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Sara Mahmoud-Davis

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NOTE

BALANCING PUBLIC HEALTH AND
INDIVIDUAL CHOICE: A PROPOSAL
FOR A FEDERAL EMERGENCY
VACCINATION LAW[†]

Sara Mahmoud-Davis^{††}

Scenario: A cell of terrorists – at least one with a background in biology from a European university – obtains samples of the Ebola virus via a corrupt official at a poorly secured lab located in Eastern Europe. The virus is smuggled into a U.S. port aboard a freighter. At the port, one of the sleeper cell members, who easily entered the United States on a European Union passport, takes delivery and deploys the virus via multiple hosts in major U.S. cities.¹

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^{††} J.D. Candidate, Case Western Reserve University School of Law, 2010; M.A., The University of Chicago, 1999; A.B., Cornell University, 1997. I must thank my husband, Charles, for his enduring love and support that sustains me in all my efforts, and for the great sacrifices that he has made over the last three years. I wish to express my endless gratitude to my mother, Diane, for her tireless devotion to me, and for being my best friend on my journey through life. I am forever grateful to my father, Ali, for his unwavering belief in my abilities to accomplish my dreams, and for teaching me the power of faith and the importance of discipline and determination. I also wish to thank Professor Sharona Hoffman, faculty advisor of the Health Matrix Journal, for her encouragement and advice throughout the note writing process. I feel privileged to have been a member of the Health Matrix Journal and wish to thank the senior editorial staff for their assistance in publishing this Note.

¹ See BOB GRAHAM ET AL., WORLD AT RISK: THE REPORT OF THE COMMISSION ON THE PREVENTION OF WMD PROLIFERATION AND TERRORISM 4-9 (2008) (assessing the United States' activities, initiatives, and programs to prevent weapons of mass destruction ("WMD") proliferation and terrorism).

INTRODUCTION

The outbreak of a pandemic in the United States poses a real threat with the potential to produce severe social and economic disruptions and significant casualties. Even more likely to occur than the above low probability, potentially high impact scenario is a widespread natural outbreak of severe acute respiratory syndrome (“SARS”),² avian influenza A (“H5N1”),³ swine flu influenza A (“H1N1”),⁴ or newly emerged respiratory viruses that pose a global threat to the human population. Only recently have researchers made progress on vaccines to fight against these deadly viruses.⁵

Since 2001, the U.S. government has devoted considerable time and effort identifying potential vulnerabilities to biological attacks, promoting prevention strategies, and anticipating how best to respond should a large-scale biological attack ever occur.⁶ Furthermore, the global spread of naturally occurring infections such as SARS, H5N1, and H1N1⁷ recently have underscored the very real possibility of an epidemic or pandemic.

² See generally NAT’L INST. FOR OCCUPATIONAL SAFETY & HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION, SEVERE ACUTE RESPIRATORY SYNDROME (SARS), <http://www.cdc.gov/niosh/topics/SARS/> (last visited Oct. 10, 2009) (providing background information on SARS); Jason W. Sapsin et al., *SARS and International Legal Preparedness*, 77 TEMP. L. REV. 155 (2004) (providing background on the SARS virus and legal responses to SARS outbreaks).

³ See CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., KEY FACTS ABOUT AVIAN INFLUENZA (BIRD FLU) AND AVIAN INFLUENZA A (H5N1) VIRUS 2-3 (2006), http://www.cdc.gov/flu/avian/gen-info/pdf/avian_facts.pdf.

⁴ See CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., H1N1 (SWINE FLU): GENERAL INFORMATION, http://www.cdc.gov/h1n1flu/general_info.htm.

⁵ See Press Release, U.S. Food & Drug Admin., FDA Approves First U.S. Vaccine for Humans Against the Avian Influenza Virus H5N1 (Apr. 17, 2007), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108892.htm>; Press Release, PRNewswire-First Call, Novavax Announces Proprietary Method to Create SARS Vaccine and Renewal of NIH Funding for SARS Vaccine Development (May 22, 2008), available at <http://www.novavax.com/download/releases/SARs%20PR%20FO1.pdf>.

⁶ GRAHAM ET AL., *supra* note 1, at 26.

⁷ See information about H1N1 at <http://www.cdc.gov/h1n1flu/background.htm>. According to the CDC, H1N1 is a new flu virus of swine origin that first caused illness in Mexico and the United States in March and April, 2009. It is believed that H1N1 flu spreads in the same way that regular seasonal influenza viruses spread, mainly through the coughs and sneezes of people who are sick with the virus, but it also may be spread by touching infected objects and then touching your nose or mouth.

Following the attacks of September 11, 2001, the federal government has implemented a number of measures to increase its capacity to prevent, to prepare for, and to respond to health emergencies caused by terrorism or a natural outbreak.⁸ In December 2008, the Report of the Commission on the Prevention of Weapons of Mass Destruction (“WMD”) Proliferation and Terrorism stated:

The more that sophisticated capabilities, including genetic engineering and gene synthesis, spread around the globe, the greater the potential that terrorists will use them to develop biological weapons Prevention alone is not sufficient, and a robust system for public health preparedness and response is vital to the nation’s security.⁹

Currently, immunization requirements are legislated at the state level. Every state grants exemptions from school-based immunization programs for medical reasons and forty-eight states permit some form of religious opt-out. Twenty states also permit philosophical exemptions based on personal beliefs or conscience. In response to threats of terrorism and viral outbreaks, states have adopted new legislation or amended former emergency laws in anticipation of a public health crisis. The changes generally grant broad sweeping powers to state governors and health officials, including the power to order forced treatment and vaccination without specifying which exemptions, if any, will be granted to individuals in an emergency. Such changes could increase the chances for state abuse of power and lead to confusion during a mass vaccination campaign. Wisconsin and Florida are examples of states with the most lenient emergency compulsory vaccination laws.¹⁰ These states allow individuals to refuse vaccinations for medical, religious and philosophical reasons but reserve state authority to isolate or quarantine such individuals. By contrast, public health emergency laws in Arizona and Hawaii impose mandatory vaccinations and make no reference to allowing exemptions, even conditional opt-outs.¹¹

⁸ GRAHAM ET AL., *supra* note 1, at 25 (explaining that the Departments of Defense, Health and Human Services, Homeland Security, and other agencies have spent or allocated approximately \$50 billion for civilian biodefense since the 9/11 attacks, and by 2012 there probably will be 15 U.S.-based Biosafety Level 4 (“BSL-4”) labs – the highest level of biological containment, required for working with the most dangerous viruses – a triple-fold increase over the five labs that existed in 2001).

⁹ *Id.* at 23-24.

¹⁰ See WIS. STAT. ANN. § 252.041 (1)(a) (West 2008); FLA. STAT. ANN. § 381.00315(1)(b)(4) (West 2007).

¹¹ ARIZ. REV. STAT. § 36-787 (c)(1) (2008); HAW. REV. STAT. ANN. § 128-8(2)

As the potential for a nationwide or multi-state public health emergency grows, so does the need for a standardized policy on vaccination exemptions. Inconsistencies among states' emergency laws, as well as among the states' applications and interpretation of exemption provisions, create the potential for confusion and the trampling of individual rights in a large-scale interstate vaccination emergency.¹² Currently, the federal government lacks authority to exert control over a state's emergency vaccination plans, regardless of whether the plans are too lenient and severely risk the public's health or too rigid and unnecessarily restrict individual liberty.

In light of the current situation, this Note argues that emergency preparedness in the post-9/11 world depends, in part, on a reformulation of our federal health laws to include informed consent and reasonable opt-out provisions in the event of a multi-state or nationwide vaccination emergency. Recognizing that in an emergency the government may have a compelling interest to abrogate individual freedoms, this Note advocates that Congress can and should craft a federal vaccination law that minimizes the tensions among government power, public health, and individual choice.

Part I discusses the relationship between vaccinations and informed consent, including exemptions. Part II examines the scientific foundation for compulsory vaccination law and looks at the inherent tension between immunization exemptions and the public health. Part III establishes the constitutional basis for permitting religious exemptions and conditional rights of refusal, while excluding philosophical opt-outs. Part IV presents arguments in favor of a federal emergency vaccination law and proposes amending the Federal Public Health Service Act.¹³ Finally, Part V explains how the mass vaccination clinics would operate and describes the informed consent and opt-out process.

I. VACCINATIONS: INFORMED CONSENT, EXEMPTIONS, AND A CONDITIONAL RIGHT OF REFUSAL

Informed consent originated as a doctrine of tort law and evolved into its present-day incarnation, according to the American Medical Association ("AMA"), as a "process of communication between a

(West 2009).

¹² See *Interstate Measles Transmission from a Ski Resort – Colorado, 1994*, 43 MORBIDITY & MORTALITY WKLY. REP. 627 (1994) (describing a measles outbreak that affected ten states).

