

# MANDATORY VACCINATIONS IN THE UNITED STATES AND THE EUROPEAN UNION

Elise Phalen\*

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\* J.D. Candidate, 2020, University of Arizona, James E. Rogers College of Law. An immense thank you to Note Advisors, Professors Roy Spece and Christopher Robertson for all of their guidance and feedback through this process. Thank you to the entire *Journal* and Bar Review communities. And a special thanks to my parents, Mike and Katie, and my brothers, Chris and Brian, for their endless love and support.

## I. INTRODUCTION

“There can be no doubt that humanity can pull itself up from its own bootstraps and protect its children from the insidious invasion of ultramicroscopic disease.” – The 1955 University of Michigan Ann Arbor Press Release announcing the success of the Salk polio vaccine trials.<sup>1</sup>

The release of Dr. Jonas Salk’s original inactivated polio vaccine in 1955, following an intensive development and testing process consisting of 1.8 million child participants, was met with resounding approval from around the country. Families lined up for blocks to have it administered to their children.<sup>2</sup> Over the next two years, incidence of polio in the United States fell by 85-90%.<sup>3</sup> Decades of innovation in epidemiology followed, including the introduction of the live, attenuated oral polio vaccine (OPV) in 1962, which became the new standard, as it is cheaper to manufacture and easier to administer.<sup>4</sup> Eventually, in 1971, a combined vaccine for measles, mumps, and rubella (MMR) was licensed and has been distributed in the United States and abroad ever since.<sup>5</sup>

In 1979, the United States saw its final case of polio, the same year that the World Health Organization (WHO) completed its landmark initiative to eradicate smallpox.<sup>6</sup> That global effort took 14 years until finally, the WHO declared smallpox, one of the great scourges of humanity, officially eradicated.<sup>7</sup> But the relationship between the public, and the scientific and medical communities, over the creation and distribution of vaccinations has not been a smooth one of mutual trust. Despite years of data and impressive success rates, concerns remain over issues like vaccine-contracted disease and vaccine injuries.<sup>8</sup> An outbreak of measles in the United States in 2014, which the Centers for Disease Control and Prevention (CDC) found had originated at Disneyland in California, led to a total of 125 cases across seven states, shows some of the dire consequences from an

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<sup>1</sup> *1955 Polio Vaccine Trial Announcement*, UNIVERSITY OF MICHIGAN SCHOOL OF PUBLIC HEALTH, <https://sph.umich.edu/polio/> (last visited Oct. 4, 2018).

<sup>2</sup> *Id.*

<sup>3</sup> *Polio: Timeline*, SMITHSONIAN NATIONAL MUSEUM OF AMERICAN HISTORY, <https://amhistory.si.edu/polio/timeline/index.htm> (last visited Oct. 4, 2018).

<sup>4</sup> *Id.*

<sup>5</sup> Christian H. Ross, *The Measles, Mumps and Rubella (MMR) Vaccine*, THE EMBRYO PROJECT ENCYCLOPEDIA (Mar. 30, 2017), <https://embryo.asu.edu/pages/measles-mumps-and-rubella-mmr-vaccine>.

<sup>6</sup> See *Polio: Timeline*, *supra* note 3.

<sup>7</sup> See *1955 Polio Vaccine Trial Announcement*, *supra* note 1.

<sup>8</sup> See Ross, *supra* note 5.

antivaccination culture.<sup>9</sup> There, at least 49 patients were unvaccinated, including 18 children who were intentionally unvaccinated or placed onto alternative vaccination schedules for religious or personal philosophy reasons.<sup>10</sup> And, according to the WHO, incidence of measles in Europe have risen significantly in the past year, with over 20,000 cases leading to 35 deaths in 2017 alone.<sup>11</sup>

With this climate of uncertainty surrounding vaccination in the United States and Europe, it is no wonder that there is a disparity in vaccination requirements across countries. Until uniformity is achieved, global initiatives to fully eradicate polio and measles may remain stalled. This Note explores the legal framework behind the vaccination programs in the United States and the European Union, specifically focusing on Sweden, which does not mandate any vaccines, and Slovenia, which has a strict mandatory vaccination policy. Focusing primarily on polio and measles, it discusses each jurisdiction's legal history that led to these programs, analyzes current laws and policies governing vaccination in each jurisdiction (especially concerning questions of privacy and state intervention in healthcare), and explores the ways in which public opinion affects the law. Lastly, it recommends how the United States can synthesize the European approaches with its own current standards to create an effective vaccination program for polio and measles, allowing exceptions only for documented medical conditions.

## II. BACKGROUND

To fully understand the discussion of vaccine law and policy this Note offers, it is necessary to understand the history of vaccines in both the United States and Europe. Specifically, this section will focus on background information relating to polio and the measles, and their respective vaccines and vaccination schemes.

### A. What are Vaccines?

Vaccines are a way to trick a person's body into "remembering" a disease and preparing the immune system to recognize and fight off any future introduction

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<sup>9</sup> Jennifer Zipprich, Kathleen Winter, et al., *Morbidity and Mortality Weekly Report: Measles Outbreak California, December 2014-February 2015*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Feb. 20, 2015), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a5.htm>.

<sup>10</sup> *Id.*

<sup>11</sup> Sarah Boseley, *WHO warns over measles immunization rates as cases rise 300% across Europe*, THE GUARDIAN (Feb. 19, 2018), <https://www.theguardian.com/society/2018/feb/19/who-warns-over-measles-immunisation-rates-as-cases-rise-400-across-europe>.

of diseases into the body.<sup>12</sup> This is accomplished by introducing a culture into the body (orally, intravenously, or intramuscularly) that resembles the pathogen, typically being a dead or weakened form of the disease-causing microbe or its toxins.<sup>13</sup> There are currently five types of vaccines used in the United States and other developed countries: 1) live, attenuated vaccines which contain a version of the living virus or bacteria that has been weakened so that it does not cause serious disease in people with healthy immune systems; 2) inactivated vaccines which contain a dead version of the virus or bacteria and usually require more than one dose; 3) toxoid vaccines which prevent diseases caused by bacteria that produce toxins in the body; 4) subunit vaccines which include only parts of the virus or bacteria, usually resulting in less side effects; and 5) conjugate vaccines which protect against a type of pathogen with a specific coating that hides it from immune defenses by connecting it to antigens in the body to develop an immune response to diseases like Influenza type B.<sup>14</sup>

Theoretically, completing the full schedule of vaccines prescribed for a disease will protect a person from succumbing to it, if encountered.<sup>15</sup> However, like many medical treatments, vaccines are not perfect and people who have been vaccinated may still be in danger during an outbreak.<sup>16</sup> So, medical experts contend that the best way to ensure full protection is *herd immunity*, in which “the entire group is protected because most individuals are.”<sup>17</sup> Furthermore, the theory of herd immunity posits if less people are vulnerable to the disease, the virus will have a decreased chance to travel between people and create an outbreak.<sup>18</sup> Thus, herd immunity is the primary way to protect people who are unable to be vaccinated due to allergies, weakened immune systems, or simply because they are too young or too old to receive vaccinations.<sup>19</sup>

## **B. A Brief History of Vaccination**

Although inoculation against disease has existed historically since as early as 1000 AD in China and India, the most famous Western historical turning point in the history of vaccines was Edward Jenner’s 1796 discovery of using material

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<sup>12</sup> *Health Topics: Vaccines*, THE WORLD HEALTH ORGANIZATION, <http://www.who.int/topics/vaccines/en> (last visited Oct. 3, 2018).

<sup>13</sup> *Understanding How Vaccines Work*, THE CENTERS FOR DISEASE CONTROL AND PREVENTION (July 2018), <https://www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-understand-color-office.pdf>.

<sup>14</sup> *Id.*

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

<sup>16</sup> Susan Scutti, *How countries around the world try to encourage vaccination*, CNN (Jan. 2, 2018), <http://cnn.com/2017/06/06/health/vaccine-uptake-incentives/index.html>.

