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Lea Ann Fracasso

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DEVELOPING IMMUNITY: THE CHALLENGES IN MANDATING VACCINATIONS IN THE WAKE OF A BIOLOGICAL TERRORIST ATTACK

Lea Ann Fracasso

INTRODUCTION

A man enters an emergency room in Chicago, Illinois. The patient presents with fever, headache, nausea, and muscle aches. He is assumed to have the seasonal flu and is sent home with instructions to take ibuprofen for his fever and to drink fluids until the fever breaks. Although he spends most of his time at home, he does carry on with his regular errands during the day. He visits the bank, the grocery store, his children’s school, the dry cleaner, and his favorite coffee shop. After three days, he notices small red bumps on his tongue and inside his mouth. By the next day the bumps have become aggravated and break open.¹ The rash spreads to his arms and legs. He returns to the emergency room. Because the patient is not in immediate danger he waits approximately four hours in the hospital waiting room. When the doctor finally sees him, his ailment is no longer a mystery, but the source of it is. The man has smallpox. He will be contagious for approximately the next two weeks.

Once the doctor realizes that smallpox is present, the United States response is set in motion. The CDC is contacted and further testing confirms the diagnosis. By now, calls from all over the Midwest are coming in with reports of individuals with the same symptoms. One thing is clear - this is not an accident. The last case of smallpox in the U.S. occurred in 1949 and the last in the world occurred in Somalia in 1977.² Within days, reports from New York, Toronto, Mexico City, London, Madrid, Dubai, Mumbai, Sydney and Tokyo are also indicating the presence of smallpox. Whether the disease has jumped the borders by infected persons or each city represents an independent attack site is not clear. While governments

² Id.
respond quickly to the news, they are operating at a disadvantage. They are already approximately three weeks behind the beginning of the infection. The country’s federal law enforcement personnel will begin looking right away for a perpetrator because the most likely suspicion when confronted with a case of smallpox is bioterrorism. The global presence of the virus will necessarily involve the World Health Organization, which will assist countries in their response to the disease.

The smallpox vaccine has been heralded as extremely effective when administered before or within three days of exposure to the disease. Current U.S. stockpiles reportedly can vaccinate the entire population, but that may not be true for other countries. The first to be vaccinated will be those who came in contact with the infected individual. The CDC prioritizes whom should be vaccinated next, including health care workers and those who will investigate the attack and path of the disease. Those who present with symptoms are to be located and isolated if possible to prevent further spread of the disease. Various scholars put the potential death rate at more than 100,000 deaths within a year. During the smallpox “era” the mortality rate for unvaccinated individuals was around thirty percent. Death tolls in other countries may reach higher as developing nations struggle to respond to the needs of an infected population.

The above is just a short example of the possible ramifications of a sophisticated biological weapons attack. However, the scenario is well within the realm of reality, given the recent global outbreak of H1N1 and the global community’s preparation and response to that disease. H1N1 was first detected in the U.S. in April 2009. On June 11, 2009, the World Health Organization declared that a flu pandemic was underway. The U.S. ordered 250 million doses of the 2009 H1N1 vaccine, but the vaccine takes time to manufacture and was not readily available in large quantities. This resulted in long lines of individuals waiting to be immunized, as deployment of the vaccine was rife with problems. At the time of this writ-

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ing more than 206 countries have detected cases of H1N1 resulting in 6,750 deaths. Around 60 million people have been vaccinated globally.

This Paper will discuss the necessary vaccination response to a terrorist smallpox attack. Part I will discuss pre and post-attack considerations in the law of mandatory vaccinations. Part II discusses the pre and post-attack considerations in governmental responses to biological diseases. Part III discusses the liabilities of parties in a pre and post-attack scenarios.

PART I – PRE AND POST-ATTACK CONSIDERATIONS IN THE LAW OF MANDATORY VACCINATIONS

A. Immunization requirements Pre-Attack

The United States Supreme Court has consistently upheld a state’s requirement for immunizations. The state’s interest in exercising its police power pre-empts the individual’s interest in remaining unvaccinated. Public health officials are given broad discretion in regulating vaccinations that protect civilian populations. Courts have declared themselves ill suited to question the medical findings of a board of health, whose expertise is essential to the execution of a state’s police power. The means by which the state protects public health is within the discretion of the state so long as it does not run afoul of any federally protected constitutional right. A court will only involve itself in the manner in which the police power is executed if it is done in an arbitrary and unreasonable manner.

The Supreme Court has analyzed a state’s power to require vaccinations under the concept of the state’s police power. In Jacobson v. Massachusetts, a resident of Cambridge refused to be vaccinated against smallpox in violation of a city ordinance requiring vaccination or forfeiture of five dollars. A jury found Jacobson guilty of violating the statute and sentenced him to pay the five-dollar fine. The U.S. Supreme Court, upon review of the case, found no fault with the Massachusetts law requiring the vaccinations of individuals against smallpox. To allow an individual to

11 Zucht, 260 U.S. at 175.
12 Id. at 175.
13 Jacobson, 197 U.S. at 25.
14 Jacobson, 107 U.S. at 28; Zucht, 260 U.S. at 177.
15 Jacobson 197 U.S. at 11.
16 Id. at 38.
refuse the vaccine without any evidence that a vaccination would necessarily result in the individual’s death, or even a detriment to the individual’s health, would allow the individual to put the health and safety of the entire population of the state at risk. This was a risk the Court was unable to accept, stating:

    If such be the privilege of a minority, then a like privilege would belong to each individual of the community, and the spectacle would be presented of the welfare and safety of an entire population being subordinated to the notions of a single individual who chooses to remain a part of that population.17

The Court also noted that vaccination requirements existed in Britain, Denmark, Sweden, Prussia, Germany, Hungary, Switzerland, and Australia, evidencing that mandatory vaccination for smallpox has at least at one time been required in other countries across the world.18

In Zucht v. King, Rosalyn Zucht was prevented from matriculating to San Antonio, Texas city schools because she did not have a valid vaccination certificate and further refused to be vaccinated.19 The city also prevented Rosalyn from attending private schools in the city. Aside from finding that Rosalyn had not presented a valid federal claim, the Court noted, “in the exercise of the police power reasonable classification may be feely applied, and that regulation is not violative of the equal protection clause merely because it is not all-embracing.”20 The Court found that the ordinance in question was not arbitrary but was rather a proper exercise of “that broad discretion required for protection of the public health.”21

B. Pre-attack Exemptions to Vaccinations

States have cited to the Jacobson and Zucht opinions to justify mandatory vaccination programs and vaccination as a prerequisite to school attendance.22 These decisions are usually attacked under three competing theories: (1) parents’ right to make decisions regarding their own children, (2) the right of children to an education, and (3) religious or philosophical aversions to vaccination. All three of these arguments have failed to consistently persuade courts to allow for vaccination exemptions, although religious exemptions have gained ground due to statutory interpretation in

17 Id. at 37-38.
18 Id. at 32.
19 Zucht, 260 U.S. at 175.
20 Id. at 177.
21 Id.
some states. Medical exemptions alone remain a consistent barrier to vaccination.