¹³ Public Health Service Act, 42 U.S.C. § 201 (2006).

patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention."¹⁴ The AMA states that the type of information that a medical practitioner should disclose and discuss with a patient before any treatment or procedure includes: the nature and purpose of the treatment, the risks and benefits, the available alternatives and the alternatives' risks and benefits, and the risks and benefits of not receiving or undergoing the treatment.¹⁵ In 1972, the District of Columbia Circuit first articulated this "patient-oriented" standard of informed consent in *Canterbury v. Spence*.¹⁶

Thirty-seven years after *Canterbury*, informed consent is applied to all medical procedures, with the exception of immunizations.¹⁷ Pursuant to the National Childhood Vaccine Injury Act of 1986 ("NCVIA"),¹⁸ federal law requires health personnel to provide each patient with a Vaccine Information Statement ("VIS")¹⁹ prior to administering a vaccine. The Centers for Disease Control and Prevention ("CDC") emphasize that the VIS provisions do not constitute informed consent.²⁰ A VIS only fulfills the federally mandated information requirements of the NCVIA. Additionally, a VIS only exists for the vaccines that are covered by the Vaccine Injury Compensation Program ("VICP")²¹ and briefly, in two pages, covers the general benefits and risks of a vaccine. Currently, healthcare workers who administer a vaccine covered by the NCVIA are required to provide a VIS to any individual who receives one of the covered vaccines.

Since Congress did not intend for the NCVIA to support a mass vaccination plan in a national public health emergency, NCVIA has limited application to current concerns of a bioterrorist attack or viral

¹⁴ AM. MED. ASS'N, INFORMED CONSENT, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml> (last visited Oct. 10, 2009).

¹⁵ *Id.*

¹⁶ 464 F.2d 772, 780 (D.C. Cir. 1972) ("The root premise [of informed consent] is the concept, fundamental in American jurisprudence, that '[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body. . .'" (quoting *Schloendorff v. Society of New York Hospital*, 105 N.E. 92, 93 (N.Y. 1914))).

¹⁷ See Karin Schumacher, Note, *Informed Consent: Should it be Extended to Vaccinations?*, 22 T. JEFFERSON L. REV. 89, 89, 91-93 (1999) (arguing in support of extending patient-based informed consent to vaccine programs).

¹⁸ 42 U.S.C. § 300aa-26 (2006).

¹⁹ CTRS. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., FACT SHEET FOR VACCINE INFORMATION STATEMENTS, <http://www.cdc.gov/vaccines/pubs/vis/vis-facts.htm> (last visited Oct. 10, 2009).

²⁰ *Id.*

²¹ 42 U.S.C. § 300aa-26 (2006).

outbreak. As of September 2008, the NCVIA was limited in scope, requiring the use of a VIS for only twelve vaccines.²² A VIS exists for eight other vaccines not covered by the NCVIA, including anthrax and smallpox.²³ However, if one of these eight vaccines is purchased under contract from the CDC, a “duty to warn” clause requires health-care personnel administering the purchased vaccine to make use of the relevant VIS.²⁴ I discuss in Part V some possible modifications to the VIS system as part of a federal emergency vaccination law.

Since no national immunization law currently exists and the federal government traditionally has allowed the states to develop and manage their own public health systems, a wide range of immunization policies have developed across the fifty states and the District of Columbia. While the Department of Health and Human Services (“HHS”) and the CDC provide guidance to the states regarding disease prevention and best practices for school vaccination requirements,²⁵ state legislatures have all independently fashioned vaccination statutes that differ greatly from one another, and, separately, state courts have interpreted and applied the statutes in a variety of ways.

Most notably, states have refrained from extending their state informed consent laws to vaccinations. Using broad-based state police powers, found applicable in the vaccination context by the Supreme Court in *Jacobson v. Massachusetts*²⁶ and *Zucht v. King*,²⁷ the states imposed compulsory vaccination laws, absent informed consent provisions. Perhaps as an alternative to informed refusal of treatment, state legislators created medical, religious, and philosophical exemp-

²² DTaP (includes DT), Td, Hib, Hepatitis A, Hepatitis B, Inactivated Influenza, Live Intranasal Influenza, MMR Pneumococcal Conjugate, Polio, Varicella, and any combination of these vaccines. Since “final” VISs have not been issued for Human Papillomavirus (“HPV”), Meningococcal, Rotavirus, and Tdap, their use is not technically mandated by the NCVIA. However, CDC states that the use of interim VISs is “strongly encouraged,” but not required. CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., FACT SHEET FOR VACCINE INFORMATION STATEMENTS, <http://www.cdc.gov/vaccines/pubs/vis/vis-facts.htm> (last visited Oct. 10, 2009).

²³ *Id.* The other six vaccines with optional VISs are Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, typhoid, and yellow fever.

²⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 22.

²⁵ THE COUNCIL OF STATE GOVERNMENTS HEALTHY STATES INITIATIVE, EXEMPTIONS FROM SCHOOL IMMUNIZATION REQUIREMENTS (2007), <http://www.healthystates.csg.org/NR/rdonlyres/7B29EF52-6408-4D67-904D-CFBE28AF35CA/0/ExemptionsLPB.pdf>.

²⁶ 197 U.S. 11, 38 (1905) (upholding state compulsory vaccination law).

²⁷ 260 U.S. 174 (1922) (dismissing a challenge to an ordinance requiring vaccination for public school admittance on the ground that *Jacobson v. Massachusetts* had conclusively decided the issue).

tions to vaccinations. However, unlike informed refusal of treatment, these opt-out provisions may be conditioned by placing restrictions on privileges, like the privilege of attending school. For example, during an outbreak of measles an unvaccinated child, exempt on a religious basis, would have to remain home from school until the outbreak subsided.

In addition to state-sanctioned immunization exemptions, states have had a long history of what may appropriately be called a conditional right of refusal where the state provides an individual with the option of either paying a fine or being imprisoned as an alternative to receiving a vaccine. For example, in *Jacobson v. Massachusetts*, the city of Cambridge fined residents five dollars if they refused vaccination during a smallpox outbreak.²⁸ More recently, in 2007, in Prince George's County, Maryland, the state's attorney summoned parents of more than 1,600 children to court, giving them a choice between vaccinating their children and facing penalties of up to ten days in jail and fifty dollars a day in fines.²⁹

The Supreme Court's long-standing ruling in *Jacobson v. Massachusetts* that grants states the authority to enact compulsory vaccination laws when there is a threat to public health and safety,³⁰ and the numerous state court opinions that have reaffirmed this state power underscore that in a federal emergency our government undoubtedly will rely on these familiar principles. Moreover, given the potential for precipitous reactions in a crisis, government officials at both the federal and state level are likely to impose even harsher vaccination mandates. As the Commission on the Prevention of WMD Proliferation and Terrorism summed up in their 2008 report to Congress, "the reaction of the political system to a major bioterrorist event would likely be extreme and even draconian."³¹

Accordingly, the federal government should not leave the states' reactions to a large-scale vaccination emergency to chance. Instead, the federal government should act swiftly to implement a federal emergency immunization law that balances public health concerns with individual liberty in a widespread crisis.

²⁸ *Jacobson*, 197 U.S. at 11; see discussion, *infra* Part III A.2

²⁹ ASS'N OF AM. PHYSICIANS & SURGEONS, DOCTORS OPPOSE MARYLAND VACCINE ROUNDUP: EXPECT DANGEROUS REACTIONS WHEN CHILDREN ARE TREATED LIKE CATTLE (Nov. 16, 2007), available at <http://www.aapsonline.org/press/nr-11-16-07.php>; Gail Russell Chaddock, *One Maryland County Takes Tough Tack on Vaccinations*, CHRISTIAN SCI. MONITOR (Nov. 19, 2007).

³⁰ *Jacobson*, 197 U.S. at 37-38.

³¹ GRAHAM ET AL., *supra* note 1, at 26.

II. HERD IMMUNITY: THE INTERDEPENDENCY OF THE INDIVIDUAL AND THE COMMUNITY

Vaccinations are a unique medical treatment because they not only affect the health of the patient who receives the injection, but also impact the health and welfare of the community-at-large. Because most vaccines protect against diseases that are transmitted from person to person, the concept of “herd immunity” calls for the immunization of a significant portion of the population so that individually vaccinated persons “serve as a protective barrier” against the disease within the community.³² Each person who receives a vaccine indirectly shields people who did not receive the vaccine and people for whom the vaccine failed.³³ The CDC explains that if Person B is immune from a disease because of vaccination, he will not contract that disease if he comes into contact with infected Person A. Because Person B is not infected, he will not pass on the disease to subsequent individuals, such as Person C. Thus, Person C is indirectly protected from the disease, even though he did not receive a vaccine.³⁴

Three key factors determine the percentage of the population that must be immunized in order to reach the herd immunity threshold: (1) the degree of the disease’s infectiousness; (2) the population’s vulnerability; and (3) the environmental conditions.³⁵ Generally, attaining herd immunity means reaching immunization rates between seventy-five and ninety-five percent.³⁶ For example, in the smallpox worldwide eradication campaign,³⁷ each country instituted a mass

³² KEVIN M. MALONE & ALAN R. HINMAN, VACCINATION MANDATES: THE PUBLIC HEALTH IMPERATIVE AND INDIVIDUAL RIGHTS 264 (2007), *available at* http://www.cdc.gov/vaccines/vacgen/policies/downloads/vacc_mandates_chptr13.pdf.

