

# COMMENTS

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## Compulsory Vaccinations: Balancing the Equitable Reality of Police Power with Provider Assistance Through an Improved Informed Consent Process

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### INTRODUCTION

Stephen Colbert once quipped,

You have to admit, the amount of vaccinations given to young children increased in the nineties, and the diagnosis of autism rose at the same time—that’s a corollary effect, okay? Also, I mean, it’s the same way that the iPhone is introduced and World War II vets

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start dying out . . . in the same decade! They've got to have something to do with each other!<sup>1</sup>

Colbert's tongue-in-cheek remarks were in response to Dr. Paul Offit,<sup>2</sup> who appeared on *The Colbert Report* to discuss how many parents, influenced by prominent opponents of vaccination, have chosen to forego vaccinating their children. These parents, however, are putting everyone their child comes into contact with at risk. All joking aside, hesitant parents should not be condemned for acting upon legitimate concern for their children when making important healthcare decisions. That being the case, we cannot tolerate misinformation, hence, we should expect transparency from health care providers.

This Comment addresses the constitutionality and viability of compulsory vaccination of adults and children in the United States. Understandably, compulsory vaccinations raise reasonable due process concerns, which must be balanced with the state's interest in providing for the public's health and safety. When challenged, courts have consistently upheld state legislatures' rights to compel vaccination for both adults and children, holding that mandates are a valid exercise of state police power.<sup>3</sup> Additionally, courts have also recognized the government's authority to interfere with parental rights as being grounded not only upon the police power vested in state legislatures, but also upon the doctrine of *parens patriae*.<sup>4</sup> The equitable reality is that people do not have absolute bodily autonomy.

Opponents of vaccination gained ground in the way of medical and religious exemptions to the mandates of public school districts. Further, some states also allow for philosophical exemptions to vaccine requirements. However, many opponents of vaccines are

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<sup>1</sup> *The Colbert Report: Michael McFaul* (Comedy Central television broadcast Apr. 28, 2014), <http://www.cc.com/video-clips/svsc0q/the-colbert-report-preventable-diseases-on-the-rise—paul-offit> (last visited Mar. 20, 2016).

<sup>2</sup> PAUL A. OFFIT, MD, <http://paul-offit.com/about/> (last visited Mar. 20, 2016) (Dr. Offit is the Director of the Vaccine Education Center at the Children's Hospital of Philadelphia, recipient of numerous medical awards, and author of more than one hundred and fifty published papers as well as the book, *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*).

<sup>3</sup> See *Jacobson v. Mass.*, 197 U.S. 11 (1905); *Zucht v. King*, 260 U.S. 174 (1922); *Prince v. Mass.*, 321 U.S. 158 (1944); *Maricopa Cty. Health Dep't v. Harmon*, 750 P.2d 1364 (Ariz. Ct. App. 1987); *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App'x 348 (4th Cir. 2011); *Caviezel v. Great Neck Pub. Sch.*, 701 F. Supp. 2d 414 (N.D.N.Y. 2010); *Phillips v. City of New York*, 775 F.3d 538 (2d Cir. 2015).

<sup>4</sup> See *Prince*, 321 U.S. at 158 (1944); *Bd. of Educ. of Mountain Lakes v. Maas*, 152 A.2d 394 (N.J. Super. Ct. App. Div. 1959); *Santosky v. Kramer*, 455 U.S. 745 (1982).

critical of the federal government's statutory institution of a vaccine injury compensation mechanism, alleging that its existence is proof that vaccines are unsafe. The National Vaccine Injury Compensation Program (NVICP) has served to insulate vaccine manufacturers from some liability, principally: large jury awards, claims for harm resulting from unavoidable side effects, and failure to warn claims. Be that as it may, the NVICP also provides a more reliable and swifter remedy to those injured than the state trial court system. The intricacies of the NVICP, the suspicion held by opponents of vaccination and hesitant parents, to say nothing of the current lack of restraint on international flights, underscore the need for a renewed commitment to informed consent by health care providers who administer vaccines. If we care about outcomes, we must insist that health care providers universally employ proper informed consent methods.

This Comment will begin with a discussion of how courts have granted state legislatures wide discretion in applying the police power in the context of public health while refusing to define its limits. Second, an introduction to the array of immunization exemptions that states offer and an appeal for their limited use will follow. Third, a description of the federal regulatory measures governing vaccination will follow, including an in-depth discussion of the NVICP. Finally, this Comment will expose the widespread failure of health care providers to employ the proper informed consent method required by law, which only exacerbates substandard vaccination rates, and the implications that declining vaccination rates will have on the public health.

## I

### **PEOPLE DO NOT HAVE ABSOLUTE BODILY AUTONOMY**

Blackstone defined police power as,

the due regulation and domestic order of the kingdom: whereby the individuals of the state, like members of a well-governed family, are bound to conform their general behaviour to the rules of propriety, good neighbourhood, and good manners; and to be decent, industrious, and inoffensive in their respective stations.<sup>5</sup>

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<sup>5</sup> 4 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND \*162.

Through the Tenth Amendment, the states have reserved the police power to maintain order, regulate behavior, and promote the public health within their respective territories.<sup>6</sup> Traditionally, the states exercised police powers in many different public health contexts, including:

[V]accination, isolation and quarantine, inspection of commercial and residential premises, abatement of unsanitary conditions or other [public] health nuisances, regulation of air and surface water contaminants and restriction of public access to polluted areas, standards for pure food and drinking water, extermination of vermin, fluoridation of municipal water supplies, and licensure of physicians and other health care professionals.<sup>7</sup>

While the Tenth Amendment grants states broad powers to promote the public health, the Fourteenth Amendment guarantees that states shall not “deprive any person of life, liberty, or property, without due process of law.”<sup>8</sup> And yet, courts have typically declined to interfere with a state’s exercise of police powers with regard to public health matters, “except where the regulations adopted for the protection of the public health are arbitrary, oppressive and unreasonable.”<sup>9</sup> As the Supreme Court held in *Jacobson v. Massachusetts*,

[T]he liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good.<sup>10</sup>

In *Jacobson*, the Supreme Court granted certiorari after the defendant’s conviction for refusing to submit to a smallpox vaccination was overturned by the Massachusetts Supreme Judicial Court.<sup>11</sup> The state legislature had enacted legislation giving local health boards the authority to compel their residents to be vaccinated if, “in the opinion of the board of health, that was necessary for the public health or the public safety,” and the power to enforce these

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<sup>6</sup> U.S. CONST. amend. X (“The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”).

