was a covered countermeasure. *See, e.g.*, 42 U.S.C. § 247d-6d(a)(4)(B) (applying the ‘reasonably-could-have-believed’ standard to predicate requirements for PREP Act immunity not involving the actual use and administration of covered countermeasures). For example, FDA has issued EUAs for certain COVID-19 tests and PPE. A covered person purchases 500,000 tests or respirators that appear to be authorized under an EUA. The covered person has taken reasonable steps – under the current, emergent circumstances – to substantiate the authenticity of the products. But it turns out that some or all of the products are counterfeit. Under those circumstances, we believe that the person would be immune against a claim arising out of the use of a counterfeit test or respirator.” (Advisory Opinion, p. 4-5).

### **2.3.2.2 Covered Persons**

A “covered person” has immunity under the PREP Act for certain activities (*e.g.*, manufacturing, distributing, using, or administering) involving a “covered countermeasure,” as defined in the PREP Act and as delineated in a PREP Act declaration issued by the Secretary. The term “covered person,” when used with respect to the administration or use of a covered countermeasure, means: (A) the United States; or (B) a person or entity that is: (i) a manufacturer of such countermeasure; (ii) a distributor of such countermeasure; (iii) a *program planner* of such countermeasure; (iv) a *qualified person* who prescribed, administered, or dispensed such countermeasure; or (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv) (42 U.S.C. §247d-6d(i)(2)).

*Program planners* (2 U.S.C §247d-6d(i)(6)) include Indian Tribes, state governments, and local governments who supervise programs that dispense, distribute, or administer covered countermeasures, or provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures.<sup>57</sup>

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<sup>57</sup> Under the Secretary’s declaration, “[A] private sector employer or community group or other ‘person’ can be a program planner when it carries out the described activities.” (85 Fed. Reg. at 15,202).

*Qualified persons* (42 U.S.C. §247d-6d(i)(8)). include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other categories of persons identified by the Secretary in a PREP Act declaration. Employees and agents of all these persons and entities are also covered persons. With respect to this category, the Secretary, through Section V of his declaration, has determined that qualified persons also include: “[a]ny person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency[.]” (85 Fed. Reg. at 15,202; *see also* Advisory Opinion, pp. 5-6).

General Counsel Charrow indicated that a common question often received in his office centered on the circumstances under which a person is a “covered person” under the PREP Act. Therefore, the following section of his OAO is particularly informative and worth quoting in its entirety:

“[A]n Authority Having Jurisdiction has broad powers to extend PREP Act immunity to additional individuals as part of a public health and medical emergency response. The Authority Having Jurisdiction does so by authorizing ‘any person’ to ‘prescribe, administer, deliver, distribute or dispense the Covered Countermeasures.’ Section VII of the declaration explains that ‘[t]he Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.’ *Id.* As the lead federal public-health agency that has legal responsibility and authority for responding to the COVID-19 emergency, HHS is an Authority Having Jurisdiction, but it is not the only Authority Having Jurisdiction to respond to the COVID-19 emergency.

“The following is an example of a qualified person under Sections V and VII of the declaration. In response to the COVID-19 emergency, the HHS Office of the Assistant Secretary for Health (OASH) issued guidance for licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the FDA has authorized. Such tests are covered countermeasures under the declaration. Thus,

under Sections V and VII of the declaration, such pharmacists are covered persons. Specifically, they are qualified persons, as they are acting in accordance with guidance from HHS – an Authority Having Jurisdiction to respond - following a declared emergency by the Secretary. The pharmacists are covered as qualified persons (and hence as covered persons) even if they may not be licensed or authorized by the State to prescribe the tests pursuant to § 247d-6d(i)(8)(A), because they fit within the alternative definition of ‘qualified persons’ pursuant to paragraph § 247d-6d(i)(8)(B), as provided by the Secretary in the declaration.

“As with covered countermeasures, an entity or person that otherwise meets the requirements for PREP Act immunity will not lose that immunity – even if the entity or person is *not* a covered person – if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person (*see, e.g.*, 42 U.S.C. § 247d-6d(a)(4)(B)).