³³ *Id.*

³⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., HISTORY AND EPIDEMIOLOGY OF GLOBAL SMALLPOX ERADICATION 16 (2003), http://www.bt.cdc.gov/agent/smallpox/training/overview/pdf/eradication_history.pdf [hereinafter CDC SMALLPOX TRAINING].

³⁵ MALONE & HINMAN, *supra* note 32, at 265. The degree of a disease’s infectiousness refers, for example, to the fact that some diseases are more infectious than others, like measles is considered to be highly infectious compared to mumps. A population’s vulnerability might depend on whether or not it is a densely populated urban area or a less populated rural area. Environmental conditions include the time of year or season.

³⁶ CDC SMALLPOX TRAINING, *supra* note 34, at 17.

³⁷ *See* WORLD HEALTH ORGANIZATION, GLOBAL ALERT AND RESPONSE: SMALLPOX, <http://www.who.int/csr/disease/smallpox/en/> (2009) (showing that smallpox was officially eradicated in 1979, two years after the last case in Somalia).

vaccination program with the goal of immunizing at least eighty percent of its total population.³⁸

The present-day school immunization programs in all fifty states and the District of Columbia are rooted in the concept of herd immunity. While herd immunity supplies the scientific foundation for our existing vaccination laws, early court cases and the Supreme Court's seminal ruling in *Jacobson v. Massachusetts* provide legal support for the government to enforce compulsory vaccination.

III. A CONSTITUTIONAL FRAMEWORK FOR A FEDERAL EMERGENCY VACCINATION LAW

*It is a well-recognized fact that our public schools in the past have been the means of spreading contagious diseases throughout an entire community. They have been the source from which diphtheria, scarlet fever, and other contagious diseases have carried distress and death into many families.*³⁹

To establish a firm legal rationale for a federal emergency vaccination law, useful lessons can be drawn from the evolution of compulsory vaccination laws, particularly those related to school vaccinations. School immunization laws provide a guide for creating and limiting federal opt-out provisions in an emergency.

A. Defining the Limits of Police Power Within a Public Health Context

At the turn of the twentieth century, when smallpox outbreaks were a common occurrence, individuals increasingly began to question the police power of their local municipalities. Although the term "compulsory vaccination" was often used to describe state and local ordinances mandating immunization, it did not mean that the state would physically coerce an individual to submit to vaccination.⁴⁰ While the courts usually found that the exercise of police power was warranted, given the risk of the spread of disease, the courts also recognized that individuals were given a choice. Indeed, individuals

³⁸ Donald A. Henderson & Bernard Moss, *Smallpox and Vaccinia*, in *VACCINES* 74, 75-76 (Stanley A. Plotkin & Walter A. Orenstein eds., 1999).

³⁹ *Blue v. Beach*, 56 N.E. 89, 94 (Ind. 1900) (holding that the local board of health had the authority to exclude an unvaccinated child from public school for the duration of a smallpox threat).

⁴⁰ *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905); *Zucht v. King*, 260 U.S. 174, 176 (1922).

could either submit to vaccination or incur the statutory penalty, which was usually a fine, or in the case of schools, the penalty was exclusion from school.

1. Conditioning Privileges on Vaccination

A number of state courts, during this period, acknowledged that conditioning individuals' privileges – such as the privilege to attend school – upon vaccination was a legitimate use of police power when a reasonable health concern existed.⁴¹ For example, between November and December 1899, smallpox spread throughout the state of Utah.⁴² In response, the State board of health authorized local health authorities to enact rules, which required parents to demonstrate proof of their child's vaccination in order to attend public school.⁴³ Fearing an outbreak among the 12,000 public school children in Salt Lake City – more than half of whom were unvaccinated – city officials adopted the recommended precautionary measures.⁴⁴ Under the new policy, school officials denied admission to Florence Cox, a ten-year-old student, who refused vaccination and failed to present a certificate of vaccination.⁴⁵ The Utah Supreme Court upheld the school board's action, recognizing that it was justified due to the likelihood of a smallpox epidemic.⁴⁶ The Court carefully noted, however, that despite the urgent situation, local officials had no intention of compelling vaccination.⁴⁷ Rather, parents had the choice to allow their children to receive the vaccine or remain out of school until the risk of contagion passed.⁴⁸

In summary, *Cox* demonstrates that authorities generally pursued a policy of barring unvaccinated children from public school until the disease threat subsided, rather than forcing the children to be vaccinated. Presently there is no federal law to offer this same choice to those who seek vaccination exemptions in the event of an interstate health emergency. For this reason, Congress should include a conditional right of refusal in a federal emergency vaccination law, mirror-

⁴¹ *Duffield v. Sch. Dist. of City of Williamsport*, 29 A. 742, 743 (Pa. 1894) (upholding a school board's power to exclude a student from school during an epidemic because he refused vaccination and failed to provide proof of vaccination); see also *Blue*, 56 N.E. at 94.

⁴² *State ex rel. Cox v. Bd. of Educ.*, 60 P. 1013, 1014 (Utah 1900).

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.* at 1013-14.

⁴⁶ *Id.* at 1017.

⁴⁷ *Id.*

⁴⁸ *Id.*

ing the emergency laws in Wisconsin and Florida.⁴⁹ Thus, the federal government would have the discretion to isolate or quarantine an individual who refuses vaccination but does not qualify for a medical or religious exemption.⁵⁰

2. *Jacobson v. Massachusetts*: Establishing the Outer Limits of Police Power

In early 1902, as a response to the increasing prevalence of smallpox, the Board of Health of the city of Cambridge, Massachusetts, adopted a regulation – in line with a Massachusetts statute – requiring all persons to demonstrate proof of recent vaccination or submit to vaccination against the disease.⁵¹ The regulation imposed a five-dollar fine on all adults who “refuse[d] or neglect[ed] to comply” with the order.⁵² Reverend Henning Jacobson of the Swedish Lutheran Church not only refused the vaccine, but also refused to pay the penalty.⁵³ At trial, Jacobson pled not guilty, and the jury returned a verdict of guilty.⁵⁴ After considering several claims Jacobson made for exemption from the law, the Supreme Judicial Court of Massachusetts concluded that these claims merely reflected Jacobson’s personal opinion and did not entitle him to exemption.⁵⁵ Moreover, the court explained that, even if Jacobson had introduced expert testimony in support of his claims alleging the “injurious or dangerous effects of vaccination,” such testimony would not have changed the court’s ruling since “for nearly a century most of the members of the medical profession have regarded vaccination, repeated after intervals, as a preventive of smallpox . . . [and] risk of . . . injury too small to be seriously weighed as against the benefits.”⁵⁶ The court affirmed the trial court’s verdict, holding that the regulation reflected the legitimate

⁴⁹ WIS. STAT. ANN. § 252.041(1)(a) (West 2008); FLA. STAT. ANN. § 381.00315(1)(b)(4) (West 2009). See *supra* text accompanying note 10.

⁵⁰ See discussion of amending federal quarantine laws *infra* Part IV.B.

⁵¹ See *Jacobson v. Massachusetts*, 197 U.S. 11, 12-13 (1905).

⁵² *Id.* at 12.

⁵³ *Id.* at 13, 36; Suburban Emergency Management Project, *Who is Reverend Henning Jacobson?*, http://www.semp.us/publications/biot_reader.php?BiotID=653 (last visited Dec. 20, 2009). Mr. Jacobson refused vaccination in part by claiming that as a child he had suffered from significant pain for a long period from a disease caused by vaccination and that he had witnessed his son among others have similar reactions to vaccinations. *Id.*

⁵⁴ *Jacobson*, 197 U.S. at 13-14.

⁵⁵ *Id.* at 23-24 (quoting *Commonwealth v. Jacobson*, 66 N.E. 719 (Mass. 1903)).