1. Parents’ Right to Make Decisions Regarding Their Children

In the United States, parents’ choices regarding the raising of their children are protected under the Due Process Clause of the 14th Amendment to the Constitution and the Supreme Court’s interpretation of that clause. Under the clause, raising children is considered a fundamental right, and therefore a state’s attempt to interfere with that right will be evaluated using the strictest scrutiny. Legislation that interferes with the right must be necessary to achieve the state’s goal, which must be compelling. In *Troxel v. Granville*, a Washington court ordered the visitation of grandparents over the surviving parent’s objection.\(^2\) In reversing the lower court and allowing the parent to deny the visitation, the Supreme Court held that

so long as a parent adequately cares for his or her children (*i.e.*, is fit), there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent’s children.\(^2\)

This case follows a long line of cases finding in favor of the parent.\(^2\)

However, the *Troxel* opinion left open the possibility that if parents were unfit, then their decisions regarding their children would not be upheld.\(^2\) This was also accounted for in the *Jacobson* case, where the only exemptions allowed in the statute were upon the recommendation of a certified physician that a child was not well enough to receive the vaccine. The power of a parent to prevent state intervention is not limitless. In *Prince v. Massachusetts*, the Court examined a violation of Massachusetts’ child labor law.\(^2\) Prince, a Jehovah’s Witness, was aunt and guardian to a nine-year-old girl whom Prince allowed to distribute the religion’s magazines on the streets of Brockton, Massachusetts.\(^2\) Noting the general ac-

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24 *Id.* at 68-69.
25 *See, e.g.* Wisconsin v. Yoder, 406 U.S. 205 (1972) (finding compulsory public school attendance statute in violation of the Free Exercise Clause as to Amish and Mennonite which prohibited school beyond the eighth grade); Pierce v. Soc’y of Sisters, 268 U.S. 510 (1925) (striking down a law requiring children to attend public school when the parents wished to send their children to private schools); Meyer v. Nebraska, 262 U.S. 390 (1923) (striking down a Nebraska statute that prohibited the teaching of foreign languages to children); *West Virginia State Board of Education v. Barnett*, 319 U.S. 624 (1943) (holding that a school board could not expel students who did not salute the flag when doing so violated the instructions of their parents regarding their religion).
26 *Troxel*, 530 U.S. at 69.
28 *Id.* at 161.
quiescence to a parent’s choices, the Court detailed the role of the state in child development, stating, “[a]cting 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.”29 A state may more readily proscribe the conduct of children than that of adults. “Parents may be free to become martyrs themselves,” stated the Court, “but it does not follow they are free, in identical circumstances, to make martyrs of their children.”30 There is no question that such an analysis will allow for overriding parental objections to mandatory vaccinations. The Court in *Prince* expressly stated, “The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.”31

2. Fundamental Right to an Education

In order to ensure the vaccination of children, states have found it easiest to mandate vaccination as a prerequisite for school enrollment. As of 1999, every state has done so, requiring that parents vaccinate children against the most common childhood diseases including measles, rubella and polio, among others.32 If parents were to claim that such requirements restrict their children’s access to education, such a claim would fail on the basis that the child’s interest in education is not protected to the extent necessary to override a state’s decision affecting public health.

In *San Antonio Independent School District v. Rodriguez*, parents of students in the school district brought suit claiming that the method of funding schools in Texas from property taxes created substantial inter-district disparities in per-pupil expenditures.33 The Supreme Court held that access to education is not a fundamental right under the federal Constitution, stating that where wealth was involved equal protection did not require absolute equality or precisely equal advantages.34 In refusing to extend the full power of the Equal Protection Clause to school attendance, the Court stated, “the undisputed importance of education will not alone cause this Court to depart from the usual standard for reviewing a State’s social and economic legislation.”35 Some state courts have examined this

29 Id. at 166.
30 Id. at 170.
31 Id. at 166-67.
34 Id. at 24.
35 Id. at 35.
issue and decided differently from the United States Supreme Court, including the courts of Vermont and West Virginia. However, both of those states still continue to exclude children from school based on immunization requirements.

3. Pre-Attack Religious and Philosophical Exemptions

While neither parental rights, nor the importance of education will enable a parent to get around mandatory vaccinations laws, every state currently exempts certain individuals from the requirements of compulsory vaccination. Forty-eight states allow for exemptions to requirements based on religious objections. West Virginia and Mississippi do not allow for religious exemptions of any kind.\(^{36}\) Moreover, fourteen states recognize philosophical exemptions to vaccinations.

While some states allow authorities to probe the parent’s beliefs in order to ensure sincerity, other states require no showing at all that the parents or their purported religion truly hold the belief.\(^{37}\) For example, the Wyoming Supreme Court has ruled that the Wyoming statute requires the Department of Health to automatically issue a religious exemption once it is requested and that no further inquiry by the Department is permissible.\(^{38}\)

In contrast, a New York District court found that a parent’s request must demonstrate [] that the espoused beliefs are sincerely held and that the stated beliefs, even if accurately reflecting plaintiffs’ ultimate conclusions about the advisability of inoculation of their children, do in fact stem from religious convictions and have not merely been framed in terms of religious belief so as to gain the legal remedy desired.\(^{39}\)

However, although the religious belief must be sincerely held, the board is not permitted to pass judgment on the beliefs of the purported religion.\(^{40}\) In *Turner v. Liverpool Central School*, the district court upheld a religious exemption for a woman who was a member of the Congregation of Universal Wisdom, a mail-order religion that did not require adherence to any religious tenants.\(^{41}\) In other words, a state cannot question validity of a particular religion; it may only scrutinize validity of belief in that re-

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38 In re LePage, 18 P.3d 1177, 1179 (Wyo. 2001).
41 Id.
ligion.

Although the majority of states currently provide religious exemptions, nothing within the bounds of the federal constitution requires them to do so.\(^4\) In the wake of a serious outbreak, there is no reason to believe that a statute such as the one in *Jacobson v. Massachusetts* would not be upheld and that millions would be vaccinated over religious objections. Even if an outbreak does not occur, case law suggests that mandatory vaccinations would still be upheld.\(^4\)

For better or worse, the United States is made up of a relatively devout population. A 2007 survey by the Pew Forum found only 16.1 percent of American adults reported being “unaffiliated” with any religion.\(^4\) However, 5.8 percent of that segment claimed to believe religion was important in their lives, but they were not affiliated with any specific religion or church.\(^4\) This means that roughly ninety percent of American adults believe that religion plays a role in their lives. However, this does not mean that ninety percent of American adults also religiously oppose vaccinations. Courts have held that states are not required to provide religious exemptions.\(^4\) On the other hand, courts have not found that states are barred from allowing religious exemptions if they choose to do so. Parties seeking to strike down religious exemptions may do so under the Establishment Clause or the Equal Protection Clause.\(^4\)

**a. Challenges to Religious Exemptions**

**Based on the Establishment Clause**

The First Amendment of the U.S. Constitution reads, “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof.”\(^4\) The first half of this is known as the Establishment Clause. Laws do not usually run afoul of the Establishment Clause if they do not favor a single religion over any other.\(^4\) In *Lemon v. Kurtzman*, the Supreme Court pieced together a three-part test based upon its


\(^{43}\) Boone v. Boozman, 217 F. Supp. 2d 938, 954 (E.D. Ark. 2002) (stating “[t]he Supreme Court did not limit its holding in *Jacobson* to diseases presenting a clear and present danger.”).


\(^{45}\) Id.

\(^{46}\) McCarthy, 212 F. Supp. 2d at 948.