“For example, a pharmacy allows its licensed pharmacists to order FDA-authorized, self-swab COVID-19 tests pursuant to OASH guidance. Notwithstanding the pharmacy’s reasonable-compliance measures to ensure current licensure, it turns out that one of the pharmacists had inadvertently allowed his license to expire. Under those circumstances, the pharmacy would still be immune against a lawsuit relating to the COVID-19 test prescribed by that pharmacist.” (Advisory Opinion, pp. 6-7).

### **2.3.2.3 Reasonable Precautions and Scope of Immunity**

Immunity under the PREP Act has been described as both sweeping and broad (Advisory Opinion, p. 7). PREP Act immunity extends to “all claims for loss” under both state and federal law. “*Loss* is broadly defined to mean ‘any type of loss,’ including (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of such injury including medical monitoring costs; and (iv) loss of or damage to property, including business interruption loss. This language seemingly includes, at a minimum, most state law tort, medical malpractice, and wrongful death claims arising from the administration of covered countermeasures.” (Congressional Research Service, 2020: 2 (hereinafter Legal Sidebar)).

Assuming that a claim falls within the PREP Act's scope, a "covered person" is generally immune from legal liability. "The 'sole exception' to liability to immunity is when a covered person proximately causes death or serious physical injury to another person through willful misconduct. A *serious physical injury* must be life threatening, permanently impair a body function, permanently damage a body structure, or require medical intervention to avoid such permanent impairment or damage. *Willful misconduct* requires that the covered person acted (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." (Emphasis in original text) (Congressional Research Service, 2020: 3; *see also*, 42 U.S.C. §247d-6d(c)(3)).

However, despite the sweeping nature of this legislative grant of immunity, the civil liability of covered persons is further protected in yet additional ways. Before being able to file a lawsuit claiming willful misconduct, injured persons must first exhaust their administrative remedies by filing a claim through the Countermeasures Injury Compensation Program (hereinafter CICIP) (see discussion in section 2.3.2.4 below) and they cannot bring a civil suit if they elect to receive compensation awarded pursuant to the CICIP (Congressional Research Service - Legal Sidebar, 2020: *supra* note 137, p. 3). Civil suits that allege an exception to immunity for covered persons may only be brought before a three-judge court in the United States District Court for the District of Columbia. There is no right there to a jury trial (42 U.S.C. §247d-6d(e)(1), (5)). In the United States, the plaintiff in a typical personal injury/medical malpractice case, has the burden of proving the elements of his/her claim by a simple preponderance of the evidence. However, in civil suits brought under the PREP Act, a plaintiff, in order to prevail, must establish by clear and convincing evidence that the willful misconduct alleged proximately caused death or serious injury (42 U.S.C. §247d-6d(c)(3)).

As observed by the General Counsel in his OAO, even assuming the plaintiff can meet this high bar, "certain acts or omissions [still] remain immune from suit" under 42 U.S.C. §247d-6d(c)(4), namely: "Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in 'willful misconduct' as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in

the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.” (Advisory Opinion, p. 7. Quoting 42 U.S.C. §247d-6d(c)(4).

The OAO refers to yet other statutory provisions that shield covered persons from liability. “[U]nder 42 U.S.C. § 247-d-6d(c)(5), certain acts or omissions by a manufacturer or distributor and ‘subject to regulation by this chapter or by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*]’ will not constitute willful misconduct if (1) ‘neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission’ or (2) ‘such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.’

“Nevertheless, HHS encourages all covered persons using or administering covered countermeasures to document the reasonable precautions they have taken to safely use the covered countermeasures.

“For example, consider a distributor of medical products that sources PPE from a new supplier abroad in a good-faith attempt to quickly deliver PPE to American communities affected by COVID-19. Among other things, that distributor assesses the supplier’s facility to confirm that the supplier actually manufactures the PPE. The distributor also confirms that the supplier has quality-control processes in place.

“Under those circumstances, the distributor may wish to make available to the purchaser information about the reasonable efforts that the distributor had taken to safely use the covered countermeasures. Purchasers such as hospitals would then be able to make more informed decisions about how best to use the PPE. Overall, this would provide greater transparency in implementing the PREP Act.” (Advisory Opinion, p. 7-8).