<sup>7</sup> LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 95 (Univ. of Cal. Press rev. 2nd ed. 2008).

<sup>8</sup> U.S. CONST. amend. XIV, § 1.

<sup>9</sup> *People ex rel. Barmore v. Robertson*, 134 N.E. 815, 817 (Ill. 1922).

<sup>10</sup> *Jacobson v. Mass.*, 197 U.S. 11, 26 (1905).

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

discretionary mandates by fine or imprisonment.<sup>12</sup> The incidence rates of smallpox were rising in Cambridge, Massachusetts, when its health board ordered all adults who had not been vaccinated to submit to vaccination or face a fine.<sup>13</sup> Henning Jacobson refused to comply with the mandate, on the grounds that vaccines were unpredictable and often caused serious injuries or death;<sup>14</sup> alleging that vaccines contained dangerous ingredients; that he had contracted a disease after being vaccinated when he was a youth; and that he had known many other people who had also contracted diseases from vaccinations.<sup>15</sup> Jacobson insisted that compulsory vaccinations were unconstitutional and infringed on his bodily autonomy.<sup>16</sup>

In holding that the commonwealth did not violate Jacobson's Fourteenth Amendment rights by compelling him to be vaccinated, the Court found that the state legislature was within its authority to enact the statute providing for compulsory vaccination.<sup>17</sup> The Court stated this was a legitimate exercise of its police power as "the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety."<sup>18</sup> "The good and welfare of the commonwealth, of which the legislature is primarily the judge," the Court insisted, "is the basis on which the police power rests in Massachusetts."<sup>19</sup> In so holding, the Court signaled that because the mandate was rationally related to the statutory objective of protecting the public health, the state legislature was acting within the authority of its police power.<sup>20</sup> As such, Jacobson's Fourteenth Amendment right of due process was not infringed upon, even if his bodily autonomy was compromised.<sup>21</sup>

It is worth mentioning that the Court was wary that its appraisal of the legislature's police power might easily be interpreted as rising to

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<sup>12</sup> *Id.* at 27.

<sup>13</sup> *Id.* at 22.

<sup>14</sup> *Id.* at 36.

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

<sup>16</sup> *Id.* at 26.

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

<sup>18</sup> *Id.* at 25.

<sup>19</sup> *Id.* at 27.

<sup>20</sup> *Id.* at 26.

<sup>21</sup> *Id.*

the level of absolute power.<sup>22</sup> The Court made no attempts to strictly define the limits of the police power but did maintain that its employment should be necessary, reasonable, and above all avoid harm.<sup>23</sup> “‘All laws,’ this court has said, ‘should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence.’”<sup>24</sup>

Just a few years before the Supreme Court heard *Jacobson*, Louisiana’s state legislature created its first Board of Health, and gave it the duty to,

protect and preserve the public health by preparing and promulgating a sanitary code for the state of Louisiana, by providing for the general sanitation of the state, and with authority to regulate infectious and contagious diseases and to prescribe a maritime and land quarantine against places infected with such diseases.<sup>25</sup>

Among other things, the Board of Health adopted a resolution granting any city or parish in the state the authority to declare quarantine.<sup>26</sup> On the same day the resolution passed, the *S.S. Britannia* was detained at the New Orleans quarantine site after sailing from France, despite the fact that none of the ship’s passengers, some of whom were U.S. citizens, were carrying disease.<sup>27</sup> “The object,” in the Board’s assessment, “was to keep down, as far as possible, the number of persons to be brought within danger of contagion or infection, and by means of this reduction to accomplish the subsidence and suppression of the disease and the spread of the same.”<sup>28</sup>

In *Compagnie Francaise de Navigation a Vapeur v. Board of Health*, the ship’s ownership, representing the passengers, argued before the Supreme Court that the quarantine violated the Constitution’s Commerce Clause, various treaties, and the Fourteenth Amendment’s Due Process Clause.<sup>29</sup> Rejecting these arguments, the Court held that the state’s police power authorized local and state

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<sup>22</sup> *Id.* at 38.

<sup>23</sup> *Id.* at 39.

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

<sup>25</sup> *Compagnie Francaise de Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380, 381 (1902).

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

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

<sup>28</sup> *Id.* at 385.

<sup>29</sup> *Id.* at 381–83.

governments to enforce the quarantine as a measure to protect the public health.<sup>30</sup>

In a subsequent case, *O'Connor v. Donaldson*, Kenneth Donaldson spent nearly fifteen years in the Florida State Hospital at Chattahoochee, where his father had involuntarily committed him.<sup>31</sup> Donaldson was released from the institution, citing the fact that he was not a danger to others.<sup>32</sup> After his release, Donaldson “brought action against the hospital’s superintendent and others alleging that defendants had intentionally and maliciously deprived him of his constitutional right to liberty,” and sought monetary damages.<sup>33</sup> Ultimately, the Supreme Court denied Donaldson damages.<sup>34</sup> In Justice Burger’s concurrence he noted, “there can be little doubt that in the exercise of its police power a State may confine individuals solely to protect society from the dangers of significant antisocial acts or communicable disease.”<sup>35</sup>

*O'Connor* only strengthened the state legislatures’ rights to exercise the police power to protect the public health.<sup>36</sup> Relying on Justice Burger’s concurrence in *O'Connor*, the court in *Best v. Bellevue Hospital Center* dismissed the plaintiff’s claim in federal court.<sup>37</sup> In *Best*, William Best went to a local hospital to be treated for tuberculosis, and, upon diagnosis, was confined to the hospital for a few days against his will.<sup>38</sup> Best then brought an action alleging the hospital denied him both substantive and procedural due process.<sup>39</sup> Following the precedent set by the Supreme Court in *Jacobson, Compagnie*, and *O'Connor*, many lower courts, like *Best*, have consistently recognized the rights of state legislatures to exercise the police power to protect the public health, so long as they are not “unreasonable, unjust, and oppressive” in their protective efforts.<sup>40</sup>

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<sup>30</sup> *Id.* at 388.

<sup>31</sup> *O'Connor v. Donaldson*, 422 U.S. 563, 564–65 (1975).

<sup>32</sup> *Id.* at 565.

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

<sup>34</sup> *Id.* at 577.

<sup>35</sup> *Id.* at 582–83.

<sup>36</sup> *Best v. Bellevue Hosp. Ctr.*, No. 03Civ.365(RMB)(JCF), 2003 WL 21767656 (S.D.N.Y. July 30, 2003).

<sup>37</sup> *Id.* at 2.

<sup>38</sup> *Id.* at 1.