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

<sup>18</sup> *Id.*

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

from a person infected with cowpox to protect others from smallpox in England.<sup>20</sup> The vaccination quickly traveled from England into Europe and the United States in the early 19th century, leading to medical advancements and wide administration, and 200 years later, total eradication of the disease.<sup>21</sup> The science of vaccines saw a series of medical breakthroughs over the following century, including Louis Pasteur's 1885 rabies vaccine.<sup>22</sup> But it was not until the 20th century that production of vaccines for a wide range of diseases began in earnest.<sup>23</sup>

The first four decades of the 20th century saw the creation and eventual combination of vaccines for diphtheria, tetanus, and pertussis (DTP).<sup>24</sup> Salk's inactivated polio vaccine (IPV), the MMR vaccine in 1971, and the oral polio vaccine (OPV) were the great mid-century successes.<sup>25</sup> And in the 1980s and 1990s, there was the creation of new vaccines for chicken pox, the rotavirus, hepatitis A, and pneumococcal pneumonia.<sup>26</sup> The OPV was eventually discontinued for use in the United States in 2000 after wild poliovirus was declared eradicated in the Americas, leaving IPV the sole recommended polio vaccine in the United States and Europe.<sup>27</sup>

### **C. What are Polio and Measles?**

#### **1. Polio**

Polio, which is short for poliomyelitis, is spread by the poliovirus and primarily affects young children.<sup>28</sup> This highly infectious disease is spread mainly by way of the fecal-oral route, and includes symptoms of fever, fatigue, vomiting, stiffness of the neck and limbs, and can potentially cause total paralysis in a matter of hours.<sup>29</sup> In fact, one in every two-hundred polio infections leads to permanent paralysis, and 5-10% of those patients die when breathing muscles become

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<sup>20</sup> Paul A. Offit ed., *Vaccine History: Developments by Year*, The College of Physicians of Philadelphia, <https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year>, (last updated Nov. 19, 2014).

<sup>21</sup> *The History of Vaccines: An Educational Resource*, THE COLLEGE OF PHYSICIANS OF PHILADELPHIA, <https://www.historyofvaccines.org/timeline#>

EVT\_58 (last visited Oct. 3, 2018).

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

<sup>23</sup> See Offit, *supra* note 20.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

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

<sup>27</sup> See Offit, *supra* note 20; see also *Poliomyelitis: Recommended vaccinations*, EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, <https://vaccine-schedule.ecdc.europa.eu/Scheduler> (last visited Oct. 5, 2018) [hereinafter *Poliomyelitis: Recommended vaccinations*].

<sup>28</sup> *Health Topics: Poliomyelitis (polio)*, WORLD HEALTH ORGANIZATION, [www.who.int/topics/poliomyelitis/en/](http://www.who.int/topics/poliomyelitis/en/) (last visited Oct. 5, 2018).

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

paralyzed.<sup>30</sup> One of the most famous polio patients was President Franklin Roosevelt, who created the March of Dimes that publicized and partly funded Jonas Salk's research.<sup>31</sup> Continued efforts to eradicate polio have increased since the introduction of the first polio vaccine, including the launch of the Global Polio Eradication Initiative in 1988 (which contributed to over a 99% decrease in polio cases), the official eradication of poliovirus type 2 in 1999, and the near eradication of type 3 since 2012.<sup>32</sup> Because there is currently no cure for polio, prevention through vaccination is the only way to control its spread.<sup>33</sup> In very rare and specific conditions within under-immunized populations, the weakened virus originally contained in OPV can mutate and cause people to contract circulating vaccine-derived poliovirus.<sup>34</sup> However, since the discontinuance of OPV in the United States and Europe and an issuance of a phase-out plan in developing countries, incidence of this genetically altered form of the disease is increasingly rare.<sup>35</sup>

## 2. Measles

Measles is a highly contagious viral disease that primarily affects young children and is easily preventable by a full course of the MMR vaccine.<sup>36</sup> The disease is transmitted via droplets from the nose, mouth, or throat of an infected person and typically includes symptoms of high fever, bloodshot eyes, white spots inside the mouth, and a gradually spreading rash that begins to show 10 to 12 days after the initial infection.<sup>37</sup> Before the advent and widespread administration of the MMR vaccine, there were an estimated 3.5 million cases of measles in the United States each year.<sup>38</sup> However, by the mid-1980s that estimate had dropped to fewer than 4,000 cases per year.<sup>39</sup> Because of the efficacy and simple administration of the vaccine, the WHO is on track to eliminate measles and rubella by 2020.<sup>40</sup>

Despite this, the measles vaccine is the focal point of the most recent anti-vaccination movement because of concerns over an alleged connection between thimerosal, a mercury-based preservative previously used in the MMR vaccine, and autism spectrum disorder.<sup>41</sup> The CDC has conducted multiple studies since the

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<sup>30</sup> *Fact Sheet: Poliomyelitis*, WORLD HEALTH ORGANIZATION (July 22, 2019), [www.who.int/en/news-room/fact-sheets/detail/poliomyelitis](http://www.who.int/en/news-room/fact-sheets/detail/poliomyelitis).

<sup>31</sup> *See Polio: Timeline*, *supra* note 3.

<sup>32</sup> *See Fact Sheet: Poliomyelitis*, *supra* note 30.

<sup>33</sup> *Id.*

<sup>34</sup> *What is Vaccine-derived Polio?* World Health Organization, <https://www.who.int/features/qa/64/en/> (April 2017).

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

<sup>36</sup> *Measles*, WORLD HEALTH ORGANIZATION, <http://www.who.int/immunization/diseases/measles/en> (last visited Oct. 4, 2018).

<sup>37</sup> *Id.*

<sup>38</sup> *See Ross*, *supra* note 5.

<sup>39</sup> *Id.*

<sup>40</sup> *See Measles*, *supra* note 36.

<sup>41</sup> *See Ross*, *supra* note 5.

original, and now discredited, paper by Andrew Wakefield published in 1998, and has found no causal connection between thimerosal and autism spectrum disorder.<sup>42</sup> Furthermore, it has been determined that the MMR vaccine is safe and highly effective for disease prevention.<sup>43</sup> Governments are making efforts to mitigate the consequences, but recent upticks in outbreaks since the one from Disneyland in 2014 and the increasing numbers of cases in Western Europe, are at least partially due to parents' trepidation against vaccinating their children on schedule or at all.<sup>44</sup>

### III. ANALYSIS

#### A. Mandatory Vaccination in the United States

##### 1. Law and Policy

In the United States, vaccine schedules and requirements are governed by the laws of individual states.<sup>45</sup> The federal government, through the CDC, makes policy recommendations, but the ultimate decisions on implementation are left up to the states.<sup>46</sup> As of 2018, every state requires that children receive a series of specific vaccines in a specific order ("vaccine schedule") to attend public schools.<sup>47</sup> Every state also has some sort of exemption policy.<sup>48</sup> All 50 states allow exemptions for medical reasons, 47 states allow for religious exemptions, and 17 states allow for exemptions on the basis of personal philosophies of medicine.<sup>49</sup> As of the writing of this article, California, Mississippi, West Virginia, Maine, and New York are the only states that do not allow for religious or philosophical exemptions to their vaccine schedules.<sup>50</sup>

Vaccine schedules in the United States have evolved through case law and statutes since the early 20th century. One of the earliest examples of vaccination litigation was in 1905 with the Supreme Court case *Jacobson v. Massachusetts*.<sup>51</sup> There, a man contested a Massachusetts law which provided that:

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<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> See Scutti, *supra* note 16.

<sup>45</sup> Kristine Goodwin et al., *Calling the Shots*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Feb. 1, 2015), <http://www.ncsl.org/bookstore/state-legislatures-magazine/trends-february-2015.aspx>.

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

<sup>47</sup> *Id.*

<sup>48</sup> *State Vaccination Exemptions map*, NATIONAL VACCINE INFORMATION CENTER, [https://www.nvic.org/CMSTemplates/NVIC/pdf/state-vaccine-exemptions\\_blue.pdf](https://www.nvic.org/CMSTemplates/NVIC/pdf/state-vaccine-exemptions_blue.pdf) (last visited Oct. 4, 2018).