⁵⁶ *Id.* at 23-24.

use of state power on behalf of the welfare of the people.⁵⁷ The court ordered that Jacobson remain in custody until he paid the fine.⁵⁸

The U.S. Supreme Court, in a majority opinion written by Justice Harlan, considered whether the Massachusetts law infringed upon any right granted or secured by the U.S. Constitution.⁵⁹ The Court established that, under the general authority of its police power, Massachusetts – just as any state – had the ability to enact legislation for the protection of its citizens' health and safety.⁶⁰ Jacobson argued that the State restricted his freedom by subjecting him to a fine or imprisonment for refusing or neglecting to submit to vaccination.⁶¹ The Court famously responded to Jacobson's contention with the following statement:

[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.⁶²

The Court explained that the state had a duty to protect the welfare of the many and to refrain from subordinating their interests to those of the few.⁶³ Consequently, the Court held that Massachusetts' law was constitutionally valid, having determined that it substantially related to the goal of stopping the spread of smallpox.⁶⁴ The Court emphasized, however, that a state's exercise of police power did not permit it to jeopardize the health or life of an individual.⁶⁵ For this reason, today, all fifty states and the District of Columbia grant exemptions from school vaccination requirements for individuals who demonstrate medical necessity.⁶⁶

⁵⁷ *Id.* at 14, 24.

⁵⁸ *Id.* at 14.

⁵⁹ *Id.* at 25-26.

⁶⁰ *Id.* at 25, 27.

⁶¹ *Id.* at 26.

⁶² *Id.*

⁶³ *Id.* at 28-29.

⁶⁴ *Id.* at 31-34 n.1, 39 (citing the global history of vaccination law and statistics to illustrate the success of vaccines in preventing disease).

⁶⁵ *Id.* at 38-39. Although Jacobson claimed that he had suffered as a child from an adverse reaction to a vaccine, he failed to present any medical evidence of the sort or a physician's recommendation that he was not a candidate for the smallpox vaccine.

⁶⁶ National Conference of State Legislatures, States with Religious and Philosophical Exemptions from School Immunization Requirements, <http://www.ncsl>

Likewise, in vaccination clinics set up in emergency situations (hereinafter, emergency vaccination clinics) a signed form from a physician or evidence of a medical condition that would endanger the health of the person who received the vaccine would justify an exemption from immunization.

B. Demanding the Right in an Emergency to Freely Exercise One's Religion

In addition to exemptions based on pre-existing medical conditions, objections on religious grounds have long been recognized by nearly all states as a valid exercise of an individual's First Amendment rights.

One of the earliest state cases to address the intersection of religion and vaccinations was *City of New Braunfels v. Waldschmidt* in 1918.⁶⁷ New Braunfels, Texas, in 1916, adopted an ordinance mandating proof of smallpox vaccination in order for a child to attend public or private school.⁶⁸ The city, and the neighboring towns of San Antonio and San Marcos – all three connected by rail and highway – experienced a smallpox epidemic in the fall of 1916, prompting the schools to close for a month.⁶⁹ Waldschmidt, a member of the Christian Science faith, sued the city when the school denied his children admission for failure to present certificates of vaccination.⁷⁰ The father claimed that his family's belief in Christian Science healing should exempt his children from vaccination.⁷¹ The Texas Supreme Court upheld the ordinance, concluding that the ordinance merely denied the children the privilege of attending school until they complied with the law, which was “passed for their own protection and for the protection of their families, along with all others residing in the community.”⁷² The Court emphasized that its ruling permitted the parent to make a choice – the state would not impose “compulsory vaccination” nor prosecute the parent for withdrawing the children from school.⁷³

[.org/programs/health/schoolexemplawschart.htm](http://www.texas.gov/programs/health/schoolexemplawschart.htm) [hereinafter School Immunization Requirements] (last visited Oct. 10, 2009).

⁶⁷ *City of New Braunfels v. Waldschmidt*, 207 S.W. 303 (Tex. 1918).

⁶⁸ *Id.* at 303.

⁶⁹ *Id.* at 303-04.

⁷⁰ *Id.* at 304.

⁷¹ *Id.*

⁷² *Id.* at 307.

⁷³ *Id.* (explaining that an unvaccinated child who remained at home would not be violating the law of compulsory education since he would fall within the law's exemption of being physically unfit to attend school).

Twenty-six years after *City of New Braunfels*, the U.S. Supreme Court in *Prince v. Massachusetts*,⁷⁴ addressed the reach of state power when it comes into conflict with both freedom of religion or conscience and a parent's right to rear her children. The Court, in reviewing prior decisions that respected parental authority,⁷⁵ emphasized that state action could not impinge upon religious freedom unless it was "shown to be necessary for or conducive to the child's protection against some clear and present danger."⁷⁶ With respect to health concerns, the Court explained that a state could interfere with the freedom of religion when an individual puts the community at risk of exposure to communicable disease or puts a child at risk of ill health or death.⁷⁷ Moreover, the Court underscored that all requests for religious exemption from compulsory vaccination should be treated equally, regardless of whether a parent is making a claim on behalf of a child or a parent is making a claim on behalf of herself.⁷⁸

Although *City of New Braunfels* and *Prince* involve challenges to state laws, these decisions are directly applicable in crafting a federal law for mass vaccinations during a public health crisis. While both cases reaffirm the government's right to pass and enforce compulsory

⁷⁴ 321 U.S. 158, 170 (1944) (holding that a Massachusetts statute that made it unlawful for a parent or guardian to permit a minor to work did not violate the freedom of religion nor the Equal Protection Clause, as applied to a guardian who furnished a minor with religious literature and permitted the minor to publicly distribute it, even though the adult and minor both acted in accordance with their religious beliefs).

⁷⁵ See, e.g., *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 535 (1925). In *Pierce* the Court held that an Oregon ballot initiative that would require all children to attend public schools violated the Due Process Clause. In the majority opinion, Justice McReynolds wrote that children were not "the mere creature[s] of the state" and that a child's parents or guardians had the right to make educational choices under the liberties protected by the Fourteenth Amendment. *Id.* Justice Kennedy, dissenting in *Troxel v. Granville*, 530 U.S. 57, 95 (2000), reasoned that, if decided more recently, the initiative in *Pierce* might have been found unconstitutional on First Amendment grounds since its effect was to eliminate parochial schools. However, it was not until after the decision in *Pierce* that the Supreme Court, in *Gitlow v. New York*, 268 U.S. 652, 666 (1925), determined that the provisions of the First Amendment were applicable to the states.

⁷⁶ *Prince*, 321 U.S. at 167; cf. *Schenck v. United States*, 249 U.S. 47 (1919), *abrogated by* *Brandenburg v. Ohio*, 395 U.S. 444 (1969) (laying out in *Schenck* the limits of free speech, Justice Oliver Wendell Holmes, Jr., writing an unanimous opinion, established the "clear and present danger" test and held that the First Amendment did not protect speech encouraging insubordination during war time or falsely shouting "fire" in a crowded theater).

⁷⁷ *Prince*, 321 U.S. at 167-68 (citing *People v. Pierson*, 68 N.E. 243 (N.Y. 1903)).

⁷⁸ *Id.* at 167 (citing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)). See *supra* notes 40-65 and accompanying text for a discussion of *Jacobson*.

immunization ordinances, these decisions also illustrate a clear government interest in balancing public health and freedom of religion. The tradition of balancing these potentially competing interests dates back to the founding of our nation. In 1777, John Jay, then Chief Justice of New York and later the first Chief Justice of the U.S. Supreme Court, referred to Article 38 of the New York Constitution of 1777, stating:

Adequate security is also given to the rights of conscience and private judgment. They are by nature subject to no control but that of the Deity and in that free situation they are now left. Every man is permitted to consider, to adore, to worship his Creator in the manner most agreeable to his conscience. No opinions are dictated, no rules of faith prescribed, no preference given to one sect to the prejudice of others. The constitution, however, has wisely declared, that the "liberty of conscience thereby granted shall not be so construed as to . . . justify practices inconsistent with the peace or safety of the State."⁷⁹

1. Emergence of Religious Exemptions Based on Deeply Held Beliefs

Beginning in the 1960s, the U.S. Supreme Court and state court decisions carved out religious-based exemptions to a host of state laws related to, *inter alia*, compulsory school attendance,⁸⁰ receipt of unemployment benefits,⁸¹ use of the hallucinogenic plant peyote in Na-

⁷⁹ JOHN JAY, CHARGE TO THE ULSTER COUNTY GRAND JURY (Sept. 9, 1777), reprinted in THE FOUNDERS ON RELIGION: A BOOK OF QUOTATIONS 135 (James H. Hutson ed., 2005) (citing THE CORRESPONDENCE AND PUBLIC PAPERS OF JOHN JAY VOL. 1, 162-63 (Henry P. Johnston ed., Da Capo Press 1971) (1777)).

⁸⁰ See, e.g., *Wisconsin v. Yoder*, 406 U.S. 205 (1972) (holding that a state compulsory school-attendance statute could not be constitutionally applied to Amish children after the 8th grade since it was contrary to the Amish religion and violated their rights under the Free Exercise Clause of the First Amendment).