\(^{48}\) U.S. CONST. amend. I, cl.1.

earlier precedent to analyze whether a statute violates the Establishment Clause. The Lemon test requires (1) that the statute have a secular legislative purpose; (2) that its principal or primary effect must be one that neither advances nor inhibits religion; and (3) that the statute must not foster an excessive government entanglement with religion.

In Sherr v. Northport-East Northport Union Free School District, a New York statute required every child in New York State to be immunized against polio, mumps, measles, diphtheria and rubella. However, the law included a religious exemption to the mandatory vaccinations. The exemption provided that required vaccinations would “not apply to children whose parent, parents, or guardians are bona fide members of a recognized religious organization whose teachings are contrary to the practices herein required.” The Court held that the exemption contained in the New York statute was a “blatant” violation of the Establishment Clause. Applying the Lemon test, the Court found that the New York statute violated two prongs of that test. According to the Court, the statute worked to inhibit the religious practices of individuals who were not members of a state-recognized religion. The statute also caused the government to involve itself too deeply into questions of religious belief, in violation of the Lemon test.

States seeking to eliminate religious exemptions in the wake of a biological attack may seek to rely on the Establishment Clause. The reasoning of Sherr could be extended to strike down exemptions that are not as limiting as those in Sherr. Allowing religious exemptions necessarily advances religion by giving those who adhere to a religion priority status over the community’s collective health. Religious exemptions also necessarily entangle governments in questions of religious dogma by attempting to decipher which religious beliefs are sincerely held and therefore merit an exemption. Even the decision whether the belief is religiously held, or rather just a moral or philosophical opposition brings the government and courts “exceedingly close to the involvement with ecclesiastical matters against which the First Amendment carefully guards.”

51 Id. at 612-13.
52 672 F. Supp. at 84.
53 Id.
54 Id. at 89.
55 Id.
56 Id. at 90.
57 Id. at 92.
b. Challenges to Religious Exemptions Based on the Equal Protection Clause

Religious exemptions can also be fought on the basis of the Equal Protection Clause of the Fourteenth Amendment. That Amendment prohibits any state from denying “to any person within its jurisdiction the equal protection of the laws.” In *Brown v. Stone*, the Mississippi Supreme Court found that religious exemptions could not be justified under the Equal Protection Clause. The plaintiff in *Brown* sought admission of his son to public school without complying with the mandatory inoculations required for public school attendance. The Mississippi statute included a similar exemption to the one in the *Sherr* case. It provided:

A certificate of religious exemption may be offered on behalf of a child by an officer of a church of a recognized denomination. This certificate shall certify that parents or guardians of the child are bona fide members of a recognized denomination whose religious teachings require reliance on prayer or spiritual means of healing.

Brown attempted to supply a certificate of exemption from his local Church of Christ. However, the certificate stated only the Brown had strong convictions against the use of immunization, not that the church taught opposition to immunization. Brown challenged the exemption under the Free Exercise Clause of the First Amendment.

The Court went further than the opinion in *Sherr* and jettisoned the entire religious exemption from the statute. The Court found that the statute requiring immunization “serves an overriding and compelling public interest.” Further, the Court found that religious exemptions unfairly favor those children whose parents’ religious beliefs oppose immunizations to the detriment of the larger majority of children whose parents hold no such beliefs. The Court found this imbalance to be in violation of the Equal Protection Clause of the Fourteenth Amendment in that “it would require the great body of school children to be vaccinated and at the same time expose them to the hazard of associating in school with children exempted under the religious exemption who had not been immunized as required by the statute.”

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58 U.S. CONST. amend. XIV, § 1.
59 378 So. 2d 218 (Miss. 1979).
60 Id. at 219.
61 Id.
62 Id. at 222.
63 Id. at 223.
1. Post-Attack Religious Exemptions

Religious exemptions indisputably endanger the community in which the exemptions are granted. As the Court stated in Prince, a person “cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.” In the event of a biological attack, politicians must do what is best for the population, not for their own re-election concerns. The theory of herd immunity posits that once a critical mass of individuals within a community is vaccinated, the disease is unable to take hold and therefore vulnerable members of the community are protected.

To ensure public safety in the wake of an attack, religious exemptions must necessarily be eliminated. Authorities will have little time for protracted legal debates about the necessity to initiate mandatory vaccinations; therefore, a mechanism should already be in place to eliminate religious exemptions in the event of a declared biological emergency. Legislation similar to the PREP Act, which would allow the Secretary of Health and Human Services to issue a declaration under which all previous vaccination exemptions are recalled for evaluation, would go a long way in ensuring immunization levels that protect herd immunity.

The Johns Hopkins Center for Law and the Public Health Institute for Vaccine Safety has proposed draft exemption legislation for use by states in defining exemptions to mandatory vaccination programs. Under the Draft Exemption statute, exemptions based on the personal beliefs of the parent would be recognized. Individuals must be granted a Certificate of Exemption from Immunization issued by the public health department. However, in order to obtain a Certificate, the parents must explain their beliefs to the Department of Health personnel issuing the certificate and must show that they understand the risks of non-vaccination, including the need to remove the child from school should a communicable disease for which the child is not inoculated appear in the school. Additionally, the

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64 Prince, 321 U.S. at 166-167.
69 Id.
Department of Health could deny the application for a certificate on the grounds that it must protect the child's or the public's health after considering the risk factors of a given disease.\textsuperscript{70} The certificate of exemption would expire every twelve months, requiring a renewal of exemption.\textsuperscript{71}

The Brown opinion rather straightforwardly presents a valid Equal Protection Clause argument on which other states may rely in eliminating religious exemptions to their mandatory vaccination requirements. The reasoning that the Brown Court applied has not changed. Children of non-religious parents still disproportionately carry the burden of preventing infectious disease, and children with medical ailments disproportionately carry the risk of contracting a potentially fatal disease. This risk is even more pronounced in a post-attack environment.

\section*{2. Pre-Attack Medical Exemptions}

One area where states seem to agree is in regards to medical exemptions. All states allow for some form of medical exemptions. Children who are allergic to vaccines, have compromised immune systems, or would otherwise suffer more harm than good from receiving a vaccine are commonly granted exemptions from mandatory vaccines. One of the purposes of mass immunizations is to protect those individuals who cannot be vaccinated.\textsuperscript{72} The statute at issue in Jacobson also provided for medical exemptions for children, and the Court chose to read into the statute a possibility for adult medical exemptions, as well.\textsuperscript{73}

Under the John Hopkins Center for Law and the Public Health Institute for Vaccine Safety draft exemption legislation, medical exemptions would be recognized.\textsuperscript{74} However, even those claiming a medical exemption must receive a Certificate of Exemption from Immunization issued by the public health department. Even for a medical exemption, the Department of Health could deny the application for a certificate on the basis of the need to protect the child's or the public's health after considering the risk factors of a given disease.\textsuperscript{75} The certificate of exemption would expire every twelve months, requiring a renewal of exemption, just as it would for a religious exemption.\textsuperscript{76}

\begin{flushright}
\textsuperscript{70} Id.
\textsuperscript{71} Id.
\textsuperscript{73} Jacobson, 197 U.S. at 39.
\textsuperscript{74} Institute for Vaccine Safety, \textit{supra} note 68.
\textsuperscript{75} Id.
\textsuperscript{76} Id.
\end{flushright}
A re-evaluation of medical conditions is a good idea considering the changes in medical technology that affect vaccines, as well as underlying medical conditions which make vaccines unsafe for certain ailments or situations. If the vaccine formula changed, for example, it could allow for a previously excluded medical condition to no longer be adverse to the vaccination. Advances in medicine could also create cures or treatments for medical conditions, which would make them less susceptible to vaccine complications. Therefore, a periodic reassessment of medical exemptions would be the best way to approach medical exemption certification.