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

the board of health of a city or town, if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit \$5. An exception is made in favor of 'children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination.'<sup>52</sup>

In 1902, the town of Cambridge, Massachusetts passed a requirement that "all the inhabitants habitants of the city who have not been successfully vaccinated since March 1, 1897, be vaccinated or revaccinated."<sup>53</sup> Defendant Jacobson refused to vaccinate himself or his family because, in his opinion, vaccination "'quite often' caused serious and permanent injury to the health . . . 'occasionally' resulted in death; that it was 'impossible' to tell 'in any particular case' what the results of vaccination would be."<sup>54</sup> He felt that Massachusetts had overstepped its power in requiring all people to be vaccinated and felt that his misgivings, rooted in medical concerns, should allow him to opt out of the vaccination program.<sup>55</sup>

Ultimately, the Supreme Court disagreed and laid down a decision that empowered states and municipalities to create the vaccine schedules with which we are familiar today.<sup>56</sup> It upheld the law in question and stated that sometimes individual rights must be subordinated to the common good, which in this case was herd immunity to smallpox.<sup>57</sup> The Court held that Massachusetts had the power to enact this legislation under its state police power and that delegating authority to the cities was a reasonable means of furthering the state's interest in protection against potential smallpox outbreaks.<sup>58</sup> It also held that the law was not "unreasonable, arbitrary, and oppressive," and citizens did not have a Fourteenth Amendment right to refuse to be vaccinated under this law because the built-in exemption for medical reasons was a sufficient safeguard against unreasonable interference, as well as the fact that the law fined, but did not forcibly vaccinate, those who refused to comply.<sup>59</sup>

*Jacobson* was decided over a hundred years ago, before the rational basis, intermediate scrutiny, or strict scrutiny frameworks were solidified ways to analyze due process questions. Currently, legal scholars disagree on how to properly categorize the Court's analysis into modern terms: some argue that the Court's deferential standard of reasonableness and focus on legitimacy of the state's

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<sup>52</sup> *Id.* at 12.

<sup>53</sup> *Id.* at 13.

<sup>54</sup> *Id.* at 36.

<sup>55</sup> *Id.*

<sup>56</sup> *Jacobson*, 197 U.S. at 38.

<sup>57</sup> *Id.* at 37-38.

<sup>58</sup> *Id.* at 38.

<sup>59</sup> *Id.* at 38-39.



purpose and not the means makes this a precursor to the rational basis test.<sup>60</sup> Others analyze the Court's standard of review as intermediate scrutiny based on its analysis of whether the regulation was reasonable "as the safety of the general public may demand" and its warnings about governmental abuse.<sup>61</sup> But ultimately, the Court found a liberty of public health, and that finding reflects the basic utilitarian theory of maximizing the greatest good for the greatest number of people.<sup>62</sup> The net "good" of allowing Massachusetts and Cambridge to exercise police power and require citizens to be vaccinated was herd immunity against smallpox.<sup>63</sup>

And so, *Jacobson* is rightly analyzed as the first legal victory for compulsory vaccination proponents, but it is also one of the early examples of an antivaccination movement in the United States.<sup>64</sup> It encapsulates the core themes that have followed the vaccination debate for over a century: healthcare autonomy, concerns over medical efficacy, and the delicate balance between individual liberty and the public good.<sup>65</sup> And although the medical landscape has developed significantly since *Jacobson*, it has been affirmed by subsequent court cases and remains relevant in the development of vaccination laws to this day.<sup>66</sup>

The next major vaccine litigation was *Zucht v. King*.<sup>67</sup> There, the Supreme Court denied a due process and equal protection challenge to a San Antonio, Texas city ordinance holding that children could not attend public school without first presenting a certificate of vaccination.<sup>68</sup> The Court rejected plaintiff Zucht's due process claims and upheld the law by citing *Jacobson* and utilizing its public health analysis.<sup>69</sup> The Court also rejected Zucht's equal protection claim based on precedent that "in the exercise of the police power reasonable classification may be freely applied, and that regulation is not violative of the equal protection merely because it is not all-embracing."<sup>70</sup> The Court found that the equal protection question raised was not about the ordinance's validity or the authority of city officials to enforce it and was not relevant to the Court's particular analysis.<sup>71</sup> *Zucht* upheld the precedent of giving rights to states and municipalities in enforcing their

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<sup>60</sup> Dorit Rubinstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 BUFF. L. REV. 881, 897 (2015).

<sup>61</sup> Michael H. Shapiro, *Updating Constitutional Doctrine: An Extended Response to the Critique of Compulsory Vaccination*, 12 YALE J. HEALTH POL'Y L. & ETHICS 87, 103 (2012).

<sup>62</sup> Julie Driver, *The History of Utilitarianism*, THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Sep. 22, 2014), <https://plato.stanford.edu/archives/win2014/entries/utilitarianism-history/>.

<sup>63</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

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

<sup>65</sup> Rubinstein Reiss, *supra* note 60.

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

<sup>67</sup> *Zucht v. King*, 260 U.S. 174 (1922).

<sup>68</sup> *Id.* at 177.

<sup>69</sup> *Id.* at 175-76.

<sup>70</sup> *Id.* at 176-77.

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

police power to exclude unvaccinated children from attending public schools, which remains the primary enforcement technique for vaccination schedules to this day.<sup>72</sup>

Decades passed before meaningful vaccine litigation made its way through the court system again. In 1974, the case *Reyes v. Wyeth Laboratories* reached the Fifth Circuit Court of Appeals and signaled a shift in the national vaccine conversation.<sup>73</sup> In particular, it focused on the dichotomy of granting power to the government in requiring vaccinations in comparison to the potential consequences individuals may be subject to when receiving those vaccines.<sup>74</sup> *Reyes* was a products liability case brought by plaintiffs in Texas whose infant child had been diagnosed with paralytic poliomyelitis two weeks after receiving the OPV manufactured by defendant Wyeth Laboratories.<sup>75</sup> The parents alleged they had not been adequately informed of the potential dangerous side effects of this vaccine included in the Texas vaccination schedule.<sup>76</sup> The Fifth Circuit ruled that where Wyeth Laboratories marketed a polio vaccine that was “unavoidably unsafe,” without warning parents of the dangers, it was liable for the consequences of its failure to warn.<sup>77</sup> It was determined to be a breach of the manufacturer’s duty to warn when marketing a vaccine made “defective” on the basis of its inherently dangerous nature.<sup>78</sup>

Although on its face *Reyes* was a products liability case, the court necessarily took public health policy into consideration in its opinion, highlighting the need to balance the greater utilitarian good of widespread immunization with the individual rights to be compensated for injuries under the relatively new doctrine of informed consent.<sup>79</sup> The Fifth Circuit responded to policy arguments it saw as cutting across the law: the fact that polio vaccination was mandatory in Texas did not make requiring warnings futile, as the overall requirement did not create a zero sum game in the face of informed consent because an alternative vaccine was available for polio at the time.<sup>80</sup> This policy consideration grounded the products liability case in the world of public health and laid the foundation for future vaccine injury cases to do the same.<sup>81</sup>

Around the time of the *Reyes* decision, a controversy erupted not unlike the current one over MMR and autism, about whether components in the whooping

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<sup>72</sup> *Zucht*, 260 U.S. at 176; Kristine Goodwin, *Calling the Shots*, National Conference of State Legislatures (Feb. 1, 2015), <http://www.ncsl.org/bookstore/state-legislatures-magazine/trends-gebruary-2015.aspx>.

<sup>73</sup> *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1269 (1974).

<sup>74</sup> *Id.* at 1294.

<sup>75</sup> *Id.* at 1269-70.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.* at 1275, 1294-95.

<sup>78</sup> *Wyeth Laboratories*, 498 F.2d at 1277-78.

<sup>79</sup> *Id.* at 1293-95.

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

<sup>81</sup> *Id.* at 1297.

cough vaccine caused, in rare cases, permanent brain injury.<sup>82</sup> A causal connection was not found, and claims were quickly debunked by scientists and medical professionals.<sup>83</sup> However, the subsequent increase in vaccine liability litigation began hurting manufacturers to the point that the government needed to step in to insulate the industry and ensure the continued production of reasonably priced vaccines.<sup>84</sup> In 1986, President Ronald Reagan signed into law the National Childhood Vaccine Injury Act, establishing a federal no-fault system to compensate people—not just children—injured by mandatory vaccines.<sup>85</sup> The National Vaccine Injury Compensation Program in the Department of Health and Human Services holds the trust from which the relatively rare legitimate injury claims are compensated,<sup>86</sup> based on strict timelines and requirements from a Vaccine Injury Table embedded in the Act.<sup>87</sup>

By establishing this program, the federal government admitted that vaccines, like any medical procedure, are potentially dangerous, while simultaneously proving its unwillingness to back down from mandatory vaccination programs. In light of public concerns and increasing litigation, the federal government chose to protect the power of each state to follow the CDC recommendations and continue to set required vaccine schedules by protecting the ability of manufacturers to create and sell vaccines on the scale required to accommodate widespread immunization.<sup>88</sup>

Vaccine courts are careful in their consideration of each vaccine injury claim, having dismissed two-thirds of the more than 16,000 petitions adjudicated as of 2017.<sup>89</sup> Various cases have been appealed and shown the importance of strictly following the injury table to establish a claim. If a symptom does not appear there or does not present in the determined timeframe, there will be no legitimate cause of action for recovery.<sup>90</sup> Courts have never compensated a petitioner alleging that

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<sup>82</sup> Joan Beck, *How a Media Scare on Vaccine Started a 'Near-Epidemic,'* CHICAGO TRIBUNE (Mar. 26, 1990), <http://www.chicagotribune.com/news/ct-xpm-1990-03-26-9001250062-story.html>.