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

<sup>40</sup> *Jew Ho v. Williamson*, 103 F. 10, 26 (N.D. Cal. 1900).

Lower courts also recognized that the scope of the police power has limits, even if they, too, refuse to define them.<sup>41</sup> In *Greene v. Edwards*, William Greene, who had been diagnosed with active communicable tuberculosis, was served with a copy of a petition and a notice of a fixed hearing to be held at the circuit court in his native West Virginia.<sup>42</sup> The papers served did not inform Greene that he was entitled to be represented by counsel at the hearing.<sup>43</sup> Upon learning that Greene had no legal counsel, the court appointed an attorney for him.<sup>44</sup> However, without taking recess for Greene to consult with his attorney in private, the court “proceeded to take evidence and to order Mr. Greene’s commitment.”<sup>45</sup> As a result of the hearing, Greene was involuntarily confined in a hospital under an order of the circuit court, pursuant to West Virginia’s Tuberculosis Control Act (TCA).<sup>46</sup>

In a habeas corpus proceeding before the Supreme Court of Appeals of West Virginia, Greene alleged, among other things, that the TCA did not provide him with procedural due process.<sup>47</sup> In granting Greene’s writ, the court ruled that the state could confine an individual to prevent the spread of disease. However, the state must also provide the individual with procedural due process protections, such as the right to counsel, the right to engage in cross-examination, and notice explaining the grounds for the confinement.<sup>48</sup>

In *Wong Wai v. Williamson*, the San Francisco Board of Health, citing nine deaths from the bubonic plague, mandated that all Chinese residents be involuntarily immunized against the plague or be confined to the city limits.<sup>49</sup> Following the order, those who were immunized experienced severe reactions including pain, high body temperatures, depression, and even death.<sup>50</sup> The plaintiff, on behalf of all the Chinese residents of the city, sought an injunction to the mandate. He alleged that the bubonic plague was not present in the city; that the confinement of the Chinese residents was a wrongful and oppressive interference with their personal liberty; and, that

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<sup>41</sup> *Greene v. Edwards*, 263 S.E.2d 661, 663–64 (W. Va. 1980).

<sup>42</sup> *Id.* at 662.

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

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

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

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

<sup>48</sup> *Id.* at 663.

<sup>49</sup> *Wong Wai v. Williamson*, 103 F. 1, 4 (N.D. Cal. 1900).

<sup>50</sup> *Id.* at 3.

because the mandate was not enforced against non-Chinese residents, its enforcement deprived the Chinese residents of the equal protection of laws.<sup>51</sup> In granting the plaintiff's injunction, the court commented on the regulations:

[T]hey are not based upon any established distinction in the conditions that are supposed to attend this plague, or the persons exposed to its contagion, but they are boldly directed against the Asiatic or Mongolian race as a class, without regard to the previous condition, habits, exposure to disease, or residence of the individual; and the only justification offered for this discrimination was a suggestion made by counsel for the defendants in the course of argument, that this particular race is more liable to the plague than any other.<sup>52</sup>

In its closing opinion, the court carefully stated that while it could not accurately define the limits of the police power, even its broadest interpretation did not overshadow the Constitution.<sup>53</sup>

A few months later, the same court invalidated the same quarantine, in *Jew Ho v. Williamson*, because it was “unreasonable, unjust and oppressive,” and constituted discrimination in violation of the Fourteenth Amendment.<sup>54</sup> Citing *Wong Wai v. Williamson*, the court vehemently confirmed its willingness to uphold the police power in reasonable circumstances:

This court will, of course, uphold any reasonable regulation that may be imposed for the purpose of protecting the people of the city from the invasion of epidemic disease. In the presence of a great calamity, the court will go to the greatest extent, and give the widest discretion, in construing the regulations that may be adopted by the board of health or the board of supervisors.<sup>55</sup>

It is worth reiterating that in both the *Wong Wai* and *Jew Ho* cases, each an egregious example of arbitrariness and oppression, Judge Morrow was careful not to undermine the future application of the police power.<sup>56</sup>

In *City of Escondido v. Coshow*, the defendant municipality planned to fluoridate its public water supply with hydrofluorosilicic

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

<sup>52</sup> *Id.* at 7.

<sup>53</sup> *Id.* at 10.

<sup>54</sup> *Jew Ho*, 103 F. 10, 26 (N.D. Cal. 1900).

<sup>55</sup> *Id.* at 21.

<sup>56</sup> *Wong Wai v. Williamson*, 103 F. at 10; *Jew Ho*, 103 F. at 21.

acid in accordance with state health laws.<sup>57</sup> A group of concerned residents opposed to fluoridation challenged the city's plans before the Superior Court.<sup>58</sup> After the Superior Court granted judgment on the pleadings in favor of the city, Coshow appeared before the Fourth District of the California Court of Appeal seeking declaratory and injunctive relief.<sup>59</sup> Coshow claimed, among other things, that the city's use of the chemical violated his constitutional right to bodily integrity under the Fourteenth Amendment, and exposed the general public to "unnecessary health risks."<sup>60</sup> Meanwhile, the city asserted that it was following policies set by the state legislature.<sup>61</sup>

The California Safe Drinking Water Act (SDWA) placed the responsibility of establishing primary drinking water standards on the California Department of Health Services, including "the maximum levels of contaminants which," in the department's judgment, "may have an adverse effect on the health of persons."<sup>62</sup> The state legislature amended the SDWA to require public water systems, with at least 10,000 service connections, to be fluoridated "to promote the public health of Californians of all ages through the protection and maintenance of dental health, a paramount issue of statewide concern."<sup>63</sup> At the time of the mandate, the city was serving nearly 25,000 service connections.<sup>64</sup> The city maintained its plan to fluoridate the public water supply was an effort to comply with the primary and secondary drinking water standards, as established in the SDWA, as well as the fluoridation mandate in the later amendment.<sup>65</sup>

In denying Coshow's request for declaratory and injunctive relief, the court stated "[c]ourts through[out] the United States have uniformly held that fluoridation of water is a reasonable and proper exercise of the police power in the interest of public health."<sup>66</sup> In its opinion, the court conceded "the right to bodily integrity is a fundamental right which limits the traditional police powers of the state in the context of public health measures under the federal and

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<sup>57</sup> Coshow v. City of Escondido, 34 Cal. Rptr. 3d 19, 22 (Cal. Ct. App. 2005).

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

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* at 23.

<sup>62</sup> *Id.* at 26.

<sup>63</sup> *Id.* at 27.

<sup>64</sup> *Id.* at 22.

<sup>65</sup> *Id.* at 23.