⁸¹ *Sherbert v. Verner*, 374 U.S. 398 (1963) (holding that the denial of unemployment benefits to a member of the Seventh-day Adventist Church, who was fired for refusing to work on the Sabbath, caused a substantial burden on the individual, thereby violating the Free Exercise Clause of the First Amendment); see also Religious Freedom Restoration Act of 1993 ("RFRA"), 42 U.S.C. § 2000bb-1(b) (2006) (adopting the Supreme Court's compelling interest test set forth in *Sherbert v. Verner* and *Wisconsin v. Yoder*); see *infra* note 105 (explaining the compelling interest test); *Gonzales v. O Centro Esp. Benef. Uniao do Vege.*, 546 U.S. 418, 439 (2006) (concluding that the federal government failed to meet its burden under the RFRA that its seizure of a sacramental tea, containing a Schedule 1 substance, served a com-

tive American rituals,⁸² and a patient's right to refuse lifesaving treatment.⁸³ The individual's free exercise of religion in these various situations did not interfere directly with the safety or health of others. By contrast, the efficacy of vaccination laws in preventing the spread of disease inherently relies upon the interdependent nature of herd immunity.⁸⁴ A community's herd immunity is measured by the ratio of resistant to susceptible members in the population.⁸⁵

Yet, despite the concept of herd immunity and the Supreme Court's ruling in *Jacobson v. Massachusetts* forty-eight states and the District of Columbia have religious-based exemptions to their compulsory school vaccination laws. Except for Mississippi⁸⁶ and West Virginia,⁸⁷ states have been unwilling to draft vaccination laws that make full use of the constitutional limits established in *Jacobson*. As noted by the U.S. district court in *Sherr v. Northport-East Northport Union Free School District*,⁸⁸ the disparity between the permissible limits of the law and actual state practice may be explained by the fact that "inoculations offend certain individuals' religious beliefs."⁸⁹ As a result, for decades, state legislators have sought to minimize the

elling government interest).

⁸² *State v. Whittingham*, 504 P.2d 950 (Ariz. Ct. App. 1973) (holding that defendants use of the narcotic peyote was protected by the First Amendment because they were engaged in a bona fide religious ceremony).

⁸³ *E.g., In re Osborne*, 294 A.2d 372, 375 (D.C. 1972) (holding that a patient, who was a member of Jehovah's Witnesses, had the right to refuse a lifesaving blood transfusion on the grounds that it was against his religion).

⁸⁴ See discussion on herd immunity *supra* Part II. See also John C. Hershey et al., *The Roles of Altruism, Free Riding, and Bandwagoning in Vaccination Decisions*, 59 *ORG. BEHAV. & HUM. DECISION PROCESSES* 177 (1994) (suggesting that public health programs should stress high vaccination rates to increase vaccine usage).

⁸⁵ *THE AMERICAN HERITAGE MEDICAL DICTIONARY* 363 (rev. ed. 2007).

⁸⁶ See *Brown v. Stone*, 378 So. 2d 218, 223 (Miss. 1979) (holding that the religious-based exemption to the Mississippi compulsory school vaccination law violated the Equal Protection Clause of the Fourteenth Amendment because it "discriminated against the great majority of children whose parents have no such religious convictions."); see also *MISS. CODE ANN. § 41-23-37* (West 2008) (following the ruling in *Brown v. Stone*, the Mississippi legislature removed all reference to a religious exemption, permitting exemptions for medical reasons only, and failure to comply constitutes a misdemeanor, which is punishable by fine, imprisonment, or both).

⁸⁷ See *W. VA. CODE ANN. § 16-3-4* (West 2008) (permitting exemptions for medical reasons only, and charging any parent or guardian who fails to comply with a misdemeanor, which upon conviction would result in a fine of between ten and fifty dollars for each offense).

⁸⁸ 672 F. Supp. 81 (E.D.N.Y. 1987).

⁸⁹ *Id.* at 83.

burden of a state's inoculation program by creating exemptions for individuals whose religious beliefs conflict with immunization laws.⁹⁰

2. Lessons in Drafting a Religious Opt-Out Provision

Determining what constitutes a religious belief or practice presents a challenge to state and federal officials since "the very concept of ordered liberty precludes allowing every person to make his own standards on matters of conduct in which society as a whole has important interests."⁹¹ Case law demonstrates that legislators often run afoul of the constitutional principle of separation of church and state when attempting to define "religion" for the purpose of crafting religious-based exemptions. As the Supreme Court held in *Everson v. Board of Education*, the Establishment Clause of the First Amendment means that "neither [a state nor the federal government] can pass laws which aid one religion, aid all religions, or prefer one religion over another."⁹²

In creating a federal emergency vaccination law with religious-based opt-out provisions, case law underscores the importance of placing emphasis on "sincerely held religious beliefs" rather than on beliefs rooted in an "organized" religion.

a. Steering Clear of the Forbidden Fruit of "Recognized" Religions

The evolution of New York State's Public Health Law Section 2164⁹³ on compulsory school vaccinations serves as a good example of the fine line that legislators walk between crafting a constitutionally valid religious-based exemption and one that violates the First Amendment. In 1968, two years after the law's enactment,⁹⁴ in *McCartney v. Austin*, the Supreme Court of New York interpreted the meaning of the religious exemption when a parent of a school-age child refused to comply with the polio vaccine requirement.⁹⁵ At the time, the statute provided an exemption for any child whose parent or guardian was a "*bona fide* member[] of a *recognized* religious organization whose *teachings* are *contrary* to" the state practice of immuni-

⁹⁰ See *id.* at 88 (recognizing the New York State legislature's attempt to give due deference to the religiously-based opposition to compulsory vaccinations by providing for a religious exemption).

⁹¹ *Wisconsin v. Yoder*, 406 U.S. 205, 215-16 (1972).

⁹² *Everson v. Bd. of Educ.*, 330 U.S. 1, 15 (1947). See *Agostini v. Felton*, 521 U.S. 203, 222-23 (1997) (supplementing the Establishment Clause test).

⁹³ N.Y. PUB. HEALTH LAW § 2164(9) (2008).

⁹⁴ See *Sherr*, 672 F. Supp. at 86.

⁹⁵ *McCartney v. Austin*, 293 N.Y.S.2d 188, 190, 196-97 (N.Y. Sup. Ct.1968).

zation.⁹⁶ McCartney unsuccessfully argued that compliance with the law would force him to violate his conscience and moral convictions – in contravention of the teachings of his faith.⁹⁷ Although the court acknowledged that McCartney was a bona fide member of the Roman Catholic faith, it determined that there was no evidence that the teachings of Roman Catholicism prohibited immunization.⁹⁸ Concluding that the statute did not interfere with the McCartney family's freedom of worship, the court held that the child did not qualify for the religious exemption.⁹⁹

b. Widening the Scope: From Recognized Religions to Sincerely Held Beliefs

Nineteen years after *McCartney v. Austin*, the district court in *Sherr v. Northport-East Northport Union Free School District*¹⁰⁰ revisited the scope and constitutionality of the religious-based exception in section 2164(9).¹⁰¹ In *Sherr*, Sherr and Levy independently claimed that despite not belonging to any “recognized” religious group, the inoculations required by the law were contrary to their sincerely held beliefs and, as a result, qualified their children for the exemption.¹⁰² The district court held that section 2164(9)'s religious exemption – limited only to “members of a recognized religious organization” – expressly violated both the Establishment and Free Exercise clauses of the First Amendment.¹⁰³ With respect to the Establishment Clause, the court acknowledged that section 2164(9), by effectively granting preferential treatment to some religions over others, entangled the state in religious matters to an inordinate degree.¹⁰⁴

⁹⁶ *Id.* at 191 (emphasis added).

⁹⁷ *Id.* at 196 (claiming in his complaint that Roman Catholicism, despite not having any proscriptions against inoculation, requires him to follow his moral convictions and it is his “deep moral conviction that his son should not receive compulsory immunization”).

⁹⁸ *Id.* at 200.

⁹⁹ *Id.*

¹⁰⁰ 672 F. Supp. 81 (E.D.N.Y. 1987).

¹⁰¹ N.Y. PUB. HEALTH LAW § 2164(9) (McKinney 1987).

¹⁰² *Sherr*, 672 F. Supp. at 84.

¹⁰³ *Sherr*, 672 F. Supp. at 89, 91 (having decided the case on First Amendment grounds, the court never reached plaintiffs' challenges to § 2164(9) under the Equal Protection Clause of the Fourteenth Amendment).