<sup>83</sup> *Id.*

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

<sup>85</sup> 42 U.S.C. § 300aa-10, 34 (2016).

<sup>86</sup> Meredith Wadman, *Vaccines on trial: U.S. court separates fact from fiction,* SCIENCE, (Apr. 27, 2017, 1:15 PM.), <http://sciencemag.org/news/2017/04/vaccines-trial-us-court-separates-fact-fiction>.

<sup>87</sup> 42 U.S.C. § 300aa-14(a).

<sup>88</sup> See Miles Coleman, *An Overview of the National Childhood Vaccine Injury Act,* 21- S.C. L. 40, 42 (2010).

<sup>89</sup> Wadman, *supra* note 86.

<sup>90</sup> See *Hines v. Sec'y of Dep't of Health and Human Servs.*, 940 F.2d 1518 (Fed Cir. 1991) (affirming that plaintiff was unable to prove by preponderance of evidence that child's hearing loss was caused by MMR vaccine because the symptoms and their timing did not meet standards in the Vaccine Injury Table).

a vaccine caused autism, and furthermore, no plaintiff has successfully appealed from those denials.<sup>91</sup>

Torts and compensation may have taken center stage in the fight over the legal and medical legitimacy of vaccines, but the foundation remains over in what circumstances—if any—the state has power to mandate medical treatment. Over a century after *Jacobson* and *Zucht* upheld the power of states to enforce mandatory vaccination schedules, the Second Circuit decided *Phillips v. City of New York*, where plaintiffs, comprised of parents of unvaccinated children, challenged the constitutionality of the State of New York’s requirement that children must be fully vaccinated to attend public school.<sup>92</sup> The parents had been granted an exemption under the religious exemption policy embedded in the statute.<sup>93</sup> But when their children were excluded from school during a chicken pox outbreak, they brought a claim primarily alleging that the statute violated their substantive due process rights to act as parents without state intervention. In addition, they brought a claim based upon the Free Exercise Clause of the First Amendment, and Equal Protection.<sup>94</sup> The Second Circuit upheld the statute based on the precedent first set in *Jacobson* that adopting vaccine regulations is a constitutionally permissible exercise of a state’s police power, and upheld additional precedent that free exercise of religion does not include “liberty to expose the community or the child to communicable diseases.”<sup>95</sup>

## 2. Effects

This evolving case law and legislation over vaccine requirements continues to mostly ignore one major issue: the lack of uniformity across states.<sup>96</sup> The courts have upheld the policy power to impose and enforce vaccine laws, but there is no centralized framework beyond the CDC’s recommendations incentivizing states to find common ground and establish real consistency.<sup>97</sup> For example, in 2014, the CDC recommended that children receive 69 doses of 16

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<sup>91</sup> See *Hazelhurst v. Sec’y of Dep’t of Health and Human Servs.*, 604 F.3d 1343 (Fed. Cir. 2010) (affirming denial of NCVIA compensation for parents who alleged their son’s regressive autism was caused by MMR vaccine); *Milik v. Sec’y of Health and Human Servs.*, 822 F.3d 1367 (Fed. Cir. 2016) (affirming denial of NCVIA compensation for parents who alleged that child’s neurological conditions were caused by the MMR vaccine).

<sup>92</sup> *Phillips v. City of New York*, 775 F.3d 538, 540 (2d Cir. 2015).

<sup>93</sup> *Id.* at 540-41.

<sup>94</sup> *Id.* at 540.

<sup>95</sup> *Id.* at 541-43 (quoting *Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944), upholding the government’s broad authority to regulate the treatment of children).

<sup>96</sup> James M. Breslow, *What Are the Vaccine Exemption Laws in Your State?*, FRONTLINE (Mar. 24, 2015), <http://www.pbs.org/wgbh/frontline/article/what-are-the-vaccine-exemption-laws-in-your-state/>.

<sup>97</sup> *Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, United States, 2018*, CDC, <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html> (last visited Nov. 9, 2018).

vaccines between birth and turning 18 years old, but most states only mandated that to be eligible to attend public school children must get 29 doses of 9 vaccines.<sup>98</sup>

Medicine has come a long way since 1905 and the threats posed by infectious diseases today are nothing like the constant imminent threat once posed by smallpox.<sup>99</sup> Upholding modern laws based on modern medical science using the precedent set a hundred years ago requires reconsideration of the way we talk about vaccines and the law.<sup>100</sup> For instance, when states choose whether they will allow religious and/or personal philosophy exemptions, how will they enforce those policies?<sup>101</sup> And if a state chooses to only allow medical exemptions, what is the burden of proof to decide eligibility?<sup>102</sup> Finally, how does the government balance its power (or even duty) to protect children with the fundamental right of parents to raise their children as they see fit, when an exemption policy could potentially put the children of pro- and anti-vaccination parents at risk? Many of these concerns are shared with European Union countries as they struggle with similar anti-vaccination movements and the need to respond to the ever-changing scientific landscape.

## **B. Mandatory Vaccination in the European Union**

### 1. Law and Policy

The European Union, an economic and political union of 28 European countries led by an executive arm called the European Commission, has a central public health authority called the European Centre for Disease Prevention and Control (ECDC), which establishes the European vaccination schedules and recommends them to its member countries accordingly.<sup>103</sup> Each country has the choice to set its own schedule and requirements based on those recommendations.<sup>104</sup> This means that there is little uniformity across Europe in vaccinations and disease control, similar to the struggle between jurisdictions in the United States.<sup>105</sup> However, in December 2018, the ECDC and the European Commission proposed a

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<sup>98</sup> *Vaccine Requirements vs. Federal Vaccine Recommendations*, NATIONAL VACCINE INFORMATION CENTER, <https://www.nvic.org/vaccine-laws/federal-recommendations-vs-state-vaccine-laws.aspx> (last visited Nov. 8, 2018).

<sup>99</sup> See Paul Offit, ed., *Vaccine History: Developments by Year*, CHILDREN'S HOSPITAL OF PHILADELPHIA, <https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year> (last updated Nov. 19, 2014).

<sup>100</sup> Shapiro, *supra* note 61.

<sup>101</sup> Isha Ann Emhoff et al., *Is There a Moral Right to Nonmedical Vaccine Exemption?*, 42 AM. J.L. & MED. 598, 606-09 (2016).

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

<sup>103</sup> *Immunisation and vaccines*, EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, <https://ecdc.europa.eu/en/immunisation-and-vaccines> (last visited Nov. 9, 2018).

<sup>104</sup> *Vaccination: Overview*, EUROPEAN COMMISSION, [https://ec.europa.eu/health/vaccination/overview\\_en](https://ec.europa.eu/health/vaccination/overview_en) (last visited Nov. 10, 2018).

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

Council Recommendation, designed to strengthen European vaccine policy.<sup>106</sup> The Commission's goals include addressing vaccine hesitancy, supporting and protecting healthcare workers combatting outbreaks, reinforcing health infrastructure across borders and especially in vulnerable communities, and aggressively supporting vaccination research and an efficient supply chain.<sup>107</sup> It did not recommend imposing a uniform law, but encouraged European countries to follow the ECDC's recommendations closely and encouraged uniformity without mandating it.<sup>108</sup>

The European Court of Justice (ECJ), the highest court in the European Union, only hears intellectual property and products liability cases when it comes to vaccine litigation. A recently decided case by this court, *W v. Sanofi Pasteur MSD SNC*, had far-reaching implications for vaccine litigation and regulation within Europe.<sup>109</sup> In *Sanofi Pasteur*, a French man and his family brought suit alleging that his multiple sclerosis was caused by the hepatitis B vaccination manufactured by the Sanofi Pasteur pharmaceutical company.<sup>110</sup> The family demanded compensation for the damage they suffered and claimed that the period between administration of the vaccine and the onset of his symptoms in conjugation with family history suggesting no predisposition to the disease was indicative of defendant's fault.<sup>111</sup>

The European Union legislation governing products liability is Article 4 of Directive 84/374, and it provides that "the injured person shall be required to prove the damage, the defect, and the causal relationship between the defect and the damage."<sup>112</sup> Deliberating over this Directive, the ECJ raised its concerns over the power dynamic between individuals and large corporations like Sanofi-Pasteur.<sup>113</sup> The court ultimately interpreted Article 4 to mean that "where medical research neither establishes nor rules out the existence of a link . . . the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim will always be considered to be established when certain predetermined causation-related factual evidence is presented."<sup>114</sup> The decision shifted a large part of the burden off of the individual plaintiff to find and prove scientific evidence that may not be widely accessible and could be impossible to replicate and on to the manufacturers to prove unequivocally the vaccines' safety before disseminating to

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

<sup>107</sup> *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Strengthened Cooperation against Vaccine Preventable Diseases*, at 2, COM (2018) 245 final (Apr. 26, 2018).