<sup>66</sup> *Id.* at 27 (alteration in original).

state Constitutions.”<sup>67</sup> However, the court declined to limit the state’s police power in this context, stating, “Coshow alleged he had a fundamental right to bodily integrity, there simply is no such right in the context of public drinking water.”<sup>68</sup>

Like *Jacobson*, the *Coshow* court found that the state legislature acted within the authority of its police power because the mandate at issue was rationally related to its statutory objective of protecting the public health.<sup>69</sup> Coshow’s Fourteenth Amendment rights of due process were not infringed upon, even if his bodily autonomy may have been subject to compromise.<sup>70</sup>

## II

### EXEMPTIONS TO IMMUNIZATION STANDARDS SHOULD BE THE EXCEPTION

The measles virus was declared eradicated in the United States in 2000, possibly due to an effective Measles, Mumps, and Rubella (MMR) vaccine, and the efforts of regulatory agencies like the U.S. Department of Health & Human Services (DHHS) and the Centers for Disease Control and Prevention (CDC).<sup>71</sup> The CDC recommends children be administered a two-dose series of the MMR vaccine at ages twelve through fifteen months and then again between ages four and six years.<sup>72</sup> Furthermore, the CDC recommends that adults be administered a third dose after they turn nineteen years old.<sup>73</sup> For a long time, these countermeasures effectively controlled the spread of the measles virus.

Unfortunately, the data suggests the measles virus may be resurging. For example, the CDC received 667 confirmed cases of the

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<sup>67</sup> *Id.* at 30.

<sup>68</sup> *Id.* at 31.

<sup>69</sup> *Id.* at 33.

<sup>70</sup> *Id.* at 31.

<sup>71</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Measles History, Measles (Rubeola)* (Mar. 20, 2016), <http://www.cdc.gov/measles/about/history.html>.

<sup>72</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Child and Adolescent Schedule, Immunization Schedules* (Mar. 20, 2016), <http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.

<sup>73</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Adult Immunization Schedule, Immunization Schedules* (Mar. 20, 2016), <http://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>.

measles virus in 2014, a record number of cases since 2000.<sup>74</sup> In the State of California alone, at least 136 new cases of measles were diagnosed between December 2014 and early April 2015.<sup>75</sup> According to the California Department of Public Health, among those individuals confirmed to have contracted the measles virus within that time frame, fifty-seven were unvaccinated, and twenty-five had one or more doses of the MMR vaccine.<sup>76</sup> A group of researchers, led by Maimuna S. Majumder of Boston Children's Hospital and the Massachusetts Institute of Technology, Boston, analyzed cumulative incidence data from the California Department of Public Health and HealthMap media alerts and published their results in *JAMA Pediatrics*.<sup>77</sup> In their published research letter, Majumder and her coauthors indicated that inadequate vaccination rates might be the cause of the recent outbreak:

Preliminary analysis indicates that substandard vaccination compliance is likely to blame for the 2015 measles outbreak. Our study estimates that MMR vaccination rates among the exposed population in which secondary cases have occurred might be as low as 50% and likely no higher than 86%. Given the highly contagious nature of measles, vaccination rates of 96% to 99% are necessary to preserve herd immunity and prevent future outbreaks. Even the highest estimated vaccination rates from our model fall well below this threshold . . . MMR vaccination rates in many of the communities that have been affected by this outbreak fall below the necessary threshold to sustain herd immunity, thus placing the greater population at risk as well.<sup>78</sup>

Adherents of compulsory vaccinations are likely to support these findings, and others like them, which support the effectiveness of vaccines. Alternatively, a growing number of individuals, opposed to compulsory vaccinations, will likely ignore findings supportive of the effectiveness of vaccines, claiming one or several various objections to mandates, including differing medical and scientific evidence as to

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<sup>74</sup> U.S. DEP'T OF HEALTH AND HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Measles Cases, Measles (Rubeola)* (Mar. 20, 2016), <http://www.cdc.gov/measles/cases-outbreaks.html>.

<sup>75</sup> CALIFORNIA DEP'T OF PUBLIC HEALTH, *California Measles Surveillance Update Apr. 17, 2015* (Mar. 20, 2016), [http://www.cdph.ca.gov/HealthInfo/discond/Documents/Measles\\_update\\_4-17-2015\\_public.pdf](http://www.cdph.ca.gov/HealthInfo/discond/Documents/Measles_update_4-17-2015_public.pdf).

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

<sup>77</sup> Majumder, Maimuna S. et al., *Substandard Vaccination Compliance and the 2015 Measles Outbreak*, 169 *JAMA PEDIATRICS* 494–95 (2015).

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

the effectiveness of vaccines,<sup>79</sup> the existence of the NVICP as proof that vaccines are a direct cause of injury<sup>80</sup> or among others, objections of a religious nature.<sup>81</sup>

Opponents to vaccinations raise objections that may differ in form. The substance of those objections, however, is almost universally tailored to implicate infringements on due process. While the Fourteenth Amendment to the Constitution guarantees that states shall not “deprive any person of life, liberty, or property, without due process of law,”<sup>82</sup> the Supreme Court has consistently held since *Jacobson* that it is within the police power of state legislatures to compel vaccination in the interest of the public health over the interest of individual liberties.<sup>83</sup> For example, in *Zucht v. King*, the Supreme Court stated that *Jacobson* long ago “settled that it is within the police power of a state to provide for compulsory vaccination.”<sup>84</sup> Then, in 2012, the United States Court of Appeals of the Second Circuit decided *Caviezel v. Great Neck Public Schools*, holding that the plaintiff’s argument against the compulsory vaccination of their school-age children was no more compelling than *Jacobson*’s was more than a century ago.<sup>85</sup> A century later, courts are no more willing to strip state legislatures of their police power in the public health context than they were in *Jacobson*.

While *Jacobson* stands for the proposition that state legislatures can compel adults and children to be vaccinated if it serves the public health, the Supreme Court also noted in this case that immune compromised children might not be suitable recipients of vaccines. Interestingly, the Court declined to grant such an exception for

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<sup>79</sup> A.J. Wakefield et al., *Ileal-lymphoid-nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children*, 351 no. 9103 THE LANCET 637 (2008) (retracted 2010).

<sup>80</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., HEALTH RES. AND SERV. ADMIN., ADVISORY COMM’N ON CHILDHOOD VACCINES, Transcript of Meeting of Nov. 18, 2008, at 11–12, <http://www.hrsa.gov/advisorycommittees/childhoodvaccines/> [hereinafter CHILDHOOD VACCINES].