¹⁰⁴ *See id.* at 88-91 (citing several Supreme Court cases addressing the Establishment Clause, including *Lemon v. Kurtzman*, 403 U.S. 602, 612-13 (1971), and concluding that section 2164(9) failed at least two of the three elements of the *Lemon* test, which mandates that the government's action: (1) must have a secular legislative purpose, (2) must not have the primary effect of either advancing or inhibiting religion, and (3) must not result in an excessive entanglement of government with reli-

Moreover, with respect to the Free Exercise Clause, the state failed to present a compelling justification for the burden the statute placed upon certain individuals' ability to freely exercise their religion while permitting others to avoid vaccination for religious reasons.¹⁰⁵ Although the state may have legitimate interests in limiting a person's ability to evade immunization and in minimizing the total number of people exempt from vaccination, the court concluded that a state may not arbitrarily discriminate along religious lines as New York did with section 2164(9).¹⁰⁶

The district court held that if New York maintained a religious-based exclusion to compulsory school vaccinations, it would have to widen its scope, offering the exemption to "all persons who *sincerely hold* religious beliefs" that forbid immunization.¹⁰⁷ In response, New York State amended section 2164(9), adopting the court's recommendation.¹⁰⁸

Sherr developed a two-part test for religious-based exemptions: (1) the beliefs asserted as grounds for exemption are religious in nature; and (2) the beliefs are sincerely held and stem from religious convictions.¹⁰⁹

c. Defining Beliefs of a "Religious" Nature

Turning to the question of whether, in *Sherr*, the plaintiffs' opposition to section 2164(9) stemmed from their religious beliefs, the

gion); cf. Susan Gellman & Susan Looper-Friedman, *Thou Shalt Use the Equal Protection Clause for Religion Cases (Not Just the Establishment Clause)*, 10 U. PA. J. CONST. L. 665, 674-78 (2008) (discussing the Supreme Court's application of the *Lemon* test and suggesting that the Equal Protection Clause provides a better standard for analyzing cases involving religion).

¹⁰⁵ *Sherr*, 672 F. Supp. at 90-91 (citing *Sherbert v. Verner*, 374 U.S. 398 (1963) (laying out a four-step inquiry in which it must be determined if "(1) a religious belief or practice is involved; (2) such a belief or practice is burdened by the governmental action in question; (3) a compelling state interest justifies such an infringement on First Amendment rights; and (4) even if such a compelling state interest is present, is there a less restrictive alternative that might allow the government to achieve its purposes without intruding upon religious liberty"). See *supra* note 81 for a discussion of *Sherbert* and its subsequent legal history.

¹⁰⁶ *Sherr*, 672 F. Supp. at 90-91.

¹⁰⁷ *Id.* at 98 (emphasis added).

¹⁰⁸ N.Y. PUB. HEALTH LAW § 2164(9) (2008) (stating currently, "[t]his section shall not apply to children whose parent, parents, or guardian hold genuine and sincere religious beliefs which are contrary to the practices herein required, and no certificate shall be required as a prerequisite to such children being admitted or received into school or attending school.").

¹⁰⁹ *Sherr*, 672 F. Supp. at 94; see also *Dalli v. Bd. of Educ.*, 267 N.E.2d 219 (Mass. 1971) (applying a similar sincerely-held standard).

district court considered the legal definition of religion under the First Amendment.¹¹⁰ In *Torcaso v. Watkins*, the Supreme Court held that state and federal laws must treat equally religions based on a belief in the existence of God and those religions based on different beliefs.¹¹¹ A few years later, in *United States v. Seeger*,¹¹² the Supreme Court further defined religion in addressing the claims of conscientious objectors. The Court interpreted section 6(j) of the Universal Military Training and Services Act,¹¹³ which defined “religious training and belief” as used in the Act, as “an individual’s belief in a relation to a Supreme Being involving duties superior to those arising from any human relation, but [not including] essentially political, sociological, or philosophical views or a merely personal moral code.”¹¹⁴ The Court determined that an individual’s belief qualified as a religious belief, if it was “sincere and meaningful” and it “occupied in the life of its possessor a place parallel to that filled by the God of those admittedly qualifying for the exemption.” The Court’s ruling in *Seeger* explained that the meaning of “religious” encompasses the notion of an individual’s “ultimate concern” and, therefore, reaches beyond the traditional Judeo-Christian or Muslim form of worship to polytheistic religions, such as Hinduism, and religions that lack the concept of one creator God, like Buddhism.¹¹⁵ Unlike section 2164(9) of New York’s Public Health Law, the Court’s test appropriately avoids the constitutionally impermissible classification of different religious beliefs, where some beliefs of a religious nature are exempt and others are not.¹¹⁶

Besides New York, currently, Hawaii,¹¹⁷ Maryland,¹¹⁸ Massachusetts,¹¹⁹ Nebraska,¹²⁰ and North Carolina¹²¹ provide religious exemp-

¹¹⁰ *Sherr*, 672 F. Supp. at 92-93 (citing Jesse H. Choper, *Defining “Religion” in the First Amendment*, 1982 U. ILL. L. REV. 579 (1982)).

¹¹¹ 367 U.S. 488, 495 (1961) (holding that Maryland’s requirement for a person in public office to state a belief in God violated the First and Fourteenth Amendments).

¹¹² 380 U.S. 163, 165 (1965).

¹¹³ 50 U.S.C. app. § 456(j) (1958).

¹¹⁴ *Seeger*, 380 U.S. at 165 (concluding that Congress’s use of “Supreme Being” instead of “God” in section 6(j) was intended to embrace all religions and to exclude political, sociological, or philosophical views).

¹¹⁵ *Id.* at 176, 187, 189-92.

¹¹⁶ *Id.*

¹¹⁷ HAW. REV. STAT. ANN. § 302A-1156 (West 2009) (referring to “bona fide religious tenets and practices”).

¹¹⁸ MD. CODE ANN., [EDUC.] § 7-403 (West 2008) (referring to “bona fide religious beliefs and practices”).

¹¹⁹ MASS. GEN. LAWS ANN. ch. 76, § 15 (1996) (referring to “sincere religious beliefs”).

tions based on sincerely held or bona fide beliefs. Although Maine allows for both philosophical and religious exemptions, religious objections must be rooted in sincere beliefs in order to qualify for an exemption.¹²²

d. Seeing Through Insincere Religious Beliefs

The district court in *Sherr* concluded that both Sherr and Levy espoused in their pleadings, affidavits, and courtroom testimony “religious” reasons for demanding exemption under section 2164(9).¹²³ Invoking the Supreme Court’s analysis in *United States v. Seeger* – to determine whether the plaintiffs’ beliefs were “truly held”¹²⁴ – the court in *Sherr* determined that only Levy was entitled to exemption.¹²⁵ Extending the Court’s principle in *Seeger* to compulsory vaccination law, the sincerity of one’s beliefs presents a threshold question of fact, which must be resolved in every case where someone requests an exemption from the law on religious grounds.¹²⁶ The district court warned that while an individual may possess sincerely held beliefs, instead of being rooted in religious convictions, those beliefs may merely be framed in religious terms to feign compliance with the law.¹²⁷ Discovering contradictions between Sherr’s espoused beliefs and his lifestyle, it became apparent to the district court that Sherr’s opposition to vaccinations was not rooted in religion but in his medi-

¹²⁰ NEB. REV. STAT. ANN. § 79-221 (West 2008) (calling for a signed affidavit “stating that the immunization conflicts with the tenets and practice of a *recognized religious denomination* of which the student is an adherent or member *or that immunization conflicts with the personal and sincerely followed religious beliefs* of the student.”) (emphasis added).

¹²¹ N.C. GEN. STAT. ANN. § 130A-157 (West 2008) (referring to “bona fide religious beliefs.”).

¹²² ME. REV. STAT. ANN. tit. 20-A, § 6355 (2008).

¹²³ *Sherr v. Northport-East Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 92 (E.D.N.Y. 1987).

¹²⁴ *United States v. Seeger*, 380 U.S. 163, 185 (1965) (explaining that the objective truth of a belief is not open to question, only whether the belief is “truly held”); *see also* *Int’l Soc’y for Krishna Consciousness v. Barber*, 650 F.2d 430, 441 (2d Cir. 1981) (stating that “[s]incerity analysis seeks to determine the subjective good faith of an adherent. . . . The goal, of course, is to protect only those beliefs which are held as a matter of conscience. Human nature being what it is, however, it is frequently difficult to separate this inquiry from a forbidden one involving the verity of the underlying belief.”).

¹²⁵ *Sherr*, 672 F. Supp. at 94-97.

¹²⁶ *Seeger*, 380 U.S. at 185.