3. Post -Attack Exemptions

If the above biological attack were to happen in the United States, a massive effort to vaccinate individuals from smallpox should begin. Exemptions following a biological attack should be limited to the most critical medically necessary exemptions. The effort to vaccinate the U.S. population should be more aggressive than that which occurred in the years leading up to the eradication of the disease. Now, as then, the first to be vaccinated would be medical personnel, first responders, and those individuals who had individual contact with the infected population.\(^77\)

Although many Americans may have been vaccinated in the past, the relative effectiveness of that vaccination will be only three to five years.\(^78\) This means that anyone not vaccinated within the last five years would need to be revaccinated. There are currently more than 307 million people residing in the U.S.\(^79\) The vaccine should reach essential personnel and exposed individuals first. While the U.S. government has a purported vaccine stockpile large enough for the entire U.S. population, vaccinating this many people, or even a large percentage of this population, is going to take time.\(^80\)

States have the authority under the police power to require vaccinations, and as already discussed, the Supreme Court has upheld those laws as constitutional. As the Supreme Court noted in the *Jacobson* case, “Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be

\(^80\) Center for Disease Control and Prevention, supra note 78..
done to others.\footnote{Jacobson, 197 U.S. at 26.} In the \textit{Jacobson} decision, the Court pointed to the reasonableness of the vaccination ordinance given the conditions in Cambridge at the time the ordinance was passed.\footnote{Id. at 27.} The court noted that smallpox was “prevalent to some extent in the city” and that occurrences of the disease were increasing.\footnote{Id.} In the event of a bio-attack like that mentioned above, the prevalence of the disease would be growing and exist in major city centers.

At the time of the \textit{Jacobson} decision, mobility was nowhere near the rate it is today. In 1905, it may have been possible to stop the spread of smallpox by mandating local vaccinations. However, it is hard to believe that in today’s world, a local ordinance vaccinating a single city population would be enough to prevent the spread of a contagious disease like smallpox. In 1905, Cambridge was the fourth most populous city in Massachusetts with 97,434 people.\footnote{Edward M. Hartwell, \textit{Federal Census Reports: Statistics of Cities, 1905}, 11 \textit{PUBLICATIONS OF THE AM. STAT. ASSN} 195, 208 (1908).} In 2008, Cambridge was still the fourth most populous city in Massachusetts, with 105,596 people. However, the rest of the country has outstripped the growth in Cambridge. In 2008, it was estimated that there were 243 cities in the U.S. with larger populations.\footnote{U.S. Census Bureau, \textit{Population Estimates}, http://www.census.gov/popest/cities/SUB-EST2008.html (last visited Nov. 19, 2009).} Were the attack above to succeed in infecting populations within major U.S. cities such as Chicago and New York, the possible number of victims would be even larger. The speed at which the disease would travel around the country and around the globe would be similar to that of the 2009 H1N1 flu, which had affected 206 countries as of November 2009.\footnote{World Health Org., \textit{Pandemic (H1N1) 2009 – Update 75}, http://www.who.int/csr/don/2009_11_20a/en/index.html (last visited Nov. 19, 2009).}

There is little doubt that the Supreme Court would uphold any similar mandatory vaccination ordinances. However, the mandating of vaccines is sure to be met with resistance by individuals much like Jacobson himself. As biological science has matured and become more sophisticated, vaccines to even more childhood diseases come to the market. While smallpox is a potentially deadly and terribly contagious disease, states have also mandated vaccination as a condition to school attendance for disease such as tetanus and Hepatitis B. Relying on Supreme Court precedent such as \textit{Jacobson} and \textit{Zucht}, these requirements extend the Supreme Court’s rationale to those diseases, which pose a smaller public health threat, but nevertheless pose a threat to individual health.
The economic realities of unvaccinated populations affect the area of lost wages for parents who are forced to stay home with their sick but non-contagious children; this is another consideration in requiring vaccinations even if the spread of the disease does not seem as prevalent as feared. A terrorist attack involving a biological pathogen is likely to shake the economy in as yet unforeseen ways. A population susceptible to infection would only worsen the economic downturn that is sure to follow.

The court in *Jacobson* left open the possibility that a court would interfere if a state passed a public health regulation that was "so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression." However, in the wake of a biological attack, it is unlikely that any mandatory vaccination program against smallpox will be considered anything but necessary.

Medical exemptions may still be necessary, but those individuals granted an exception should submit to a screening and certification process. If the threat of the spread of the disease continues to last past a prescribed length of time, such as a year, the medically exempt individually should be required to apply for recertification. Both the initial and recertification process should take place in person with medical officials; in this way, the sincerity of the medical claim can be evaluated and a professional opinion rendered.

**PART II – GOVERNMENT RESPONSES TO BIOLOGICAL EMERGENCIES**

Today, safeguarding the public health is largely the realm of state governments, who are given guidance and support from a web of federal agencies. Following a biological terrorist attack, the governmental response to medical and biological needs of infected and not-yet-infected populations will necessarily involve the federal government as a lead actor in the struggle against a deadly pathogen.

**A. Pre-Attack Federal and State Tools for Responding to a Biological Emergency**

Today, issues of public health and safety fall largely under the purview of state public health officials. How public health offices are designed and function varies from state to state. The federal government provides planning, support, and guidance to state officials, but it largely leaves details to the states.

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87 *Jacobson*, 197 U.S. at 38.
The main agency of federal health planning and policy is the Department of Health and Human Services (HHS). Falling under the organizational umbrella of HHS is the CDC and the National Institutes of Health (NIH). The CDC serves as national epicenter for “developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States.” The CDC attempts to identify health issues and concerns in order to develop ways to treat and prevent such issues. CDC is also tasked with controlling the introduction and spread of infectious diseases and provides guidance and assistance to other state and international agencies in developing their own disease prevention strategies. On the development side, the NIH is the key federal agency for conducting and supporting medical research. NIH officials “investigate ways to prevent disease as well as the causes, treatments, and cures for common and rare diseases.” NIH is mostly concerned with research and development, whereas the CDC focuses more on policy.

The current mechanism of state execution with federal oversight is evidenced in the HHS response plans for pandemic influenza. While the plan provides for an overall strategy for fighting a flu pandemic, it leaves certain decisions in the hands of the states. The plan describes the federal role in a pandemic as it relates to collaboration with state authorities. Within the realm of state decision are those issues of purchase, distribution, and administration of vaccines. The plan also leaves the priority of vaccinations up to the individual states. States were given the opportunity to review the plan and develop their own plans in conjunction.

B. Post-Attack Federal Response to a Biological Emergency

Since a biological attack like that detailed above will have a nationwide if not global effect, it is imperative that the response to the attack likewise be nationwide in scope and authority. Therefore, in the event of a declared emergency following a biological attack, federal law and authority should usurp the traditional state police power in mandating vaccina-
tions. While the states have historically had control over those issues affecting the public health, federal power is necessary to ensure a speedy and standard response to the crisis. The exercise of federal power in a traditional state area requires an understanding of both (1) what unique tools the federal government has with which it can respond to an attack and (2) how to use those tools following a biological terrorist attack.