<sup>108</sup> *Id.*

<sup>109</sup> Case C-621/15 *W v. Sanofi Pasteur MSD SNC*, 2017 E.C.R. 484.

<sup>110</sup> *Id.*

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

<sup>112</sup> Council Directive 85/374/EEC, art. 4, 1985 OJ (L 210) 29.

<sup>113</sup> Case C-621/15 *W v. Sanofi Pasteur MSD SNC*, 2017 E.C.R. 484.

<sup>114</sup> *Id.*

the public.<sup>115</sup> Such a choice to hold pharmaceutical companies accountable and focus on that inherent power disparity is not unreasonable or unfair.<sup>116</sup> However, it does create implications for a future where vaccine litigation is not based on science or medical evidence, but on the kind of circumstantial causation analysis that led to the whooping cough vaccine scare in the 1980s.<sup>117</sup> Of course, there is no guarantee that plaintiffs like W will win every time with any vague chain of causation they can come up with, because there is a “preponderance of the evidence” standard.<sup>118</sup> But a precedent now exists in the highest European court that can feed anti-vaccination sentiments without a constructive framework in place to protect the larger public health needs from individual rare side effects or claims purely on misinformation.<sup>119</sup>

## 2. Effects

The fundamental lack of consistency in vaccination policies across Europe allows for some wildly opposing public health requirements. Some, like Sweden and the other Nordic countries, do not require their citizens to receive any vaccinations.<sup>120</sup> Those countries may recommend that certain vaccines be administered at certain points in a child’s life, but do not require them, and have no legal repercussions for parents who choose not to vaccinate their children.<sup>121</sup> A few countries, primarily in Western Europe, require some vaccines while merely recommending others.<sup>122</sup> And others, including Slovenia and other Central and Eastern European countries, strictly require vaccines to be administered on certain schedules, while only allowing for medical exemptions under specific circumstances.<sup>123</sup>

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<sup>115</sup> *ECJ Lowers Evidence Standard in Vaccine Liability Case*, VAN BAEL & BELLIS (June 26, 2017), <https://www.vbb.com/insights/corporate-commercial/corporate-commercial/ecj-lowers-evidence-standard-in-vaccine-liability-case>.

<sup>116</sup> Gretchen Vogel, *Decision by Europe’s top court alarms vaccine experts*, SCIENCE (June 27, 2017), <https://www.sciencemag.org/news/2017/06/decision-europe-s-top-court-alarms-vaccine-experts>.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Poliomyelitis: Recommended vaccinations*, *supra* note 27; *Vaccine Scheduler, Measles: Recommended vaccinations*, European Centre for Disease Prevention and Control, <https://vaccine-schedule.ecdc.europa.eu/Scheduler>

[/ByDisease?SelectedDiseaseId=8&SelectedCountryIdByDisease=-1](#) (last visited Nov. 9, 2018) [hereinafter *Measles: Recommended vaccinations*].

<sup>121</sup> *Vaccination Programmes*, THE PUBLIC HEALTH AGENCY OF SWEDEN, <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/vaccination-programmes/> (last visited Jan. 3, 2018).

<sup>122</sup> *Poliomyelitis: Recommended vaccinations*, *supra* note 27; *Measles: Recommended vaccinations*, *supra* note 120.

<sup>123</sup> *Poliomyelitis: Recommended vaccinations*, *supra* note 27; *Measles: Recommended vaccinations*, *supra* note 120.

However, decisions like *Sanofi Pasteur* may place a wrench in the Commission's plans for stronger vaccine policy because it opens the litigation and legislation up to non-scientific opposition.<sup>124</sup> Furthermore, individual countries' laws could be undermined if citizens are permitted to sue governments and vaccine manufacturers for alleged injuries without medical proof.<sup>125</sup> Many fear additional measles outbreaks if immunization rates remain as low as they currently are across Europe, especially in light of the anti-vaccination movement continuing to gain steam.<sup>126</sup> That is not to say that European vaccination rates are as low as they are in developing countries around the world, but for a collection of wealthy nations connected by economic and political ties, the numbers are lower than they should be.<sup>127</sup> According to data compiled by the WHO and UNICEF, in 2017 there were zero reported cases of polio and 24,356 reported cases of measles in the European Region.<sup>128</sup> Moreover, an estimated 71% of the target polio population received the appropriate vaccination, and 95% and 90% of the target population received the first two measles vaccines respectively.<sup>129</sup>

Slovenia and Sweden represent the two ends of the vaccine regulation spectrum and understanding the legal and social constructs behind these programs is important to analyze how they can find common ground and increase overall vaccination rates in the European Union. Understanding how the individual countries work with the whole will provide a comparison point to consider what the United States can learn for the creation of its own uniform vaccination standard.

## **C. Mandatory Vaccination in the Republic of Slovenia**

### **1. Law and Policy**

The Republic of Slovenia, a small nation in central Europe that gained its independence from the former Yugoslavia and ratified its constitution in 1991, has an aggressive vaccination policy.<sup>130</sup> The government requires that every child be

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<sup>124</sup> *See Pasteur*, *supra* note 113.

<sup>125</sup> Laurie Garrett, *Science Won't Save Vaccines From Lawsuits Anymore*, FOREIGN POLICY (June 26, 2017 12:56 P.M.), <https://foreignpolicy.com/2017/06/26/science-wont-save-vaccines-from-lawsuits-anymore/>.

<sup>126</sup> *Id.*

<sup>127</sup> Samantha Vanderslott, *Despite scepticism, Europe has high vaccination rates – but it shouldn't be complacent*, THE CONVERSATION (Apr. 24, 2017 11:12 A.M.), <http://theconversation.com/despite-scepticism-europe-has-high-vaccination-rates-but-it-shouldnt-be-complacent-75169>.

<sup>128</sup> *Global and regional immunization profile: European Region*, (July 29, 2019), THE WORLD HEALTH ORGANIZATION [http://www.who.int/immunization/monitoring\\_surveillance/data/g\\_s\\_eurprofile.pdf?ua=1](http://www.who.int/immunization/monitoring_surveillance/data/g_s_eurprofile.pdf?ua=1).

<sup>129</sup> *Id.*

<sup>130</sup> *Slovenia: Overview*, THE EUROPEAN UNION, [https://europa.eu/european-union/about-eu/countries/member-countries/slovenia\\_en](https://europa.eu/european-union/about-eu/countries/member-countries/slovenia_en) (last visited Jan. 3, 2018).



administered the vaccine for nine childhood diseases.<sup>131</sup> The polio vaccine must be administered by the time a child is three-months old and the MMR vaccine by the time a child is 18 months old.<sup>132</sup> All of the required vaccines are provided and in the case of vaccine injuries, the government employs a generous no-fault compensation system for victims.<sup>133</sup> The punishment for failure to comply with the mandate is a fine.<sup>134</sup> As of 2017, the compliance rates for polio and measles topped 94% and 93%, respectively.<sup>135</sup> Parents can request their child be exempt from vaccination for medical reasons, but not for personal philosophy or religious reasons.<sup>136</sup> To receive a medical exemption from vaccination, an application must be filed with the Ministry of Health by a physician, the recipient, or the recipient's parents and the Ministry must make a decision within 90 days.<sup>137</sup> The government mandates the vaccine schedule and holds itself as the ultimate gatekeeper for the exemption process, although the opinions of physicians and vaccine recipients are the primary source of evidence.<sup>138</sup>

The Slovenian government, through its National Institute for Public Health (NIJZ) and Institute of Public Health Center for Communicable Diseases, derives its authority to enforce these policies from the country's constitution.<sup>139</sup> Article 51 of the constitution, in the list of human rights and fundamental freedoms, enumerates a fundamental right to health care "under conditions provided by law," which allows the state to provide health care from public funds, and gives the government power to compel citizens to undergo medical treatment only "in cases

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<sup>131</sup> Vaccine Scheduler, *Slovenia: Recommended Vaccinations*, EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, <https://vaccine-schedule.ecdc.europa.eu/Scheduler/ByCountry?SelectedCountryId=188&IncludeChildAgeGroup=true&IncludeChildAgeGroup=false&IncludeAdultAgeGroup=false> (last visited Jan. 4, 2018).