<sup>81</sup> DV Rodgers et al., *High Attack Rates and Case Fatality During a Measles Outbreak in Groups with Religious Exemption to Vaccination*, 12 no. 4 PEDIATRIC INFECTIOUS DISEASE J., 288–92 (1993).

<sup>82</sup> U.S. CONST. amend. XIV, § 1.

<sup>83</sup> *Jacobson v. Mass.*, 197 U.S. 11 (1905); *see, e.g., Zucht v. King*, 260 U.S. 174 (1922).

<sup>84</sup> *Zucht*, 260 U.S. at 176.

<sup>85</sup> *See Caviezel v. Great Neck Pub. Sch.*, 500 F. App’x. 16, \*\*2 (2d Cir. 2012) (unpublished table decision).

“adults in like condition.”<sup>86</sup> Courts recognize the authority of state legislatures to compel vaccination in adults and children through state police powers, and likewise uphold laws authorizing public school districts to exclude unimmunized children,<sup>87</sup> even absent any confirmed cases of disease.<sup>88</sup> Opponents of vaccinations argue that these actions by public school districts constitute unreasonable government interference. However, the Supreme Court, more than once, recognized a government privilege to interfere with parental rights as grounded not only upon the police power vested in state legislatures, but also upon the doctrine of *parens patriae*,<sup>89</sup> meaning, “parent of his or her country.”<sup>90</sup> To illustrate, in *Prince v. Massachusetts*, the Court held that “the state has a wide range of power for limiting parental freedom and authority in things affecting the child’s welfare.”<sup>91</sup>

Opponents to vaccination also maintain that public schools that exclude students based upon vaccination requirements violate First Amendment rights to freely exercise one’s religion.<sup>92</sup> Admittedly, the Supreme Court recognized that “the values of parental direction of the religious upbringing and education of their children in their early and formative years [has] a high place in our society.”<sup>93</sup> Nevertheless, the Court also held there exists no constitutional right to religious exemption from compulsory vaccination,<sup>94</sup> and that “generally the right of parents to raise their children in accord with their personal

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<sup>86</sup> Jacobson, 197 U.S. at 30.

<sup>87</sup> See, e.g., *Maricopa Cty. Health Dep’t v. Harmon*, 750 P.2d 1364, 1368 (Ariz. Ct. App. 1987) (“In our opinion the Maricopa County Health Department’s temporary district-wide exclusion order of February 21, 1986 was well within its authority. It constituted a specific measure ‘reasonably necessary’ to achieve a specific legitimate result.”).

<sup>88</sup> See, e.g., *Bd. of Ed. of Mountain Lakes v. Maas*, 152 A.2d 394, 405 (N.J. Super. Ct. App. Div. 1959) (“The absence of an existing emergency does not warrant a denial to the regulative agency of the exercise of preventive means. A local board of education need not await an epidemic, or even a single sickness or death, before it decides upon action to protect the public. To hold otherwise would be to destroy prevention as a means of combatting the spread of disease.”).

<sup>89</sup> See, e.g., *Prince v. Mass.*, 321 U.S. 158, 166 (1944) (“Acting to guard the general interest in youth’s well being, the state as *parens patriae* may restrict the parent’s control by requiring school attendance, regulating or prohibiting the child’s labor, and in many other ways.”); *Santosky v. Kramer*, 455 U.S. 745, 766 (1982).

<sup>90</sup> *Parens Patriae*, BLACK’S LAW DICTIONARY (10th ed. 2014).

<sup>91</sup> *Prince*, 321 U.S. at 167.

<sup>92</sup> *Id.* at 164.

<sup>93</sup> *Wis. v. Yodor*, 406 U.S. 205, 214–15 (1972).

<sup>94</sup> *Prince*, 321 U.S. at 166.

and religious beliefs must yield when the health of children is at risk, or when there is a recognized threat to public safety.”<sup>95</sup> Lower courts have responded by holding that states are not required to include religious exemptions in compulsory vaccination laws.<sup>96</sup>

Despite having the power to strictly limit, or even bar, religious exemptions to the compulsory vaccination requirements of public school districts, forty-seven states allow them.<sup>97</sup> Only Arizona’s, Mississippi’s, and West Virginia’s statutory schemes do not provide for a religious-based exemption to immunization requirements.<sup>98</sup> At least one faith, the Congregation of Universal Wisdom, expressly forbids its members from vaccination:

It is sacrilege to introduce into the body living organisms or any unnatural matter that may alter the natural balance of that organism rendering it into a state of dis-ease. The laying on of hands, that basic manner of conveying universal forces by man, shall serve as the sole means of conveying and radiating the life forces from above, downward and outward.<sup>99</sup>

While express prohibitions almost certainly meet the criteria for a religious-based exemption, the Supreme Court applies a very broad stroke to the term “religion.” Rather, its definition need not be confined to a particular denomination, congregation, or formalized set of beliefs so long as there is substance to an individual’s beliefs and those beliefs are sincerely held.<sup>100</sup> Consequently, failure to demonstrate that one holds “genuine and sincere religious beliefs which prohibit vaccinations”<sup>101</sup> might foreclose a petitioner’s attempt

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<sup>95</sup> See *Caviezel v. Great Neck Pub. Sch.*, 701 F.Supp.2d 414, 428 (E.D.N.Y. 2010), *aff’d*, 500 F. App’x 16 (2d Cir. 2012). See also, *In re Christine M.*, 595 N.Y.S.2d 606, 611 (Kings Cty. Fam. Ct. 1992) (“The United States Supreme Court has historically recognized that the right of parents to rear their children in accordance with their personal and religious beliefs must give way when the health or safety of children is threatened or when parental conduct poses some substantial threat to public safety.”).

<sup>96</sup> E.g., *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App’x 348, 354 (4th Cir. 2011) (unpublished table decision).

<sup>97</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Childcare and School Vaccination Requirements 2007–2008* (2008), <http://www2a.cdc.gov/nip/schoolsurv/combinedlaws2007.pdf>.

<sup>98</sup> See 15 ARIZ. REV. STAT. ANN. § 873 (2007); MISS. CODE ANN. § 41-23-37 (2005); W. VA. CODE R. § 64-95-9 (2015).

<sup>99</sup> *Healing*, CONGREGATION OF UNIVERSAL WISDOM, <http://www.cuwisdom.org/healing.php> (last visited Mar. 20, 2016).

<sup>100</sup> *United States v. Seeger*, 380 U.S. 163, 184–85 (1965).