1. Post-Attack Federal Tools for Responding to a Biological Attack

Under the auspices of HHS, the CDC will most likely be the lead actor in any response to a biological attack. The CDC's regional entities would play a critical role in coordinating a response to a biological attack and positioning vaccines for distribution.

The federal government is already positioned through the Federal Emergency Management Agency (FEMA) to respond to national emergencies such as a biological attack. FEMA is tasked with disaster mitigation, preparedness, response and recovery planning. Parallels exist between FEMA's response to hazardous material incidents and probable actions in the wake of a biological attack.

A response to biological terrorism may also involve issues of national security and therefore require response from the Department of Homeland Security (DHS). DHS' Weapons of Mass Destruction and Biodefense Office provides a bio-aerosol environmental monitoring system in many major U.S. population centers. DHS also utilizes Project BioShield along with the U.S. Department of Health and Human Services to identify medical countermeasures and prepare to respond to biological attacks. With the weight of all these federal agencies prepared to respond in the advent of a biological attack, their collective decisions and directives should take priority over any state authority.

The World Health Organization (WHO) has the authority to order quarantine requirements in order to prevent a global spread of disease, which will be mirrored by actions taken by the U.S. federal government. The federal government can also take the lead in implementing and communicating WHO directives to regional and state authorities.

While the CDC handles the biological fallout of an attack, the Federal Bureau of Investigation will head the criminal investigation into the attack. The FBI is the lead investigative agency into all areas of counterterrorism,

95 KELLMAN, supra note 66, at 188.
specifically investigations involving weapons of mass destruction (WMD). In July 2006, the FBI consolidated all WMD investigations into a new WMD Directorate (WMDD). The head of the Directorate is a former scientist from Los Alamos National Laboratory in New Mexico. The Directorate focuses not just on post-attack investigation, but also countermeasures and preparedness. The FBI specifically utilizes InfraGard, an information sharing partnership between the Bureau and the private sector to take information and distill it into useful intelligence analysis. InfraGard could prove a very useful tool following a biological terrorist attack for identifying infection hot zones and concentrating law enforcement efforts in areas likely to bear evidence or clues regarding the origination of the disease.

Following a report to the FBI of something unusual, such as an individual exhibiting symptoms of small pox, a WMD coordinator from one of the fifty-six FBI field offices will begin constant communication with local authorities to monitor the situation. Between calls with local authorities, the local WMD coordinator will inform the WMDD headquarters about the alert. WMDD will consult with WMD experts to gain insight into the possible attack. The experts will participate in a conference call with the field office to ensure constant updates and communication. The experts then give advice as to what response scenarios would be appropriate for the Bureau to follow.

The federal government’s involvement in traditionally state police power actions usually requires justification under the Commerce Clause of the Constitution. While Commerce Clause jurisprudence has undergone significant changes over the course of this nation’s history, the basic understanding is that the federal government has the unfettered ability to pass legislation regarding interstate commerce. Stockpiles of smallpox vaccine are unlikely to be found solely within one state, and it is even more unlikely that any response to a smallpox epidemic would not require some amount of interstate commerce. Recent Supreme Court decisions require only a jurisdictional nexus between the law being passed and the federal

99 Id.
100 Id.
101 See Gibbons v. Ogden, 22 U.S. 1 (1824).
government’s constitutional authority to pass such legislation. Therefore, legislation regarding distribution of smallpox vaccine in the event of a declared national emergency need only contain a jurisdictional nexus to the federal government’s authority to regulate interstate commerce. This can be done by referencing the transportation and distribution of the vaccine stockpiles, thereby making its delivery to a state contingent on that state’s acceptance of federal requirements of mandatory vaccinations.

2. Post-Attack use of Federal tools

Once the federal government has established its authority to mandate vaccinations, it is necessary to ask how the federal government will ensure that its directives are being carried out by the states that may resent federal intrusion into this area of regulation. It is not likely that the federal government will have the necessary personnel to directly vaccinate large populations of the United States; therefore, that job will necessarily fall to the states. But how should the federal government ensure that federal guidelines and requirements for vaccinations are being followed? The federal government has many far-reaching tools to use in order to ensure compliance.

First, the federal government can cut federally funded programs in those states where immunizations are not being carried out according to federal guidelines and regulations. This can be legislation that either links the granting of federal dollars to health programs specifically or that links the granting of federal dollars to general programs. While the federal government will likely have control over the vaccine itself, delaying the distribution of the vaccine to non-complying states would not further the federal goal of protecting the public health and is thus not a viable option.

Alternatively, a system similar to that set up under the No Child Left Behind (NCLB) legislation could be incorporated regarding biological terrorism preparedness. In advance of a biological attack, specific milestones could be set for state health agencies. States that fail to meet those milestones would have an opportunity to take corrective action. Consistently underperforming states would risk federal intervention into programs if deficiencies were not eliminated. Federal health funds could be flexible, just as in the NCLB legislation. States would be permitted to use the funds in whatever way they see fit. This should be done prior to any

biological attack, since post-attack cooperation by states will inherently be less flexible. The protection of the public health following a biological attack is certainly no less serious than the concerns that led to the passing of NCLB.

**PART III – PRE AND POST-ATTACK LIABILITY CONSIDERATIONS**

As with any government interference in matters of health, there are sure to be those individuals who resent the legislation and will try to avoid complying with it. A biological attack also necessarily involves a substantial cost in both government resources and in the effect on a national workforce that is in one stage or another of being vaccinated against a deadly pathogen. The effects of the above recommendations fall into two categories: (A) practical impact, including the pre-attack and post-attack uses of quarantine, and (B) economic impact.

**A. Practical Impact**

Any biological attack that occurs in the next few years will find a current U.S. population that has become more skeptical of vaccinations and less willing to accept the assurances of doctors and governmental entities that espouse the benefits of vaccinations. A recent development in this area is the belief that vaccines are somehow linked to the onset of autism in children. Fervor in the belief of a connection is so extreme that immunologists have received death threats for their support of vaccine safety and childhood inoculations. Ironically, since children are arguably the most likely to be injured by any increase in non-immunized children, the move to not vaccinate them puts them at an even higher risk of harm than complications from vaccines.

Any issue that involves the safety of children is likely to be a lightning rod for debate. An essential step in mandating vaccines is to get accurate information to the public often and early. Any delay will allow quacks, hacks, pundits, and celebrities a chance to offer their own opinions as fact, undermining any government effort at protecting the public health. The Department of Health and Human Services in coordination with the National Institutes of Health have tried to combat the barrage of misinformation.

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mation regarding the flu on a specially dedicated website.\textsuperscript{108} The CDC also collaborated with the popular WebMD site to provide accurate and timely flu information to the public.\textsuperscript{109} However, government information systems are subject to the political realities of the countries in which they are located. While the U.S. has maintained a robust public information campaign during the H1N1 outbreak, this can be contrasted with the slow Chinese response to the 2002 SARS outbreak.\textsuperscript{110}

Providing prompt and accurate information to the public may also prevent ill-advised practices such as the “Swine Flu” parties that appeared in the wake of the 2009 H1N1 flu pandemic. According to the CDC,

‘Swine flu parties’ are gatherings during which people have close contact with a person who has 2009 H1N1 flu in order to become infected with the virus. The intent of these parties is for a person to become infected with what for many people has been a mild disease, in the hope of having natural immunity 2009 H1N1 flu virus that might circulate later and can cause more severe disease.\textsuperscript{111}

The CDC discourages this practice and recommends that people stay away from people infected with the disease. However, the topic would not have been brought up if groups of individuals in the country were not participating in such gatherings.