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

<sup>133</sup> Erin Walkinshaw, *Mandatory vaccinations: The international landscape*, 183 CAN. MED. ASS'N J. E1167 (2011).

<sup>134</sup> *Id.*

<sup>135</sup> *Polio Vaccine*, The World Health Organization Immunization Monitoring, [http://apps.who.int/immunization\\_monitoring/globalsummary/timeseries/tscoverageipv1.html](http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tscoverageipv1.html) (last visited Jan. 4, 2018); *Measles-containing Vaccine*, The World Health Organization Immunization Monitoring, [http://apps.who.int/immunization\\_monitoring/globalsummary/timeseries/tscoveragemcv1.html](http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tscoveragemcv1.html) (last visited Jan. 4, 2018).

<sup>136</sup> Walkinshaw, *supra* note 133.

<sup>137</sup> *Slovenia Vaccination Policy*, EUROPEAN FORUM FOR VACCINE VIGILANCE, <https://www.efvv.eu/slovenia-2/> (last visited Jan. 1, 2018).

<sup>138</sup> *Id.*

<sup>139</sup> Constitution of Slovenia, Official Gazette of the Republic of Slovenia Nos. 33/91-I, 42/97, 66/2000, 24/03, 69/04, 68/06, and 47/13; *European and World Immunization Week 2018 in Slovenia: vaccination is the right of the individual and responsibility of everyone*, THE WORLD HEALTH ORGANIZATION EUROPE (May 15, 2018), <http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/news/news/2018/5/european-and-world-immunization-week-2018-in-slovenia-vaccination-is-the-right-of-the-individual-and-responsibility-of-everyone>.

provided by law.”<sup>140</sup> The vaccination mandates are just such law to compel its citizens to receive medical treatment within the bounds of its own legal framework.<sup>141</sup> Slovenia employs a similar utilitarian public health framework to the United States, favoring the greater community public health good and creating a system to accommodate the consequences.

However, unlike the United States, Slovenia has a legal system of civil law, not common law, and thus any vaccine or vaccine injury litigation is not necessarily binding on future courts or lawmakers setting vaccination standards.<sup>142</sup> Lawmakers draw the authority to create and to enforce these from its constitution and the country’s own precedent of laws, not from case decisions.<sup>143</sup> The country’s national vaccine program is a product of its publicly funded health care system and relatively small population of approximately 2 million.<sup>144</sup> But despite the differences in demographics and legal systems, the United States and Slovenia share an underlying value of herd immunity and dedication towards disease prevention and eradication.<sup>145</sup> Slovenia’s legal system allows it to implement the recommendations of a central group in a way that conforms to its constitution and values, similar to the way that American states implement the CDC’s recommendations.<sup>146</sup>

## 2. Effects

Slovenia’s choice of aggressive vaccine policy contributes, at least in part, to its low rates of any of the nine diseases, and specifically of polio and the measles. Between 2017 and 2018, Slovenia had zero reported cases of polio<sup>147</sup> and only ten reported cases of the measles, resulting in zero deaths.<sup>148</sup>

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<sup>140</sup> Constitution of Slovenia, Official Gazette of the Republic of Slovenia Nos. 33/91-I, 42/97, 66/2000, 24/03, 69/04, 68/06, and 47/13.

<sup>141</sup> *Id.*

<sup>142</sup> Marko Novak, *Ensuring Uniform Case Law in Slovenia: Jurisprudence Constante, Stare Decisis, and a Third Approach*, *STUDIA IURIDICA LUBLINENSIA* vol. XXVII, 1 (2018).

<sup>143</sup> See Constitution of Slovenia, *supra* note 140.

<sup>144</sup> *EU in Figures: Size and population*, The European Union, [https://europa.eu/european-union/about-eu/figures/living\\_en#population](https://europa.eu/european-union/about-eu/figures/living_en#population) (last visited Oct. 13, 2019).

<sup>145</sup> Cynthia Leifer, *Mandatory vaccination will protect all citizens*, *THE PHARMACEUTICAL JOURNAL* (Apr. 2, 2015), <https://www.pharmaceutical-journal.com/opinion/comment/mandatory-vaccination-will-protect-all-citizens/20068190.fullarticle?firstPass=false>.

<sup>146</sup> *Id.*

<sup>147</sup> *WHO Vaccine-Preventable Diseases: Monitoring System*, [http://apps.who.int/immunization\\_monitoring/globalsummary/incidences?c=SVN](http://apps.who.int/immunization_monitoring/globalsummary/incidences?c=SVN) (last visited Oct. 13, 2019).

<sup>148</sup> *Monthly Measles and Rubella Monitoring Report*, EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, Table 1,

The anti-vaccination movement spreading throughout the Western world over the past decade or so has not missed Slovenia.<sup>149</sup> However, in April 2018, the NIJZ hosted the European and World Immunization Week in collaboration with the WHO country office in Slovenia.<sup>150</sup> The event, which was a conference open to medical professionals, public health experts, and journalists, highlighted individual rights to be vaccinated and societal responsibilities to ensure access to those vaccinations, and held discussions about the vaccine situation in Slovenia, emphasizing that vaccination is one of the most effective public health measures to reduce the burden of infectious disease.<sup>151</sup> Public health officials reported that the event was a success in continuing to educate those people who may be wary of vaccines in the current antivaccination climate, especially in major cities where trust in the system is vital.<sup>152</sup> Additionally, those same authorities note that much of the remaining unvaccinated population who dodge the vaccine mandates are nomadic Roma groups.<sup>153</sup>

While Slovenia represents one of the most aggressive vaccine programs, countries like Sweden represent the opposite end of the spectrum.

## **D. Mandatory Vaccinations in the Kingdom of Sweden**

### **1. Law and Policy**

The Kingdom of Sweden, a country in Northern Europe, does not require parents or healthcare professionals to administer any vaccinations to children for any disease.<sup>154</sup> The Swedish government provides a recommended schedule for vaccinations of the same nine childhood diseases that Slovenia mandates, but at a slower pace and with no legal incentive for parents to follow the recommendation.<sup>155</sup> Any parent who does choose to vaccinate their children for

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<https://ecdc.europa.eu/sites/portal/files/documents/measles-rubella-monthly-monitoring-report-december-2018.pdf> (Dec. 2018).

<sup>149</sup> *Dozens Turnout at Rally Against Compulsory Vaccination*, THE SLOVENIA TIMES (May 10, 2015), <http://www.sloveniatimes.com/dozens-turnout-at-rally-against-compulsory-vaccination>.

<sup>150</sup> *European and World Immunization Week 2018 in Slovenia: vaccination is the right of the individual and responsibility of everyone*, THE WORLD HEALTH ORGANIZATION EUROPE (May 15, 2018), <http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/news/news/2018/5/european-and-world-immunization-week-2018-in-slovenia-vaccination-is-the-right-of-the-individual-and-responsibility-of-everyone>.

<sup>151</sup> *Id.*

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

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

<sup>154</sup> *Vaccination Programmes*, The Public Health Agency of Sweden, <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/vaccination-programmes/> (last visited Jan. 3, 2018).