¹²⁷ *Sherr*, 672 F. Supp. at 94; *see infra* pp. 23-25 (discussing the institution of practical measures to test individuals’ sincerity and thwart deception during an emergency mass vaccination program).

cal and philosophical views as a chiropractor.¹²⁸ By contrast, the district court noted that the Levys' "conception of human existence and the physical world *seems to pervade their whole way of life*, including their eating habits and methods of combating illness."¹²⁹

The *Sherr* case raises two issues. First, how much proof an individual must provide to demonstrate to the government the sincerity of the individual's religious beliefs. Second, how public health officials in an emergency will determine quickly and fairly whether an individual meets the requisite burden of proof.

i. Burden of Proof

In the case law, an individual requesting an exemption always carries the burden of showing a sincerely held religious belief by a preponderance of the evidence.¹³⁰ For example, in *Morin v. MGH Institute of Health Professions*, a health science student claimed that her objection to immunization was based on a religious belief, which stemmed from her upbringing. Specifically, Morin believed that "there is a unifying force in nature, rather than a supreme being, and that the introduction of foreign substances into the human body is contrary to that belief."¹³¹ Although Morin provided the court with evidence that she had never been vaccinated, she failed to present the court with any information regarding her religion.¹³² Morin failed to provide the court with any examples of other beliefs she held as a part of her religion or of religious rituals that she performed.¹³³ The Massachusetts court stressed that the lack of information made it unclear whether Morin's opposition to vaccines derived from a religious or a secular belief.¹³⁴ As a result, the court held that Morin failed to meet her burden of proof because she was unable to show that her objection was grounded in a sincerely held religious belief.¹³⁵

¹²⁸ *Sherr*, 672 F. Supp. at 96.

¹²⁹ *Id.* (emphasis added).

¹³⁰ See *Sherr*, 672 F. Supp. at 94; *Morin v. MGH Inst. of Health Professions*, No. 02-4484-F, 2002 Mass. Super. LEXIS 375, at *6 (Nov. 1, 2002); *Farina v. Bd. of Educ. of N.Y.*, 116 F. Supp. 2d 503, 508 (S.D.N.Y. 2000).

¹³¹ *Morin*, 2002 Mass. Super. LEXIS 375, at *6.

¹³² *Id.* at *6-7.

¹³³ *Id.* at *13.

¹³⁴ *Id.* at *6-7.

¹³⁵ *Id.* at *7; *contra* *Turner v. Liverpool Cent. Sch. Dist.*, No. 30, slip op. at 18 (S.D.N.Y. Mar. 8, 2001) (finding that plaintiff had limited knowledge of her church's tenets and her statements and actions were inconsistent with her beliefs opposing vaccination, but holding that she was entitled to relief because "the one consistent aspect of plaintiff's testimony was that she believed in a universal life force or wisdom and that immunization would be violating that life force").

Unlike in *Morin*, the plaintiffs in *Farina v. Bd. of Educ.* were members of an organized church and presented a considerable amount of documentation and testimony to support their religious beliefs.¹³⁶ However, the testimony was “evasive and inconsistent” with the documents the plaintiffs provided, and the plaintiffs admitted to having downloaded from the Internet information on immunizations and information on parents with similar beliefs.¹³⁷ The court found the evidence unconvincing, concluding that the plaintiffs’ beliefs were not the product of personal conviction, but rather “borrowed from outside sources.”¹³⁸

Sherr, *Morin*, and *Farina* underscore the inherent difficulties in discerning the sincerity and religious nature of one’s beliefs. In particular, the accessibility of the Internet and the proliferation of information on it about religion and vaccines makes the task of distinguishing between legitimate and fraudulent opt-out requests even harder.¹³⁹ While these courts were successful in identifying fraudulent or insufficiently documented exemption requests, the courts also had ample time to question the individuals and review their written statements and other documentation. In a mass vaccination scenario, clinics will have to make determinations quickly without the luxury of a court room.

ii. A Checklist to Aid Decision Makers in an Emergency

Public health officials working in an emergency vaccination clinic will need tools to assist them in evaluating religious-based opt-out requests. Although the two-step inquiry into religious convictions is naturally subjective, an official “may draw inferences from [an individual’s] words and actions in determining whether they hold genuine and sincere religious beliefs against inoculations.”¹⁴⁰ A key tool to assist officials in the assessment process could be a checklist of objective indicators of religion.

¹³⁶ 116 F. Supp. 2d 503, 508 (S.D.N.Y. 2000).

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ The online search query “vaccines and religion” produced 558,000 hits on Google (last visited Apr. 30, 2010). The first ten results included three stories from mainstream news agencies on parents using religion to avoid vaccines for their children, five blogs, a Wikipedia entry on the history of vaccines and religion, and the Vaccination Liberation Organization. The Vaccination Liberation Organization’s website includes definitions of religion and legal terminology, generic forms for use in requesting an exemption or writing a letter of refusal, biblical support for non-vaccination and a list of churches opposed to vaccines. See Vaccination Liberation, <http://www.vaclib.org/> (last visited Apr. 5, 2010).

¹⁴⁰ *Farina*, 116 F. Supp. 2d at 508.

Lower courts, building upon the broad definition of religion expressed by the U.S. Supreme Court in decisions like *Seeger* and *Torcaso*, have identified some factors to aid in deciding whether a set of beliefs is religious in nature. Factors that should be included in a checklist are:

First, a religion addresses fundamental and ultimate questions having to do with deep and imponderable matters. Second, a religion is comprehensive in nature; it consists of a belief-system as opposed to an isolated teaching. Third, a religion often can be recognized by the presence of certain formal and external signs.¹⁴¹

The Third Circuit, in *Malnak v. Yogi*, explained that the third factor might include "formal services, ceremonial functions, the existence of clergy, structure and organization, efforts at propagation, observation of holidays and other similar manifestations associated with the traditional religions."¹⁴² The court emphasized that these formal or external signs are not dispositive of the presence or absence of a religion but are useful to the inquiry. While public officials should incorporate the factors from *Malnak* into any religious-exemption inquiry, these factors alone are not completely determinative of the sincerity of one's religious beliefs.

Some additional guidelines for officials conducting a religious-exemption inquiry would include the following: (1) avoid impermissible assessments of the credibility or validity of an individual's beliefs;¹⁴³ (2) recognize that personal religious beliefs do not need to be consistent with the dogma or orthodoxy of the religion, regardless of whether or not an individual belongs to an "organized" religion;¹⁴⁴ (3) refrain from demanding a letter from the person's clergy or religious organization, as it is not obligatory;¹⁴⁵ (4) attempt to distinguish between personal fears and genuine religious beliefs;¹⁴⁶ (5) remember that a person's recent conversion to a religion is not dispositive of a fraudulent claim; (6) ask individuals to describe their religion in their own words, describing their belief system and lifestyle; and (7) scru-

¹⁴¹ *Africa v. Penn.*, 662 F.2d 1025, 1032 (3d Cir. 1981) (citing *Malnak v. Yogi*, 592 F.2d 197, 207-10 (3d Cir. 1979) (Adams, J., concurring)).

¹⁴² *Malnak*, 592 F.2d at 209.

¹⁴³ *Int'l Soc'y for Krishna Consciousness v. Barber*, 650 F.2d 430, 441 (2d Cir. 1981).

¹⁴⁴ See *Sherr v. Northport-East Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 91 (E.D.N.Y. 1987); *Farina*, 116 F. Supp. 2d at 508.

¹⁴⁵ *Farina*, 116 F. Supp. 2d at 508.

¹⁴⁶ *Id.* at 513.

tinize oral and written responses to a set of standardized questions, looking for inconsistencies.¹⁴⁷ The questions should address the factors discussed in *Malnak* and related issues such as the spiritual nature of the religion, the individual's religious experiences, the individual's past and current religious beliefs, the extent to which the individual incorporates his religious beliefs into his daily life, and the connection between the individual's religious beliefs and the requested exemption from vaccination.

Finally, an individual's religious beliefs may not prohibit the use of all immunizations, just certain types of vaccines. Depending on the state a person lives in, she might have a medical history that indicates she has received some vaccines, but not others. Officials should be aware of the potential for a discrepancy of this sort in a person's medical history and should pursue a full inquiry as described above, rather than automatically concluding that a person with this type of vaccine history lacks sincerely held religious beliefs. For example, Missouri, Oregon, and South Dakota, which all have religious exemptions for sincere beliefs, pursue a policy of partial exemption.¹⁴⁸ This means that parents may pick and choose the vaccines for which they would like to exercise their opt-out privilege.¹⁴⁹ By contrast, in Connecticut, any child whose parent claims a religious exemption is prohibited from receiving all vaccinations.¹⁵⁰ The general logistics of how the emergency vaccination clinics will operate are discussed in Section V of this Note.

¹⁴⁷ The general line of questioning performed by employers to determine the sincerity of an employee's religious beliefs for accommodation purposes may serve as a guide for officials who must perform a similar inquiry in an emergency vaccination situation. Title VII only requires employers to accommodate religious beliefs that are "sincerely held" and social, political, and economic philosophies, as well as personal preferences, are not "religious" beliefs protected by Title VII. The EEOC Compliance Manual provides some examples of the type of case-by-case inquiry that occurs within the employment context: "Religious observances or practices include . . . attending worship services, praying, wearing religious garb or symbols, displaying religious objects, adhering to certain dietary rules, proselytizing or other forms of religious expression, or refraining from certain activities. Determining whether a practice is religious turns not on the nature of the activity, but on the [individual's] motivation. The same practice might be engaged in by one person for religious reasons and by another person for purely secular reasons." EEOC Compl. Man., Directive No. 915.003 § 12-1 on Religious Discrimination (July 22, 2008).