The Food and Drug Administration monitors fraudulent treatments and products related to disease outbreak.\textsuperscript{112} Profiteers will try to capitalize on the fear that a disease outbreak engenders. Considering the number of fraudulent H1N1 products,\textsuperscript{113} which seek to capitalize on fear over the disease, the number of scams following a biological terrorist attack will likely be exponentially larger. There are a number of laws of which these types of scams can run afoul, including FDA regulations and common mail fraud. The FDA monitors websites and attempts to alert consumers to threats as soon as they are discovered.\textsuperscript{114} However, the FDA’s resources are not limitless, and consumers should approach any supposed quick fix to an epidemic with caution. Once a website or product is added to the

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\textsuperscript{108} Dep’t of Health and Human Serv., Know What to do About the Flu, http://www.flu.gov/ (last visited Nov. 19, 2009).
\textsuperscript{110} KELLMAN, supra note 66, at 185.
\textsuperscript{113} Id.
\textsuperscript{114} Id.
FDA’s list of fraudulent products, it will remain on the list until contrary evidence is presented to the FDA. Some products appearing on the list are authorized treatments for other conditions but are not approved by the FDA for treatment of the disease claimed by the fraudulent website. The FDA is charged with taking regulatory action against such scams.

Given the resistance to immunizations, once vaccines are mandated, how can the government ensure that individuals are inoculated? For school-age children, this is readily answered by the current policy of mandating vaccinations for school attendance and daycare admittance. This has been the case for both public and private schools at both the elementary and collegiate level. In some cases, vaccinations have been required before a student can participate in interscholastic athletics.

For adults it may not be as simple as rounding up entire cities and making them stand in line. One possibility for states is to require a vaccination certificate before allowing a driver’s license renewal or vehicle registration renewal. States may also connect vaccinations to such things as state aid payments such as welfare or food stamps. However, states should be careful that such policies do not unduly burden only the poor populations of their communities. States could partner with employers to ensure that employees are vaccinated as a contingency to being allowed to work. Vaccination could be a condition on filing a tax return.

Federal governments can implement similar checks on vaccination at the federal level if necessary. Under the authority of the Federal Aviation Administration and the Transportation Security Administration, individuals would not be able to fly on commercial airplanes without a certificate of vaccination. Customs and Border officials could close the borders to anyone not vaccinated. While this is considered a drastic measure and was rejected during the beginning of the 2009 H1N1 outbreak, a biological attack of smallpox necessarily requires even more vigilance. A decision to immunize the entire population of the United States is a drastic step in itself and will have little practical effect if other individuals can enter or exit the United States without abiding by the same vaccination guidelines.

None of these policies is assured of reaching each and every individual in the country; each, in turn, has gaps that may or may not be filled by another policy. However, just as empirical evidence suggests that even a slight scrutiny of a requested religious exemption for vaccinations resulted in a significant decrease in those actually receiving an exemption, admin-

115 Id.
116 Id.
administrative red tape that would surround obtaining government services without a certificate of vaccination may promote vaccinations.\textsuperscript{118} All these policies will also demonstrate the seriousness of the government regarding the importance of the vaccine.

The Federal government should consider a plan of action prior to any biological attack. Any plan discussed and developed ahead of a biological attack will have better public reception than ad hoc reactions to a real and worsening situation post-attack. Taking steps to settle mandatory vaccine issues would be an important step in any preparation. While significant government resources should be aimed at preventing a biological attack to begin with, the government cannot stand by after an attack occurs and expect the public to be mollified by the effort put into prevention. If nothing is being done to respond to an attack, none of the prevention steps will matter at all to a community suffering the after-effects without relief. Considering the criticism already leveled at the White House’s level of preparation for a biological attack, the government should ensure that both its prevention and response plans are as thorough and comprehensive as possible.\textsuperscript{119}

1. Pre-Attack Quarantine law

In general, states are permitted under their police powers to prevent the spread of dangerous infectious diseases.\textsuperscript{120} At one time or another, every state in the United States has used the police power to enforce quarantine.\textsuperscript{121} At one time the federal government also tried to exercise its power to quarantine, but state quarantine regulation has largely usurped this.\textsuperscript{122} However, the power to effect quarantine is not limitless. Courts will only uphold those regulations they find to be reasonable.\textsuperscript{123} Under the police power, a state’s department of health has the power to “isolate persons who are throwing off disease germs and thereby endangering the public health.”\textsuperscript{124} The purpose of the isolation is to prevent the spread of disease to other individuals, not to quarantine a number of individuals within

\textsuperscript{118} Ciolli, supra note 32, at 295.
\textsuperscript{120} Jew Ho v. Williamson, 103 F. 10 (3d Cir. 1900); People ex rel Barmore v. Robertson, 134 N.E. 815 (1922); In re Smith, 40 N.E. 497 (1895).
\textsuperscript{121} Robertson, 134 N.E. at 817.
\textsuperscript{123} Jew Ho, 103 F. at 21.
\textsuperscript{124} Robertson, 134 N.E. at 819.
a large area where they may infect each other at will. General assumptions of exposure are not enough to subject an individual to quarantine. Public health officials must point to specific facts that evidence the existence of danger in the actual infection of the individual or his exposure.

In *Jew Ho v. Williamson*, public health officials quarantined twelve square blocks of San Francisco in response to nine alleged deaths from bubonic plague. In striking down the quarantine, the court noted that while a 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," it would not uphold a regulation that is not reasonably related to its stated purpose. The court reasoned that if the purpose of quarantine were to isolate those individuals who had been infected to keep them from spreading the disease, the regulation enacted by San Francisco officials would have the opposite effect.

In *People ex rel. Barmore v. Robertson*, a court upheld the quarantine of a woman known to be a carrier of typhoid fever. The court noted that quarantines are not uniform in nature, but subject to change with the individual facts of each case. However, the court was cautious in allowing quarantines in all cases, stating, “where danger of an epidemic actually exists, health and quarantine regulations will always be sustained by the courts.” The court further explained, “Health authorities cannot promulgate and enforce rules which merely have a tendency to prevent the spread of contagious and infectious diseases, which are not founded upon an existing condition or upon a well-founded belief that a condition is threatened which will endanger the public health.” Therefore, the authority of public health officials to effect quarantine is not limitless and cannot be based on speculation and conjecture, but should be designed to be effective and endure for only as long as the threat to public safety is imminent.