<sup>155</sup> *Id.*

one of the diseases within the Swedish vaccination schedule can do so free of charge through their child's school health services.<sup>156</sup>

Like Slovenia, and unlike the United States, Sweden follows a civil law system, so its constitution and statutes are the main source of law over case law, which is not formally binding on future laws or decisions.<sup>157</sup> The Swedish Constitution does not state its citizens' right to health care explicitly, but it does include a provision that "public institutions shall secure . . . favorable conditions for good health."<sup>158</sup> And it also safeguards the rights of children and includes a provision that the government can interfere with fundamental rights such as expression or assembly for public safety reasons.<sup>159</sup> But the Riksdag, Sweden's central legislative body,<sup>160</sup> voted down in 2017 a proposal that would have paved the way for a mandatory vaccine program.<sup>161</sup> This was because the representatives believed such laws would directly interfere with the freedoms from coercion embedded in their constitution.<sup>162</sup>

And so, the country's vaccine program remains governed, as it has since 2013, by the Swedish Communicable Diseases Act.<sup>163</sup> The Act stipulates that the Public Health Agency of Sweden (PHA) implement the government's regulations and legislation and keep a national vaccination record.<sup>164</sup> The PHA's program includes positive vaccine education to engender trust in the medical science behind vaccines in order to increase rates of vaccination without implementing any legal mandates.<sup>165</sup> Sweden's Medical Products Agency monitors vaccine safety, but Sweden does not currently have any vaccine injury program like many developed countries with mandatory vaccinations have.<sup>166</sup>

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<sup>156</sup> *Id.*

<sup>157</sup> *The Swedish Courts*, Högsta domstolen [the Supreme Court of Sweden], <http://old.domstol.se/Funktioner/English/The-Swedish-courts/The-Supreme-Court/> (last visited Jan. 5, 2019).

<sup>158</sup> REGERINGSFORMEN [RF] [CONSTITUTION] 1:2 (Swed.).

<sup>159</sup> *Id.* at 1:2, 2:20-01, 2:23-04.

<sup>160</sup> *How Sweden is Governed*, GOVERNMENT OFFICES OF SWEDEN, <https://www.government.se/how-sweden-is-governed/> (last visited Oct. 12, 2019).

<sup>161</sup> *The Swedish Parliament voted against all vaccine motions*, NATIONAL HEALTH FEDERATION – SWEDEN (May 10, 2017), <http://www.thenhf.se/riksdagen-rostade-nej-till-alla-vaccinmotioner/>.

<sup>162</sup> *See Id.*

<sup>163</sup> *Responsibility for national programmes*, The Public Health Agency of Sweden, <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/responsibility-for-national-programmes/> (last visited Jan. 3, 2019).

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

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

<sup>166</sup> *Id.*; see also Clare Looker & Heath Kelly, *No-fault compensation following adverse events attributed to vaccination: a review of international programmes*, World Health Organization Bulletin 7 (Mar. 21, 2011), <https://www.who.int/bulletin/10-081901.pdf>.

## 2. Effects

Despite having no legal requirement, vaccination rates in Sweden are quite high.<sup>167</sup> But the recommended schedule for polio and measles includes less doses starting later in a child's life than in Slovenia or most American states.<sup>168</sup> In 2017, there were zero reported cases of polio in Sweden.<sup>169</sup> There were ten reported cases of the measles, resulting in zero deaths.<sup>170</sup> The outbreaks in Western Europe in recent years have not made their way to this Northern European country yet.<sup>171</sup> But the anti-vaccination movement has. Fears over negative side effects coupled with grassroots misinformation caused Sweden's whooping cough vaccination rates to drop in the 1980s and threatens to do so again in the face of the current MMR-autism concerns.<sup>172</sup> As recently as 2017, a childhood vaccination clinic was under local investigation for allegations of providing parents false information to persuade them to delay or altogether abstain from administering the MMR vaccine to their children.<sup>173</sup>

Sweden's choice not to mandate vaccinations shows its legal framework favoring the individual decision-maker over the larger public health outcomes. But their high IPV and MMR rates show that those individuals value the greater good themselves. This may be at least in part because of the PHA's education campaigns to keep public trust in vaccines alive and well.<sup>174</sup> It is not a complete abandonment of utilitarian principles, but for a relatively small country with public funding and national healthcare, Sweden is doing alright balancing its higher value on individual rights with the protection of the greater good at stake in disease prevention.<sup>175</sup> It is not a perfect system, but other countries can learn from their choices and it could certainly learn from others as well.

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<sup>167</sup> EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, *Surveillance Report: Monthly measles and rubella monitoring report*, at 6 fig. 4 (Dec. 2018), <https://ecdc.europa.eu/sites/portal/files/documents/measles-rubella-monthly-monitoring-report-december-2018.pdf>.

<sup>168</sup> *Measles: Recommended vaccinations supra* note 120.

<sup>169</sup> Polio Now, Global Polio Eradication Initiative, <http://polioeradication.org/polio-today/polio-now/> (last visited Jan. 5, 2018).

<sup>170</sup> *Surveillance Report: Monthly measles and rubella monitoring report supra* note 167.

<sup>171</sup> *Anti-vax fear drive a measles outbreak in Europe*, THE ECONOMIST, (Aug. 25, 2018), <https://www.economist.com/europe/2018/08/25/anti-vax-fears-drive-a-measles-outbreak-in-europe/>.

<sup>172</sup> *Six common misconceptions about immunization*, THE WORLD HEALTH ORGANIZATION, [https://www.who.int/vaccine\\_safety/initiative/detection/immunization\\_misconceptions/en/index1.html](https://www.who.int/vaccine_safety/initiative/detection/immunization_misconceptions/en/index1.html) (last visited Jan. 2, 2019).

<sup>173</sup> *Stockholm clinic to be investigated over vaccine advice to parents*, THE LOCAL (May 10, 2017), <https://www.thelocal.se/20170510/stockholm-clinic-to-be-investigated-over-vaccine-advice-to-parents>.

<sup>174</sup> See *The Swedish Parliament voted against all vaccine motions, supra* note 161.

<sup>175</sup> Isha Ann Emhoff et al., *Is There a Moral Right to Nonmedical Vaccine Exemption?*, 42 AM. J.L. & MED. 598, 606-09 (2016).

### III. RECOMMENDATIONS FOR THE UNITED STATES

The United States should implement a national mandatory vaccine program and only offer exemptions for medical reasons.

As of April 2019, measles rates in the United States were at a five-year high.<sup>176</sup> It is the largest number of reported cases nationwide since the 2014 Disneyland outbreak.<sup>177</sup> A growing total of 465 measles cases is exceptionally high for a country where the disease was declared eradicated nearly 20 years previously.<sup>178</sup> Some of the regional outbreaks have been linked to insular religious communities which benefit from religious exemptions, and clustered areas like Clark County, Washington, with historically low vaccination rates.<sup>179</sup>

While New York City declares a public health emergency and schools in the Pacific Northwest deny access to sick or unvaccinated children until the outbreak is contained, the public health and legal communities must also consider the future.<sup>180</sup> If the anti-vaccination movement can bring measles back from the edge of eradication, who is to say that a disease like polio won't be next? One community health organizer in New York described the public mindset about measles as a sort of collective amnesia following an outbreak.<sup>181</sup> If that is at all indicative of the truth, the disturbing reality is that many Americans alive today have never seen polio or lived through a true epidemic and have no concrete understanding of the consequences of a decision not to vaccinate their children.

Anti-vaccination leaders capitalize on that as well as fear and misinformation. The most well-publicized argument from those groups is the overwhelmingly-debunked MMR connection to autism.<sup>182</sup> But it is not uncommon to encounter tactics like explaining the basic vaccination process as injecting poison into a child's body, which this Note has explained is not the case.<sup>183</sup> Or alleging that vaccines are not effective or that diseases like the measles are not as bad as

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<sup>176</sup> Julie Mazziotta, *Measles Cases Hit 5-Year High as New York City Declares a Public Health Emergency*, PEOPLE (Apr. 9, 2019, 4:27 PM), <https://people.com/health/measles-cases-5-year-high-new-york-city-public-health-emergency/>.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> Ken Alltucker, *A Quarter of all Kindergarteners in this County in Washington are not immunized. Now there's a measles crisis*, USA TODAY (Feb. 11, 2019, 8:15 AM), <https://www.usatoday.com/story/news/health/2019/02/11/measles-spread-anti-vaccination-communities-new-york-clar-county-washington/2812667002/> [hereinafter *A Quarter of All Kindergarteners*].

<sup>180</sup> Ken Alltucker, *Do 'the right thing': People who can't get vaccinated during a measles outbreak rely on the healthy*, USA TODAY (Apr. 11, 2019, 11:22 AM), <https://www.usatoday.com/story/news/health/2019/04/11/measles-outbreaks-some-cant-get-vaccinated/3425585002/>.

<sup>181</sup> *Id.*

<sup>182</sup> See Ross, *supra* note 5.

<sup>183</sup> See *id.*

people say and thus the alleged risks of vaccinating outweigh any benefits.<sup>184</sup> But the various successful eradication campaigns of the past century are evidence that vaccines are incredibly effective, and as children contracting measles today can attest, it is just as bad as doctors would lead us to believe.<sup>185</sup> It takes a 95% vaccination rate for a community to achieve herd immunity, but in January 2019, Clark County, Washington only had an estimated 80% of school-aged children with the MMR vaccine.<sup>186</sup> The law is the key to address the underlying issues that have allowed this culture to thrive.