On December 3, 2020, the Secretary issued a fourth amendment to the HHS Declaration. This amendment states that the HHS Declaration “must be construed in accordance with” the HHS advisory opinions, which are expressly “incorporate[d]” into the Declaration (85 Fed. Reg. 79190). The fourth amendment makes several changes to expand the scope of the PREP Act immunity, including “mak[ing] explicit” that the HHS Declaration (1) covers “all qualified pandemic and epidemic products” within the meaning of the statute; and (2) may apply to claims based on *not administering* a covered countermeasure, such as when the countermeasure is in short supply. The fourth amendment also creates a new category of “qualified persons” to cover health care providers using telehealth to order or administer covered countermeasures across state lines; adds a third covered means of distribution to extend liability protections to “additional private distribution channels”; and clarifies the licensing requirements for pharmacists to administer routine pediatric vaccinations under the Third Amendment, while expanding this category to expressly include FDA-authorized COVID-19 vaccines as well.

#### **2.3.2.4 Additional Office of General Counsel Advisory Opinions on the PREP Act**

On October 23, 2020, the HHS OGC issued two additional Advisory Opinions, No. 20-03 and 20-04. Advisory Opinion 20-03 addressed three vaccination-related issues. The following are the issues and the advisory opinions regarding each:<sup>58</sup>

1. Whether the PREP Act preempts pharmacy-related state licensing laws that are less stringent than federal standards under the Third Amendment to the Secretary’s March 2020 Declaration.<sup>59</sup> The HHS OGC notes that relevant state-licensing laws that are less stringent than those in the Declaration are not preempted.

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<sup>58</sup> See, [www.oig.hhs.gov](http://www.oig.hhs.gov)

<sup>59</sup> The Third Amendment identifies, as Qualified Persons covered under the PREP Act, certain state-licensed pharmacists and state-licensed or registered pharmacy interns acting under the supervision of a state-licensed pharmacist. The Amendment authorizes those pharmacists to order and administer, and authorizes those pharmacy interns to administer, any vaccine that the ACIP recommends for ages 3 through 18, according to ACIP’s standard immunization schedule. The Amendment clarifies that “the category of disease, health condition, or threat for which [the Secretary] recommends the administration or use of the Covered Countermeasures includes not only COVID-19 . . . but also other diseases, health conditions, or threats that may have been caused by COVID-19 . . . including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.”

2. Whether a state may require a pharmacist to enter into a collaborative-practice agreement with a licensed physician as a condition of administering vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for children between ages 3 and 18. The HHS OGC states that “any state of local law requiring a pharmacist to enter into a collaborative-practice agreement would be preempted if that requirement prohibits or effectively prohibits a pharmacist from ordering and administering vaccines as set forth in the Third Amendment and related issuances.”
3. Whether epinephrine, when used to treat a severe acute vaccine reaction, is a “covered countermeasure” as defined in the PREP Act. HHS OGC indicates that epinephrine is a “covered countermeasure” under the PREP Act when used to treat severe acute reactions to an ACIP-recommended vaccine.

Advisory Opinion 20-04 focuses on the question of who qualifies as a “program planner” under the PREP Act and the Secretary’s March 10, 2020, Declaration, as amended, and the activities authorized by an “Authority Having Jurisdiction.” The Opinion, which again served to re-emphasize the breadth of PREP Act immunity, states that any individual or organization can potentially receive PREP Act coverage as a “program planner” when they act in accordance with the PREP Act and the Secretary’s Declaration. Private businesses may so qualify (and thus fall into the category of “covered persons”) when performing certain functions. Concerning what activities are authorized by an Authority Having Jurisdiction, this Advisory Opinion expands upon examples provided in an earlier Opinion with additional manners in which activities might be authorized and notes that all of the examples may collectively be considered as guidance. The Opinion also provides some examples of how a program planner may or may not qualify for PREP Act immunity when local, state, and/or federal Authorities Having Jurisdiction issue conflicting guidance. Taken cumulatively, these two additional Advisory Opinions express the General Counsel’s view of the broad, sweeping immunity Congress intended to grant under the PREP Act.