<sup>101</sup> *Caviezel v. Great Neck Pub. Sch.*, 701 F. Supp. 2d 414, 429 (E.D.N.Y. 2010).

to claim a religious exception. This applies even to school district's vaccination requirements in states that recognize religious-based exemptions, when the applicant does not belong to a church, nor identifies with a particular religion.<sup>102</sup>

Further exemplifying state legislatures' discretion, state laws authorizing exemptions to compulsory vaccinations are statutorily based, and can be repealed by their enacting bodies. However, all fifty states allow for some form of medical exemption to public school district vaccination requirements, be it temporary or permanent.<sup>103</sup> Sixteen states, including Idaho, Oregon, and Washington, allow for philosophical exemptions that are neither religiously nor medically based.<sup>104</sup> For example, in Oregon, parents may decline any immunization on behalf of their children without explanation.<sup>105</sup> However, the parent must either provide verification from their health care provider that they have received information about the risks and benefits of the vaccine's administration, or the parent must submit documentation to verify completion of an approved vaccine educational module.<sup>106</sup>

While opponents of vaccination raise valid due process concerns, state legislatures may enact religious, medical, and philosophical exemptions to accommodate the wary. Be that as it may, inadequate vaccination rates may cause outbreaks, even for diseases that were declared eradicated, such as the measles virus.<sup>107</sup> Hesitant parents should strongly consider vaccinating their children, absent

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<sup>102</sup> *Seeger*, 380 U.S. at 171–72.

<sup>103</sup> See generally U.S. DEP'T OF HEALTH AND HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, OFFICE FOR STATE, TRIBAL, LOCAL AND TERRITORIAL SUPPORT, *State School Immunization Requirements and Vaccine Exemption Laws 5* (2015).

<sup>104</sup> IDAHO CODE ANN. § 39-4802 (2015), OR. REV. STAT. § 433.267 (2013), WASH. REV. CODE ANN. § 28A.210.080 (2015), see also 15 ARIZ. REV. STAT. ANN. § 873 (2007); ARK. CODE ANN. § 6-18-702 (2015); COLO. REV. STAT. § 25-4-903 (West 2015); LA. ADMIN. CODE tit. 51, § 701 (2015); ME. REV. STAT. ANN. tit. 20-A, § 6355 (2015); MICH. COMP. LAWS ANN. § 333.9215 (2015); MINN. STAT. ANN. § 121A.15 (2015); N.D. CENT. CODE ANN. § 23-07-17.1 (2015); OHIO REV. CODE ANN. § 3313.671 (2015); OKLA. STAT. ANN. tit. 70, § 1210.192 (West 2015); TEX. EDUC. CODE ANN. § 38.001 (West 2015); UTAH CODE ANN. § 53A-11-302 (West 2015); and WIS. STAT. ANN. § 252.04 (West 2015).

<sup>105</sup> OR. REV. STAT. § 433.267 (2013).

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

<sup>107</sup> Majumder et al., *supra* note 77.

exceptional circumstances, because maintaining vaccination rates at necessary thresholds is vital to limiting outbreaks.<sup>108</sup>

### III THE INTRICACIES OF THE NVICP

Historically, the body of doctrines comprising compulsory vaccinations was largely a matter of state law, save the Supreme Court's ruling in *Jacobson*, and the subsequent cases that reinforced its holding over the last 111 years.<sup>109</sup> Prior to the late 1980s, injured recipients of vaccines sought remedies from vaccine manufacturers through the state tort law system, known by practitioners to be wildly unpredictable. In 1986, the NVICP was created with the passage of the National Childhood Vaccine Injury Act, and Congress spoke clearly that vaccination is a scientifically valid national public health strategy that deserves full legal protection.<sup>110</sup> According to the U.S. Department of Health and Human Services (DHHS), the NVICP "was established to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines."<sup>111</sup>

In addition to creating a new compensation scheme, separate from the traditional state tort law system, the NVICP limits the tort remedies available to an injured recipient of certain vaccines.<sup>112</sup> Under general legal principles, a product may be found to be defective if the seller or distributor failed to warn the consumer about foreseeable risks of harm, even in cases where the product was manufactured properly and lacks any design flaws.<sup>113</sup> The NVICP removes a vaccine manufacturer's liability "arising from a vaccine-

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

<sup>109</sup> See *Zucht v. King*, 260 U.S. 174, 176 (1922); *Prince v. Mass.*, 321 U.S. 158, 166 (1944); and *Phillips v. City of New York*, 775 F.3d 538, 542 (2015).

<sup>110</sup> 42 U.S.C. § 300aa-6 (2016).

<sup>111</sup> U.S. DEP'T OF HEALTH AND HUMAN SERV., HEALTH RES. AND SERV. ADMIN., *National Vaccine Injury Compensation Program* (Mar. 20, 2016), <http://www.hrsa.gov/vaccinecompensation/index.html>.

<sup>112</sup> 42 U.S.C. § 300aa-22 (2016).

<sup>113</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. c (AM. LAW INST. 1998) ("A product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor . . . and the omission of the instructions or warnings renders the product not reasonably safe.").

related injury or death associated with the administration of a vaccine . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”<sup>114</sup> The NVICP eliminates the duty to warn of foreseeable risks of harm, which creates a presumption that proper directions and warnings accompanied the vaccine, so long as the vaccine manufacturer can show that it materially complied with the requirements of the Food, Drug, and Cosmetic Act.<sup>115</sup>

Most importantly, the NVICP preempts the traditional state tort law system in many instances and features a simplified adjudication process. Through this simplified process, the injured recipient of a vaccine, or his legal representative, must bring a claim in the United States Court of Federal Claims.<sup>116</sup> The claimant receives predetermined compensation if the injured party: “(1) received a vaccine covered by the Act; (2) suffered injuries associated with that vaccine; and (3) it cannot be shown by a preponderance of the evidence that the injuries were not caused by the vaccine.”<sup>117</sup> Thus, while limiting a claimant’s potential recovery amount and foreclosing some types of claims, the NVICP provides the claimant with a predictable outcome and a greater likelihood of compensation. Above all, the NVICP signals to the public that vaccination is a national public health priority and, for the very small number of cases where adverse events do occur, full and fair compensation will be promptly paid.

The NVICP began accepting petitions from injured vaccine recipients and their guardians in October 1988.<sup>118</sup> Since then, the total compensation paid to claimants over the life of the program is just under \$3.1 billion.<sup>119</sup> In that time, roughly thirty-eight percent of claimants who submitted complete petitions received awards.<sup>120</sup> Additionally, forty-eight percent of unsuccessful petitions were dismissed because the claimant’s petition was deemed “non-

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

<sup>115</sup> 42 U.S.C. § 300aa-22 (2016).