Perhaps the most analogous case to our scenario, In re *Smith*, involved the quarantine of two deliverymen who refused vaccination for

125 Jew Ho, 103 F. at 21-22; Robertson, 134 N.E. at 819.
126 Smith, 40 N.E. at 499.
127 Id.
128 Jew Ho, 103 F. at 10.
129 Id. at 21.
130 Id. at 22.
131 Robertson, 134 N.E. at 815.
132 Id. at 820.
133 Id. at 819.
134 Id.
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smallpox. The two men had delivered such items as trunks, bedding, furniture and other personal belongings to and from a heavily infected area of Brooklyn, New York. The Court struck down a quarantine of the two men despite the public health officials’ concern regarding the men’s exposure. In holding that the city could not detain the men in quarantine, the court stated “obviously, there must be an inspection of persons and things and the resulting discovery, if they are not actually ‘infected’ with disease, that they have been ‘exposed’ to it, and that the conditions actually exist for a communication of contagion, in order to bring into operation the power to isolate.” The court further found that the city health commissioner’s position and power did not give him the right to quarantine an individual on the basis of his refusal to be vaccinated. The court called it a rather “extraordinary declaration” to allow city health officials that breadth of power.

2. Post-Attack Quarantine considerations

Following a major biological terrorist attack, those assertions considered extraordinary in Smith may be warranted. Depending on the size of the infected population, health authorities may have to quarantine in their homes people who refuse to be vaccinated without any evidence of their being exposed to smallpox, at least until it can be ascertained that the individual is not infected. During the first few days following the attack, health officials will still be uncertain of the size of the attack, and the FBI may not yet know if the attacker has expended his entire stockpile of pathogen. While enforcing a quarantine is traditionally a state concern, the U.S. federal government has enforced a quarantine when there is “an ‘imminent threat to national security.’”

Once the massive immunization effort begins, those who still refuse to be vaccinated may have to decide between receiving the vaccine and facing quarantine. Quarantines should be used sparingly, as they stress already burdened medical facilities during an outbreak and present additional problems of finding locations to house those with no immunity to the current health crisis. For this reason, quarantines should also include the smallest number of individuals possible. As the court pointed out in

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135 Smith, 40 N.E. at 497.
136 Id. at 499.
137 Id. at 498.
138 Id.
139 Page, supra note 123, at 528 (quoting Victoria Sutton, Bioterrorism Preparation and Response Legislation -- The Struggle to Protect States' Sovereignty While Preserving National Security, 6 GEO. PUBLIC POL'Y REV. 93, 97 (2001))
Jew Ho, a quarantine that encompasses large swaths of territory is not likely to be effected, as those individuals will continue to interact and pass the contagion among themselves in an enclosed environment.140

Quarantines in response to vaccination refusal would not be preemptive but rather the result of a specific choice of an individual to not be immunized against smallpox, at least until it can be determined if the individual has been exposed to smallpox. If it is known that the individual refusing vaccination has had contact with an infected individual, then solitary quarantine would be authorized even under pre-attack considerations. If the individual has not been exposed to the disease, she can placed into a group quarantine with other community members who have refused the vaccine to protect this vulnerable group from infection until the rest of the community is sufficiently vaccinated as to protect this group.

Any quarantine also necessarily involves some measure of security, as some people will try to defeat the quarantine.141 Therefore, the security associated with the quarantine should be responsible to an authority subject to a command structure and working knowledge of the use of force spectrum available to ensure compliance with the quarantine.142 In modern parlance, quarantines are referred to as “isolation precautions” in cooperation with “infection control.”143 The WHO has issued International Health Regulations authorizing the WHO to initiate quarantines of people and goods if they are suspected of infection.144 The federal government, moreso than the individual states, has the money and the manpower to affect a successful quarantine initiative. However, the federal government’s power is limited in the realm of quarantine, so it should either be expanded by new legislation, such as the PREP Act, or expanded under existing legislation.145 However, again, quarantines should be used sparingly and only if no other measure is possible due to the cost and intrusiveness of quarantine.

**B. Economic Impact**

Quarantines are not the only significant cost of a biological attack. Responding to naturally occurring pandemics can be expensive.
ing to a malicious attack may cost significantly more. The current battle against the 2009 H1N1 flu strain has already taken an economic toll. In June 2009, Congress appropriated $7.65 billion to fight the flu, which included the H1N1 strain. Of that amount, $6.12 billion has reportedly been spent or set aside for vaccines and vaccine related materials. This does not even include the costs estimated for the closings of schools and the necessary corollary of parents missing work to be at home with sick children. Should the H1N1 become more fatal and serious, the estimated cost of fighting the virus will reach into the tens of billions. The Commission on the Prevention of Weapons of Mass Destruction, a bipartisan commission established by Congress in 2008 warned in a report to Congress that an anthrax attack using a crop-duster could create an economic impact to the tune of more than $1.8 trillion in cleanup and other additional costs.

Any consideration of expenditure must analyze the cost of mandating a vaccine weighed against the cost of letting the virus run its course with only voluntary vaccinations occurring. Clearly, a resurgence of the smallpox virus after such an effort to eradicate the disease would go against a century of public health policy. Taken in this light, not mandating vaccinations seems even more like a major policy mistake.

A serious question to be addressed is: who bears the costs of a violent pandemic following a biological terrorism attack? An additional consideration is that of tort liability, which involves two important aspects: (1) responsibility of non-vaccinated individuals for the spread of disease, and (2) responsibility of state and federal governments for side effects of mandatory vaccines.

1. Responsibility of Non-Vaccinated Individuals for the Spread of Disease

It will be difficult for governments to completely absorb the costs of fighting an intentionally catalyzed pandemic. Those refusing vaccinations without a medical exemption may be asked to bear a certain portion of the economic burden. In the Jacobson case, the criminal fine assessed against Jacobson was $5 for refusing to comply with the mandatory vacci-
The possibility of a fine may work to promote immunization, especially if the vaccination is free, but not getting a vaccination carries an economic cost. In New York, the Board of Education has created a policy requiring school principals to pay $2,000 for each day “an unvaccinated child is in school.” This cost shifting makes the individual schools responsible and answerable to the presence of unvaccinated children in the school.

As with any tort claim, a plaintiff must establish duty, breach, causation and damages. If a government were to mandate vaccinations for the protection of the community, each person in that community would be under a duty to receive a vaccination, unless medically exempted. The requirement of vaccination also establishes the minimum required standard in order to be in compliance with that duty. By refusing immunization, an individual would automatically be in breach of his duty to the public health of the community. The most difficult element to establish in the event of a biological attack would be causation. While causation could be established as to those who initiate the attack, it would be much more difficult to trace the source of the infection back to an individual who refused vaccination. This would be especially true if that person was subject to quarantine following his refusal. If the criminals are discovered, they may be liable for damages caused by the disease, but it is unlikely a plaintiff will gain much monetary satisfaction from an individual who commits a biological attack.

Another option would be for those who elect not to be vaccinated to pay into a fund established for disease monitoring or medical supplies. This method would negate the need for post-exposure proof of causation. In Donovan v. Phillip Morris USA, Inc., a putative class of smokers brought suit against a cigarette manufacturer. At the time the suit was filed, none of the class members were diagnosed with lung cancer or even being treated by a physician for suspected lung cancer. The only damages sought by the class were payment for a medical surveillance program that used advanced technology to screen the plaintiffs at an earlier state than previously available. The court noted that the class was asking for “medical expenses reasonably to be incurred because of the alleged negligence of Phillip Morris . . . These damages are indeed the only presently

150 Jacobson, 197 U.S. at 12.
151 Ciolli, supra note 32, at 294.
152 Rubin & Kasimow, supra note 108, at 117.
154 Id. at 895.
155 Id. at 897.
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provable damages for the impact these plaintiffs have suffered as a result of the alleged negligence of Phillip Morris.  The Court found that if the class could prove at least some sub-cellular changes that increased the plaintiffs’ risk of disease, along with the other elements of negligence on the part of Phillip Morris, then it could recover damages in the amount necessary for future medical monitoring. The Court left open the possibility that exposure to a toxin known to cause cancer could qualify for the same damages.