### 2.3.2.5 The Countermeasures Injury Compensation Program (CICP)

Persons that have either been seriously injured or died as a direct result of a covered countermeasure administered or used under a declaration may seek compensation through the CICP. The CICP, as is the case under a typical workers' compensation scheme or the National Vaccine Injury Compensation Program, "substitutes a no-fault, speedy compensation system in place of expensive and uncertain litigation." (Advisory Opinion, p. 8). The CICP has only a one-year statute of limitations.<sup>60</sup> The claimant has the right to retain a lawyer to provide legal assistance, but in contradistinction to the NVICP, the CICP does not allow for the recovery of attorney fees.<sup>61</sup> Furthermore, under the CICP there are no hearings or appeals available from the CICP decisions with the exception that a claimant may request reconsideration of a claim within sixty days in situations where the CICP originally rejected the claim.<sup>62</sup> As stated by Holland (2018: 415, 448): "There are no published records of CICP's compensation decisions, so it is impossible to analyze them. CICP's website lists medical expenses, lost employment income, and survivor death benefits as possible compensation, but it is unclear whether or to what extent CICP has paid them, as there are no published decisions.

"As of September 2015, HHS adopted a final rule regarding compensation through the CICP (42 C.F.R. §110.30-33). The rule includes a Covered Countermeasures Injury Table (Countermeasures Table), which contains presumptive injuries from pandemic flu vaccines and, specifically, the pandemic flu vaccine for the 2009 H1N1 virus, as well as antiviral drugs to treat pandemic flu (42 C.F.R. §110.100). The Countermeasures Table creates presumptions of causation in the event of anaphylaxis within zero to four hours after administration of a pandemic flu vaccine or the onset of Guillain-Barre Syndrome from three to forty-two days after vaccine administration (42 C.F.R. §110.100).

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<sup>60</sup> See Health Resources & Services Administration, 2017: "[Y]ou have ONE (1) YEAR from the date that the covered countermeasure was received to file for CICP benefits . . . .", Health Resources & Services Administration (Oct. 2017) Frequently Asked Questions, retrieved from: <https://www.hrsa.gov/cicp/faq> (22 December 2020)

<sup>61</sup> Health Resources & Services Administration (Oct. 2017) Frequently Asked Questions. <https://www.hrsa.gov/cicp/faq> (22 December 2020)

<sup>62</sup> See previous.



“HHS has created these presumptions based on ‘compelling, reliable, valid, medical and scientific evidence.’<sup>63</sup> The Countermeasures Table creates a rebuttable presumption of injury causation for people who meet its criteria, but HHS still has the right to contest eligibility in individual cases. In addition, if an individual alleges injuries that do not fall within the Countermeasures Table, she may still pursue her claim, but she must demonstrate that ‘the covered countermeasure directly caused the injury’ by ‘compelling, reliable, valid, medical and scientific evidence.’<sup>64</sup>

General Counsel Charrow succinctly describes benefits available under the CICP in the following terms:

“A serious injury generally means a physical injury that warranted hospitalization (whether or not the person was actually hospitalized) or that led to a significant loss of function or disability. 42 U.S.C. § 110.3(z). CICP pays reasonable and necessary medical benefits. CICP also pays lost wages to eligible recipients. Death benefits may also be available to certain survivors of eligible individuals who died as a direct result of the administration or use of a covered countermeasure. CICP is payer of last resort. So benefits are reduced by the amounts payable by other public and private third-party payers (such as health insurance and workers’ compensation). The regulations implementing the CICP are at 42 C.F.R. pt. 110.

“Compensation for injuries is more limited than the liability afforded under the PREP Act. As described above, the PREP Act provides immunity for all claims for loss. But CICP will provide compensation only for eligible claims of serious physical injury or death. CICP will not compensate claims related to emotional injury, fear of injury, business losses, or other types of claims for which immunity is provided. Information about this program can be found at <http://www.hrsa.gov/cicp/about/index.html> or by calling 855-266-2427.” (Advisory Opinion, p. 8).<sup>65</sup>

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<sup>63</sup> Ctrs. for disease control & prevention, U.S. Dep’t of Health & Human Servs., at pp. D-9.