<sup>116</sup> 42 U.S.C. § 300aa-12 (2016).

<sup>117</sup> 42 U.S.C. § 300aa-13 (2016).

<sup>118</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., HEALTH RES. AND SERV. ADMIN., *National Vaccine Injury Compensation Data Report* (Mar. 20, 2016), <http://www.hrsa.gov/vaccinecompensation/data/statisticsreport.pdf> [hereinafter *Vaccine Report*].

<sup>119</sup> *Id.* at 9.

<sup>120</sup> *Id.* at 5.

compensable.”<sup>121</sup> “Non-compensable” petitions include claims where: (1) “the Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine,”<sup>122</sup> or the person did not have injuries for which the program compensates claimants; (2) the petition was dismissed because it did not meet other statutory requirements, “such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute’s severity requirement”;<sup>123</sup> or (3) “[t]he injured person voluntarily withdrew his or her petition.”<sup>124</sup> DHHS claims that on average, cases are adjudicated in two to three years.<sup>125</sup>

The NVICP accepts petitions for 31 covered vaccines.<sup>126</sup> Of those vaccines, 18 have received less than 100 petitions total.<sup>127</sup> The Diphtheria, Tetanus, and Pertussis (DTP) vaccine is the most litigated vaccine before that Federal Court of Claims, receiving petitions seeking compensation for a total of 3,286 injuries and 696 deaths.<sup>128</sup> In addition, the DTP vaccine is the only vaccine for which more than 100 death petitions have been filed.<sup>129</sup> Understandably, the DTP vaccine was replaced by the much safer Diphtheria, Tetanus, and Pertussis (DTaP) vaccine in 1991.<sup>130</sup> Since 1996, only 394 injury petitions and 79 death petitions were filed following administrations of the DTaP vaccine.<sup>131</sup>

Opponents of vaccination, disturbed by the NVICP’s preemptory status, cite numerous concerns about the validity and necessity of the program. Critics of the program maintain that the NVICP is a result of pharmaceutical lobbying and argue that the mere existence of the NVICP serves as an acknowledgement that vaccines are not safe.<sup>132</sup>

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<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at 4.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Id.* at 7.

<sup>126</sup> *Id.* at 5.

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

<sup>128</sup> *Id.*

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

<sup>130</sup> *Diphtheria: Questions and Answers*, IMMUNIZATION ACTION COAL (2013), <http://www.immunize.org/catg.d/p4203.pdf>.

<sup>131</sup> *Vaccine Report*, *supra* note 118.

<sup>132</sup> CHILDHOOD VACCINES, *supra* 80, at 11–12.

While the DHHS acknowledges that lobbying contributed to the statute's conception,<sup>133</sup> they expressly deny claims that the NVICP's existence is proof that vaccines are unsafe.<sup>134</sup>

In addition to providing an expedited compensation scheme, albeit with some procedural hurdles, the NVICP places informed consent requirements on health care providers who administer vaccines. The NVICP requires health care providers to inform the parents or legal guardian of the recipient of a vaccine of the following: "(1) concise description of the benefits of the vaccine; (2) a concise description of the risks associated with the vaccine; [and] (3) a statement of the availability of the National Vaccine Injury Compensation Program . . . prior to the administration of such vaccine."<sup>135</sup> When followed, these informed consent procedures reinforce public support for vaccination.

#### IV

#### CAUSE FOR CONCERN

What should be concerning to both adherents and opponents of vaccination is the widespread failure by health care providers to employ the proper informed consent method required by law. In a private study conducted among thirty-two focus groups in six cities, researchers discovered that physicians informed parents of common side effects during roughly seventy percent of vaccinations; initiated discussions regarding risks less than fifty percent of the time; and only informed parents of the NVICP in less than ten percent of vaccine administrations.<sup>136</sup> To illustrate, imagine health care providers performing invasive surgery without warning the patient of the health risks involved with the recommended surgery. Alternatively, imagine if health care providers operated on patients and released them without provided post-operative instructions. If we care about outcomes, we must insist that health care providers employ proper informed consent methods universally. Like invasive procedures, vaccinations pose risks and require that patients be apprised of the

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<sup>133</sup> U.S. DEP'T OF HEALTH AND HUMAN SERV., HEALTH RES. AND SERV. ADMIN., *What You Need to Know About the National Vaccine Injury Compensation Program (VICP)*, 1 (2011), <http://www.hrsa.gov/vaccinecompensation/84521booklet.pdf>.

<sup>134</sup> U.S. DEP'T OF HEALTH AND HUMAN SERV., HEALTH RES. AND SERV. ADMIN., *Frequently Asked Questions* (2016), <http://www.hrsa.gov/vaccinecompensation/faq.html>.

<sup>135</sup> 42 U.S.C. § 300aa-26 (2012).

<sup>136</sup> Terry C. Davis et al., *Childhood Vaccine Risk/Benefit Communication in Private Practice Office Settings: A National Survey*, 107 PEDIATRICS 1, 4 (2001), <http://pediatrics.aappublications.org/content/pediatrics/107/2/e17.full.pdf>.

details of treatment. The United States Government Accountability Office has taken notice of this widespread failure to inform the public of the NVICP, placing blame on both health care providers and the Health Resources and Services Administration in a 2014 report.<sup>137</sup> Surely, public health is not advanced when providers are so often shirking their responsibilities to inform.

Meanwhile, the public's trust in vaccinations is dropping, as evidenced by generally declining child immunization rates. For example, according to a 2015 report by the National Committee for Quality Assurance, a nonprofit organization dedicated to improving health care quality, child vaccination rates for Pertussis dropped by as much as one percent in the year 2014.<sup>138</sup> Pertussis, also known as whooping cough, is a highly contagious respiratory disease.<sup>139</sup> While incidence rates for Pertussis are very low in the United States, they are not nearly as low as they have been in the past.<sup>140</sup> According to the World Health Organization, allowing immunization levels for Pertussis to continue dropping could have catastrophic consequences:

[W]e can look at the experiences of several developed countries after they allowed their immunization levels to drop. Three countries—Great Britain, Sweden and Japan—cut back the use of pertussis (whooping cough) vaccine because of fear about the vaccine. The effect was dramatic and immediate. In Great Britain, a drop in pertussis vaccination in 1974 was followed by an epidemic of more than 100,000 cases of pertussis and 36 deaths by 1978. In Japan, around the same time, a drop in vaccination rates from 70% to 20%-40% led to a jump in pertussis from 393 cases and no deaths in 1974 to 13,000 cases and 41 deaths in 1979. In Sweden, the

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<sup>137</sup> UNITED STATES GOV'T ACCOUNTABILITY OFF., GAO-15-142, *Vaccine Injury Compensation: Most Claims Took Multiple Years and Many Were Settled through Negotiation* 31 (2014), <http://www.gao.gov/assets/670/667136.pdf>.