Following a biological attack, refusal to be vaccinated is an exactly the type of harmful conduct left open in Donovan. Depending on the prevalence of the disease, refusal to be vaccinated could be analogous to an abnormally dangerous activity in tort law. An abnormally dangerous (or ultra-hazardous) activity is one that cannot be mitigated or controlled no matter how much care is exercised. An intentionally unvaccinated individual in the middle of a serious biological attack is a risk that cannot be mitigated. The only mitigation available would be the vaccination of that individual — the refusal of which is the cause of her dangerous condition. The Second Restatement of Torts considers the following factors in deciding if something amounts to an abnormally dangerous activity:

(a) existence of a high degree of risk of some harm to the person, land or chattels of others; (b) likelihood that the harm that results from it will be great; (c) inability to eliminate the risk by the exercise of reasonable care; (d) extent to which the activity is not a matter of common usage; (e) inappropriateness of the activity to the place where it is carried on and; (f) extent to which its value to the community is outweighed by its dangerous attributes.

The last factor is clearly applicable in a non-vaccination scenario. The value of a non-vaccinated individual to the community does not outweigh its dangerous attributes. The danger to the community comes from the decision not to be vaccinated. In a minority of jurisdictions, foreseeability is added as a factor to deciding if an activity is abnormally dangerous. However, even were that to be applied in the case of non-vaccinated individuals, there is little trouble in foreseeing the particular harm caused by remaining non-vaccinated in the middle of a biological terrorist attack. Abnormally dangerous activities carry with them a strict liability standard. Therefore, any individual not vaccinated would be strictly liable for the harm caused by her non-vaccination.

156 Id. at 900.
157 Id. at 901.
158 Id. (emphasis in original).
159 RESTATEMENT (SECOND) OF TORTS § 520 (1977).
2. Responsibility of State and Federal Governments for Side Effects of Mandatory Vaccines

State and federal governments should assume liability for the side effects of the vaccine as the U.S. did during the 1976-1977 Swine Flu Immunization Program. Given the compelling justification for immunizing a population, it is important that the pharmaceutical companies are protected from liability when the government mandates vaccinations. The government payouts following that Program were a small fraction of what has already been paid to fight the 2009 H1N1 Flu, and a small fraction of the estimated costs of not providing vaccinations at all. Liability should also be limited to actual damages such as in the Support Antiterrorism by Fostering Effective Technologies Act of 2002. Punitive damages in the wake of a national emergency arising from a biological terrorism attack would be inappropriate. Another option would be to enlarge the Smallpox Vaccine Injury Compensation Program to include claims of those individuals inoculated following a bio-attack. This Program currently covers only specific personnel.

Mandatory vaccination of first responders necessarily invokes the question: to what extent is the government prepared to compensate a first responder who submits to vaccination, only to suffer serious side effects.

Further down the chain of responsibility is the liability of the government to first responders in the event of a biological emergency. If the government prepared for the emergency, then any claim of negligence on the part of first responders would thus be weakened. However, if the government fails to plan, or plans poorly, then negligence may become an issue. Illustrative of this issue are two lawsuits that arose from the 2003 SARS outbreak in Toronto, Canada. The suits alleged negligence on the part of the provincial government in responding to the SARS outbreak. In 2005, Congress enacted the Public Readiness and Emergency Preparedness Act (PREP Act). Under the PREP Act, the Secretary of HHS issues a declaration that allows for immunity from tort liability for claims “caused, arising out of, relating to, or resulting from” disease countermea-

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161 KELLMAN, supra note 66, at 153.
162 Id. at 154.
If the Secretary determines that the threats and conditions constitute a "present, or credible risk of a future public health emergency," then the immunity from tort liability is granted to "entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures" unless the harm is caused by the willful misconduct of those entities.\textsuperscript{166} Although a PREP Act declaration may arise at the same time as a federally declared emergency, the PREP Act declaration is not dependent on a declaration of national emergency and may be issued in isolation from any other federal action.\textsuperscript{167}

On October 10, 2008, the Secretary of HHS exercised this authority and issued a declaration "to provide targeted liability protections for smallpox countermeasures based on a credible risk that the threat of exposure to variola virus, the causative agent of smallpox or other orthopoxvirus and the resulting disease constitutes a public health emergency."\textsuperscript{168} The declaration remains in effect until December 31, 2015. The declaration claimed a starting date of January 24, 2008, almost nine full months before the declaration was even made. The PREP Act provides a crucial tool in the federal government's arsenal to ensure the continued production of critical vaccines and medication.

3. Criminal Responsibility

Of course, those individuals responsible for carrying out the smallpox attack can be held criminally liable for the results of their crime. What would be the responsibility of those individuals who refused vaccination? What if a parent refused vaccination of her child, and before the state can force a vaccination, the child falls ill and eventually died of smallpox infection? Under those circumstances, could the parent be held criminally liable under a theory of involuntary manslaughter resulting from the parent's negligence? These are all questions that communities will have to answer following a biological attack, and the answers will not always come easily. First, considering the confusion and chaos following a terrorist attack, it will take some time before law enforcement can adequately respond to accusations of negligently caused deaths of children. Second, if a parent has refused vaccination for her child, then she probably refused vaccination for herself. If a child falls ill with the disease, it is even more

\textsuperscript{166} Id.
\textsuperscript{167} Id.
likely the parent has likewise been ill. A government authority may not want to spend resources prosecuting smallpox victims for the deaths of their children.

CONCLUSION

There remains little question that in the wake of a major biological attack using smallpox, the United States has the means to provide vaccination for every individual in the country who would not be medically exempted. It is also evident that any requirement mandating smallpox vaccinations during this time will be upheld under *Jacobson* and *Zucht*.

In addition, under these Supreme Court decisions, any repeal of religious exemptions to vaccinations will be likewise upheld. After a biological attack, religious exemptions are an accommodation that the public health can no longer afford. The federal government stands better prepared to tackle the significant challenges and needs of a country reeling from a terrorist attack; it will require assistance from the states to implement vaccination regulations and to ensure that individuals are being vaccinated against smallpox. However, the federal government should take the lead in coordinating and planning any response to ensure standards are met, and to ensure that all individuals in the United States have a clear picture of the situation as it develops. Communication should come from quickly from a central office, with an authority only the federal government can supply.

Governments need to prepare for the inevitable results of such policies; they should be prepared to deal with non-complying individuals who, regardless of the consequences, insist on remaining unvaccinated. Governments should also set up a legal framework to deal with the side effects of the smallpox vaccine that will affect a small portion of those immunized. Vaccine producers should be protected from liability by either government indemnity or vaccine compensation programs. Any preparations made in advance of a biological attack will save the government time and money that would be far more significant if not considered until after the attack has taken place and the catastrophic consequences are already underway. The logic of the *Prince* case can be extended to the broader situation of a biological attack, and could read, "[People] may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their [neighbors]." Mandatory vaccinations protect people from their neighbors, even if they cannot protect people from themselves.

169 *Jacobson*, 197 U.S. at 39; *Zucht*, 260 U.S. at 175.
170 *Prince*, 321 U.S. at 170.