<sup>64</sup> Countermeasures Injury Compensation Program: Pandemic Influenza Countermeasures Injury Table, 80 Fed. Reg. 47,411, 47,412 (Aug. 7, 2015) (codified at 42 C.F.R. §110.30) (“[T]his Table creates a rebuttable presumption of causation for eligible individuals . . .”).

<sup>65</sup> See Advisory Opinion, *supra* note 119, at p. 8.

### 3 Final Remarks

As we are all acutely aware, the various governments around the world have struggled mightily in trying to manage the current COVID-19 pandemic/crisis. Trying to understand new viruses and then developing countermeasures in an effort to control, if not eradicate them, creates severe challenges even for the best medical/scientific minds in the world. As we all have seen, scientists and medical experts from all corners of the world have worked full-time, literally around the clock, since the pandemic erupted trying to find effective and safe vaccines to place into public use. We can all agree that the medical/scientific community has performed admirably under the most difficult of circumstances.

We also each have seen, in real time, the conflicting interests that government/society must try to balance and manage during a pandemic. The quarantines, travel restrictions, business closures, work-at-home rules, school closures (and on-line learning) and other governmental measures have been imposed in an attempt to control the spread of the virus. While necessary and effective, they have come at significant costs. The economic fall-out from this pandemic will be felt for years to come. Many businesses will never return.<sup>66</sup> Many will go bankrupt. Students are losing valuable classroom time, that can never be effectively restored. Hospitals and those in any way connected to the medical profession are literally overwhelmed. The COVID-19 virus has and will continue to claim many lives, and there is the distinct possibility that those that caught the illness may suffer symptoms (currently unknown) in the future.<sup>67</sup>

It has been repeated over and over that effective vaccines are the only way out of the crisis. Fortunately, the world's great scientists have now developed number of them. As we have all seen, these have been vetted. All went through numerous clinical trials. They also were approved by various regulatory bodies before being approved for large-scale use. And this all was done in record time. Many literally await taking their vaccine injections "with open arms." Others are skeptical, and the

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<sup>66</sup> Your author listened to a Sky News report on or about January 18, 2020 indicating that the British Government forecasts that as many as one-third of the nation's businesses will never return.

<sup>67</sup> Mayo Clinic (2020) COVID-19 (coronavirus): Long-term effects, retrieved from: <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351> (12 January 2021).

sheer speed with which these vaccines have come to market fuel the skepticism that a substantial segment of the public has. While the clinical trials of the vaccines have shown them to have a high degree of efficacy with few (mild) side-effects, it also is likely, as with other vaccines, that a small percentage of the inoculated population will sustain more severe injuries.

As we have seen, in recent years the United States Congress enacted two major pieces of legislation designed to encourage the speedy development and distribution of vaccines (countermeasures) and to help ensure that the American public can receive vaccines in times of medical emergencies such as being caused by the current COVID-19 crisis. The first was the 1986 National Childhood Vaccine Injury Act and the second was the 2005 Public Readiness and Emergency Preparedness Act. Both Acts provide manufacturers and distributors of vaccines with substantial protection from the usual tort/contract liability. Indeed, it is fair to say that both create plenteous, almost insurmountable barriers to justiciability for those who are injured by vaccines and who would attempt to pursue a traditional remedy through the court system. In lieu of these traditional remedies, Congress made institutional value judgments that persons sustaining defined, injurious effects as a consequence of vaccines should have recourse through administrative-type tribunals, not the courts.

This author is not necessarily opposed in principle to the kind of no-fault schemes Congress has crafted in the area of vaccines. Both the NVICP and the CICP have their virtues. After all, the traditional litigation model is not without its negative consequences. It is expensive. It is time-consuming. It often yields inconsistent results. There are winners. There are losers. Any additional substantive area of litigation burdens already-crowded courts. Litigation takes a heavy physical and emotional toll on its participants. The costs associated with litigation can put businesses into bankruptcy. And in the case of vaccine manufacturers, history revealed that many were afraid of staying in the business if they had to fear traditional litigation. The schemes developed by Congress incentivized companies to continue to develop vaccines.