Ultimately, the United States currently suffers from the same problem as the European Union without uniformity of vaccine law (i.e. the health decisions of one jurisdiction cause outbreaks across several others).<sup>187</sup> There is no consistency in what vaccines are required and recommended, or in what exemptions are available and, if so, how to request one.<sup>188</sup> The cost of this problem goes beyond the increased burden on the healthcare systems during an outbreak or in anticipation of them.<sup>189</sup> The cost also comes in the form of death and disablement of the children who may contract one of these diseases.<sup>190</sup>

Mississippi, California, and West Virginia have started a movement that other states should be compelled to follow: requiring the full CDC-approved schedule of childhood vaccines and only offering medically necessary exemptions.<sup>191</sup> The United States has eradicated polio within its borders and until fairly recently, had not seen an outbreak of measles in years.<sup>192</sup> But where vaccination exemptions are allowed for a wide variety of non-medical reasons and are not difficult to obtain, incidence of these vaccine-preventable diseases can and will continue to rise.<sup>193</sup>

Here in the United States, children are required to attend school until they are at least 16, and unless their parents choose to homeschool them, must do so at the public or private schools where their parents send them.<sup>194</sup> In vaccine litigation all the way back to *Jacobson*, there has been a right upheld against subjecting others

<sup>184</sup> See *Stockholm clinic to be investigated*, *supra* note 173.

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

<sup>186</sup> See *A Quarter of All Kindergarteners* *supra* note 179.

<sup>187</sup> Jennifer Zipprich, Kathleen Winter, et al., *Morbidity and Mortality Weekly Report: Measles Outbreak – California, December 2014-February 2015*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Feb. 20, 2015), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a5.htm>.

<sup>188</sup> See Ross, *supra* note 5.

<sup>189</sup> Zipprich, *supra* note 187.

<sup>190</sup> *Id.*

<sup>191</sup> *State Vaccination Exemptions map*, NATIONAL VACCINE INFORMATION CENTER, [https://www.nvic.org/CMSTemplates/NVIC/pdf/state-vaccine-exemptions\\_blue.pdf](https://www.nvic.org/CMSTemplates/NVIC/pdf/state-vaccine-exemptions_blue.pdf) (last visited Oct. 4, 2018).

<sup>192</sup> See Ross, *supra* note 5.

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

<sup>194</sup> See *Table 5.1: Compulsory School Attendance Laws*, NATIONAL CENTER FOR EDUCATION STATISTICS (2017), [https://nces.ed.gov/programs/statereform/tab5\\_1.asp](https://nces.ed.gov/programs/statereform/tab5_1.asp).

to an outbreak of disease.<sup>195</sup> If children are to be required to attend public schools, it is not unreasonable to have that protection extend there, and herd immunity is the best way to ensure that protection. The school system is designed to accommodate those utilitarian values through its power (or even duty) to protect children by making vaccination a requirement to attend school.<sup>196</sup> But the anti-vaccination movement complicates the full use of this power because parents have a fundamental right extending nearly as far back as *Jacobson* to control the upbringing of their children.<sup>197</sup> Thus, it will be important to make clear, as the Supreme Court did in *Phillips v. City of New York* with freedom of religion, that that right does not go so far as to where it may endanger other peoples' children.<sup>198</sup>

Ultimately, the United States needs more aggressive vaccination policies to ensure full and lasting protection against diseases like polio and measles. And the European Union and its member countries Slovenia and Sweden can teach the United States about what and how to implement more aggressive vaccination policies.

From Slovenia, the United States can take the data that mandatory vaccinations lead to high vaccination rates overall and thus less outbreaks.<sup>199</sup> In recent years, despite its location near recent outbreaks in Spain, Germany, and Romania, it has not been effected by them.<sup>200</sup> The United States should mandate that every child who attends school be vaccinated for at least those same nine childhood vaccine-preventable diseases and should model any exemption requests after the Slovenian system. Exemption requests should come only from physicians, recipients, or their parents, and medical evidence must be provided for why the recipient cannot receive that particular vaccine. It should be reviewed by physicians following a standardized approach with no exemptions made for reasons of religion or personal philosophies.<sup>201</sup> Additionally, the required vaccines should be provided free of charge, as they are in Sweden, in order to make sure that no one is left out of the herd because of lack of health insurance or inability to pay.<sup>202</sup> Consequences

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<sup>195</sup> See *Jacobson*, 197 U.S. at 11.

<sup>196</sup> Goodwin, et al., *supra* note 45.

<sup>197</sup> See *Pierce v. Society of the Sisters*, 268 U.S. 510 (1925); *Meyer v. Nebraska*, 262 U.S. 390 (1923).

<sup>198</sup> See *Phillips*, 775 F.3d at 541-43.

<sup>199</sup> *Monthly measles and rubella monitoring report*, EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, Table 1, <https://ecdc.europa.eu/sites/portal/files/documents/measles-rubella-monthly-monitoring-report-december-2018.pdf> (Dec. 2018); *Polio Now*, GLOBAL POLIO ERADICATION INITIATIVE, <http://polioeradication.org/polio-today/polio-now/> (last visited Jan. 5, 2019).

<sup>200</sup> *Anti-vax fear drive a measles outbreak in Europe*, THE ECONOMIST (Aug. 25, 2018), <https://www.economist.com/europe/2018/08/25/anti-vax-fears-drive-a-measles-outbreak-in-europe/>.

<sup>201</sup> See *Monthly Measles*, *supra* note 148.

<sup>202</sup> *Vaccination Programmes*, THE PUBLIC HEALTH AGENCY OF SWEDEN, <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/vaccination-programmes/> (last visited Jan. 3, 2019).



are equally important, and fines have been shown in Slovenia to be an appropriate measure.<sup>203</sup>

From Sweden, the United States can learn about the value of education and information to build the trust necessary to ensure that people are willing to vaccinate their children.<sup>204</sup> For a mandatory vaccination program to be created and to last, having that level of trust is invaluable. The CDC needs to have the opportunity, through funding and local participation, to be aggressive with education campaigns to reduce vaccine stigma and help individuals reach a mindset that values the public health's greater good in the way that Sweden has.

However, the United States is significantly larger than either Sweden or Slovenia, and in practice resembles more closely the European Union and its struggle to implement the uniformity that currently has both entities in a pickle. Major issues that it will have to address include finding funding for these programs within larger health care legislation and finding the appropriate authority to implement it. The United States should synthesize these recommendations into a uniform law that each state will be strongly compelled to adopt. The government has imposed health and safety uniform laws on the states in the past, so this would not be without precedent. For example, in *South Dakota v. Dole*, Congress used its Commerce Clause power to withhold highway funds from South Dakota until it implemented the uniform law making 21 the legal drinking age in all 50 states.<sup>205</sup> And with a successful education campaign about the science behind vaccines and their public health necessity, states and individuals can build a necessary trust and become invested in health. This will then encourage communities to become unified in protecting the herd from disease and be more willing to implement this kind of vaccination program.

#### IV. CONCLUSION

Vaccinations are a hot and controversial topic today, and the conversations surrounding them are a perfect example of how we struggle with maintaining individualism in the face of the need to value a greater public good. As evidenced by the ways that different countries handle vaccine laws, these concepts need not be mutually exclusive of each other. In Sweden, low rates of disease are as much about people valuing the greater good as it is about valuing individual health liberty, and in Slovenia, successfully mandating vaccines stems from a constitutional fundamental right to health and healthcare for every citizen. Americans need not fear losing independence or having medical choices stolen from their hands.

These recommendations for a nationalized vaccination mandate are not about changing the way that Americans make health decisions or imposing the

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<sup>203</sup> *Slovenia Vaccination Policy*, EUROPEAN FORUM FOR VACCINE VIGILANCE, <https://www.efvv.eu/slovenia-2/> (last visited Jan. 1, 2018).

<sup>204</sup> See *Vaccination Programmes*, *h6 supra* note 202.

<sup>205</sup> *South Dakota v. Dole*, 483 U.S. 203, 205 (1987).

government's will on individuals. It is about finding a balance where our already-existing utilitarian framework of health is valued not just by the courts and the government, but by the individual decision-makers who can place their own health in context of the community's and be willing to trust modern medicine and its power to protect them.