<sup>138</sup> NAT'L COMM. FOR QUALITY ASSURANCE, *Childhood Immunization Status* (Mar. 20, 2016), <http://www.ncqa.org/ReportCards/HealthPlans/StateofHealthCareQuality/2015/ContentofContents/ChildhoodImmunizationStatus.aspx>.

<sup>139</sup> U.S. DEP'T OF HEALTH AND HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Pertussis (Whooping Cough)* (Mar. 20, 2016), <http://www.cdc.gov/pertussis/>.

<sup>140</sup> U.S. DEP'T OF HEALTH AND HUM. SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Pertussis Cases by Year (1922-2014)* (Mar. 20, 2016), <http://www.cdc.gov/pertussis/surv-reporting/cases-by-year.html> (The CDC reports 32,971 pertussis cases in the United States in 2014, while there were only 1010 cases in 1976, the United States' best year on record.).

annual incidence rate of pertussis per 100,000 children of 0-6 years of age increased from 700 cases in 1981 to 3,200 in 1985.<sup>141</sup>

Admittedly, a one percent drop in vaccination rates of pertussis over one year is at most one-sixth of the decline experienced over the cited five-year period in Japan. Nevertheless, if pertussis vaccination rates continue to drop at this pace incidence rates will most likely rise.

With greater incidence rates, fatalities are highly possible. Because viable vaccinations exist to combat preventable diseases, like pertussis, health care providers have an ethical duty to help restore public trust in vaccinations by implementing the NVICP's informed consent procedures. If the public's trust in vaccination rises immunization rates will likely increase, which will likely strengthen herd immunity and limit the threat of outbreak. Conversely, if U.S. parents increasingly forego immunizing children in this country, we may suffer similar consequences to those experienced by Great Britain, Sweden, and Japan.

Ultimately, prevention falls on the parents of unvaccinated children. However, because health care providers serve as the point of contact between vaccine manufacturers and potential vaccine recipients the healthcare providers are principally accountable for the public's confidence in our nation's immunization policies. Julie Leask, an Associate Professor at the University of Sydney, School of Public Health and Sub-Dean in the Sydney Medical School, explained in recent research that health care providers play a vital role in parental attitudes towards vaccination:

A critical factor shaping parental attitudes to vaccination is the parent's interactions with health professionals. An effective interaction can address the concerns of vaccine supportive parents and motivate a hesitant parent towards vaccine acceptance. Poor communication can contribute to rejection of vaccinations or dissatisfaction with care. . . . A parent's trust in the source of information may be more important than what is in the information.<sup>142</sup>

With a renewed commitment to informed consent by health care providers, including compliance with the NVICP directives, it is very

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<sup>141</sup> WORLD HEALTH ORG., *Six common misconceptions about immunization* (Mar. 20, 2016), [http://www.who.int/vaccine\\_safety/initiative/detection/immunization\\_misconceptions/en/index1.html](http://www.who.int/vaccine_safety/initiative/detection/immunization_misconceptions/en/index1.html).

<sup>142</sup> Leask, Julie et al., *Communicating with Parents about Vaccination: A Framework for Health Professionals*, 12 BMC PEDIATRICS 154 (2012).

likely that hesitant parents will have their children vaccinated and overall immunization rates will remain at safe levels.

Augmenting the need for higher immunization rates is the risk of outbreak posed by international travelers. Currently, there are effective preventative vaccines for many, but not all, communicable diseases, including diphtheria, Hepatitis A, Hepatitis B, influenza, measles, mumps, pertussis, polio, rubella, tetanus, and varicella.<sup>143</sup> In addition, researchers are currently developing vaccines to guard against other communicable diseases, like Ebola.<sup>144</sup> Unfortunately, despite the imminent threat that highly contagious diseases, like Ebola, pose to the public health, the Federal Aviation Administration has declined to restrict international flights to and from affected countries.<sup>145</sup> We are not safe from outbreak when individuals choose to forego vaccinating themselves and their children.

As a final point, the intricacies of the NVICP and the suspicion held by opponents of vaccination should motivate health care providers to recommit to employing proper informed consent procedures. Likewise, the current lack of restraint on international flights, specifically flights from countries where highly contagious diseases are prevalent, highlights the urgency with which health care providers must employ proper informed consent procedures. If a greater portion of the population chooses to immunize their children, it will most likely minimize the risks posed by communicable diseases for which effective vaccines exist.

## CONCLUSION

The United States judiciary has spoken authoritatively in support of states' rights to exercise their police powers with regard to public health matters, including compulsory vaccination. Courts also recognize the government's authority to interfere with parental rights is grounded not only upon the police power vested in state legislatures

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<sup>143</sup> U.S. DEP'T OF HEALTH AND HUM. SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, *Vaccine-Preventable Childhood Diseases* (Mar. 20, 2016), <http://www.cdc.gov/vaccines/parents/diseases/index.html>.

<sup>144</sup> WORLD HEALTH ORG., *Ebola vaccines, therapies, and diagnostics* (Mar. 20, 2016), [http://www.who.int/medicines/empEbola\\_q\\_as/en/](http://www.who.int/medicines/empEbola_q_as/en/).

<sup>145</sup> *Press Release—FAA Statement on Ebola*, U.S. DEP'T OF TRANSP., FED. AVIATION ADMIN. (Oct. 23, 2014), [https://www.faa.gov/news/press\\_releases/news\\_story.cfm?newsId=17375](https://www.faa.gov/news/press_releases/news_story.cfm?newsId=17375).

but also upon the doctrine of *parens patriae*. The equitable reality is that state legislatures can force citizens to be vaccinated in the interest of public health, absent oppression or arbitrariness.

Meanwhile, the NVICP has served to insulate vaccine manufacturers from some liability and provides an improved compensation mechanism for injured persons. Because of the intricacies of the NVICP, the suspicion held by opponents of vaccination, and the current lack of restraint on international flights, it is important that health care providers renew their commitment to the informed consent methods mandated by the NVICP. These disclosures must include the risks and benefits of the vaccine to be administered, as well as the remedies provided by the NVICP in the unfortunate event that the patient is injured.