This author devoted a significant portion of his legal career to representing companies that either manufactured or sold products containing asbestos. The asbestos litigation is the longest running mass tort litigation in the history of the world. In the 1970's – 1990's in particular, thousands of asbestos personal injury cases flooded both the federal and state courts. This litigation was responsible for compelling well over one hundred large companies to file for bankruptcy protection.<sup>68</sup> Some of these companies, along with their insurers, and others, had extensively lobbied the Congress to pass legislation that would have resolved claims administratively and not through the courts. In 2005, Congress considered but did not pass legislation entitled the "Fairness in Asbestos Injury Resolution Act of 2005 (FAIR)." FAIR would have established a \$140 billion trust fund in lieu of litigation. The transaction costs of asbestos litigation will by some estimates reach \$275 billion.<sup>69</sup> The many companies that filed for bankruptcy protection typically have been required to fund special "bankruptcy trusts." Claimants (usually through counsel) can apply to these trusts, managed by administrators, to receive compensation. Sometimes that compensation is substantial and the process is much quicker and cheaper than the traditional tort system. Additionally, claimants often can also pursue traditional remedies against solvent companies.

While the many lawyers and others<sup>70</sup> that have benefitted financially from the asbestos litigation would undoubtedly disagree with me, from my firsthand perspective I have reached the conclusion that on balance most claimants, businesses, insurers, and society as a whole would have benefitted had Congress passed legislation along the lines of FAIR and had it done so in the 1980's, before many companies went bankrupt. There are similarly no-fault worker's compensation schemes in place both at the state and federal level, and they generally work well.

The purpose of this Article was not to critically examine the wisdom of the two Acts mainly discussed, but rather to explain them, as it is my belief that many Americans probably do not even know they exist, let alone how they work. As indicated a few

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<sup>68</sup> Asbestos bankruptcy trusts (United States), retrieved from: [https://en.wikipedia.org/wiki/Asbestos\\_bankruptcy\\_trusts\\_\(United\\_States\)](https://en.wikipedia.org/wiki/Asbestos_bankruptcy_trusts_(United_States)) (15 December 2020). For a list of (asbestos) companies filing for bankruptcy protection from 1982 – 2020 (approximately 140) see <https://www.crowell.com/files/20201007-List-of-Asbestos-Bankruptcy-Cases-Chronological-Order.pdf> accessed January 19, 2021).

<sup>69</sup> Asbestos and the Law, retrieved from: [https://en.wikipedia.org/wiki/Asbestos\\_and\\_the\\_law](https://en.wikipedia.org/wiki/Asbestos_and_the_law) (19 January 19 2021).

<sup>70</sup> Records gathering/production entities; court reporters; experts; jury/litigation consultants, etc.

paragraphs earlier, however, I am not opposed in principle to such no-fault schemes as a philosophical matter, although I also have no doubt that my many friends “on the other side of the table” in the courtroom would disagree with me.<sup>71</sup> However, the devil, as they say, is always in the details. As we have seen, the NVICP is the more generous of the two schemes. However, I would argue that the \$250,000 statutory limit for pain and suffering is woefully low, especially given inflationary factors. I would argue in favor of, at minimum, amending the legislation to substantially increase that limit.

The remedies available under the CICP are even more limited and the jurisdictional requirements for claimants to avail themselves of those remedies are, in my judgment, unfairly one-sided in favor of business. While I am mindful of the circumstances faced by manufacturers (and others) when they are under such time pressure to develop countermeasures, and while I am sympathetic in general to their fears of litigation, and the distinct possibility that any extensive litigation can put them out of business, I also am sympathetic to those relatively few that sustain substantial harm due to their decision to take a vaccine, especially when health authorities and governments urge them to do so for the greater good of society. Again, it is beyond the scope of this Article to analyze these matters in detail and indeed that is beyond my purview. However, I do think a more appropriate balance can be struck legislatively and as a society we should be sure that anyone that has a significant, serious injury (or death) stemming from a vaccine receives fair compensation.

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*Althen v. Secretary of Health and Human Services* (Fed. Cir. 2005).

*Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003).

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<sup>71</sup> By tradition, the party with the usual burden of proof, a plaintiff in a civil case, sits at the table closest to the jury box. Hence, my plaintiff counsel colleagues sat closest to the jurors, while I sat at the “other table.”

Biologics Control Act of 1902

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