¹⁴⁸ Sean Colletti, Note, *Taking Account of Partial Exemptors in Vaccination Law, Policy and Practice*, 36 CONN. L. REV. 1341, 1371 (2003).

¹⁴⁹ See *id.* at 1371.

¹⁵⁰ *Id.*

C. Drawing the Line between Secular and Non-Secular Beliefs

The number of individuals who might claim vaccination exemptions on philosophical grounds could pose significant risks to the public health and safety of the population of the United States in an emergency vaccination situation. Currently thirty states and the District of Columbia have compulsory school vaccine laws that only permit religious exemptions.¹⁵¹ The remaining twenty states permit some form of philosophical exemption.

In a nationwide or multi-state emergency where time is limited to inoculate the population, permitting individuals to claim an exemption based on their personal moral, ethical, or philosophical beliefs¹⁵² would likely: (1) seriously risk vaccination rates falling below the herd immunity threshold; and (2) jeopardize the efficiency of vaccine distribution by overtaxing limited resources to process exemption requests. Legal arguments and scientific data suggest that the Federal Government should deny philosophical exemptions in a mass vaccination emergency.

1. Constitutional Reasons for Denying Philosophical Exemptions in an Emergency

While individuals acting in accordance with religious beliefs may seek protection from the Religious Clauses, no similar constitutional protection exists for individuals who claim their way of life is built upon personal secular beliefs or philosophy.¹⁵³

Moreover, the Supreme Court's reasoning in *Texas Monthly, Inc. v. Bullock*¹⁵⁴ provides the government with a justification to deny phi-

¹⁵¹ School Immunization Requirements, *supra* note 66.

¹⁵² Hereinafter, referred to collectively as "philosophical" exemptions. See *supra* text Part III.B.2.c Defining Beliefs of a "Religious" Nature for an explanation of the distinction between philosophical and religious beliefs.

¹⁵³ U.S. CONST. amend. I; see *Wisconsin v. Yoder*, 406 U.S. 205, 215-16 (1972) ("A way of life, however virtuous and admirable, may not be interposed as a barrier to reasonable state regulation of education if it is based on purely secular considerations; to have the protection of the Religion Clauses, the claims must be rooted in religious belief . . . Thus, if the Amish asserted their claims because of their subjective evaluation and rejection of the contemporary secular values accepted by the majority, much as Thoreau rejected the social values of his time and isolated himself at Walden Pond, their claims would not rest on a religious basis. Thoreau's choice was philosophical and personal rather than religious, and such belief does not rise to the demands of the Religion Clauses.").

¹⁵⁴ 489 U.S. 1 (1989) (Six Justices held that a Texas statute violated the Constitution when it exempted religious publications from paying state tax, but denied the same tax-exemption to other non-religious literature. Five of the six Justices relied on the Establishment Clause for their ruling. The majority agreed that the statute consti-

philosophical exemptions during a vaccination emergency. The Court explained that it balanced two goals when previously considering legislative religious exemptions. Specifically, the Court focused on: (1) not imposing a substantial burden on non-beneficiaries, and (2) permitting others to act in accordance with their religious beliefs.¹⁵⁵ If the government were to permit philosophical exemptions in a vaccination emergency, it likely would find it difficult to avoid imposing a burden on non-beneficiaries.¹⁵⁶

The primary burden on non-beneficiaries (i.e., those individuals who are not entitled to an exemption) within a mass vaccination context arises from herd immunity concerns. Individuals who could claim an exemption based on a sincerely held religious belief constitute a small enough proportion of the population so as to not jeopardize the requisite herd immunity threshold. In 2005, only a few thousand of the 3.7 million children entering kindergarten claimed a religious exemption.¹⁵⁷ By contrast the number of individuals who might claim a philosophical-based exemption poses a significantly greater risk to the herd immunity, escalating the spread of the disease and harming the non-beneficiaries. The statistics in the next section provide an indication of the extent of the danger to public health that philosophical exemptions could pose in a mass vaccination emergency.

2. Scientific Reasons for Denying Philosophical Exemptions in an Emergency

Several studies have analyzed the effect on public health of philosophical exemptions to school vaccinations. It is inevitable that as the probability of contact between nonexemptors¹⁵⁸ and exemptors¹⁵⁹ in-

tuted impermissible preferential treatment by conferring a government subsidy to religious organizations.).

¹⁵⁵ *Tex. Monthly*, 489 U.S. at 18 n.8 (explaining that the majority opinion in “no way suggest[s] that *all* benefits conferred exclusively upon religious groups or upon individuals on account of their religious beliefs are forbidden by the Establishment Clause unless they are mandated by the Free Exercise Clause” (citing *Zorach v. Clauson*, 343 U.S. 306 (1952) and *Corp. of Presiding Bishop of The Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327 (1987))).

¹⁵⁶ Applying these goals to a philosophical exemption, they would be: (1) not imposing a substantial burden on non-beneficiaries, and (2) permitting others to act in accordance with their philosophical beliefs.

¹⁵⁷ Steve LeBlanc, *Parents Use Religion to Avoid Vaccines*, WASH. POST, Oct. 18, 2007, <http://www.washingtonpost.com/wp-dyn/content/article/2007/10/18/AR2007101800244.html>.

¹⁵⁸ Nonexemptors are individuals – in the case of children, a parent or guardian – who are not entitled to exemption or who do not exercise their exemption right.

creases, so too does the risk of acquiring a vaccine-preventable disease.¹⁶⁰ Such a risk of contact increases significantly in areas where state legislatures provide for philosophical exemptions.

One study found that seven of the ten states with the highest estimated rates of unvaccinated children had philosophical exemptions in addition to religious exemptions.¹⁶¹ States that allowed philosophical exemptions for child immunizations also had significantly higher estimated rates of unvaccinated children ranging from nineteen to thirty-five months old.¹⁶² The study also looked at the counties in America with the greatest number of unvaccinated children. Among the top twenty counties, seven of them were in California.¹⁶³ California's school immunization exemption is broad, allowing for exemptions based on "personal belief."¹⁶⁴ Los Angeles County, California had the largest numbers of unvaccinated children in America, followed by four counties in Michigan.¹⁶⁵ Like California, Michigan's school immunization exemption is very broad, allowing for exemptions based on "religious convictions or other objection[s] to immunization."¹⁶⁶

A different study looked specifically at the state of Colorado, which allows both religious and philosophical exemptions.¹⁶⁷ The Colorado statute permits exemption for "an adherent to a religious belief whose teachings are opposed to immunizations" and a "personal belief that is opposed to immunizations."¹⁶⁸ Over an eleven-year period in Colorado, the study found that philosophical exemptions accounted for eighty-seven percent of all exemptions.¹⁶⁹ During 1994,

¹⁵⁹ Exemptors are individuals—in the case of children, a parent or guardian—who exercise their exemption right.

¹⁶⁰ Philip J. Smith et al., *Children Who Have Received No Vaccines: Who Are They and Where Do They Live?*, 114 PEDIATRICS 187, 192 (2004) (stating that a model constructed using data from California showed that the incidence of acquiring measles increased from 5.5% to 30.8% as the probability of contact between non-exemptors and exemptors increased from 20% to 60%).

¹⁶¹ *Id.* at 193 (showing on a chart the estimated rates, based on data collected between 1995 and 2001; listing Utah, Colorado, Oklahoma, Maine, Washington, Idaho and Vermont as the seven states with the highest rates).

¹⁶² *Id.* at 190.

¹⁶³ *Id.*

¹⁶⁴ CAL. HEALTH & SAFETY CODE ANN. § 120325(c) (West 2006).

¹⁶⁵ Smith, *supra* note 160, at 190-91 (listing Detroit, Wayne, Oakland, and Macomb counties).

¹⁶⁶ MICH. COMP. LAWS § 333.9215 (2001).

¹⁶⁷ Daniel R. Feikin et al., *Individual & Community Risks of Measles & Pertussis Associated with Personal Exemptions to Immunization*, 284 JAMA 3145, 3145-46 (2000).

¹⁶⁸ COLO. REV. STAT. ANN. § 25-4-903 (West 2008).

¹⁶⁹ Feikin, *supra* note 167, at 3147 (using data from 1987-1998 and also finding that the percentage of philosophical exemptions among school-aged children in

the percentage of school-aged children who were unvaccinated in Colorado as a result of exemptions based on philosophical beliefs was 1.4 percent – more than twice the national average that year.¹⁷⁰

Overall, these studies reflect the inordinate health risk that could result from allowing philosophical exemptions in a federal law designed to deal with the emergency vaccination of a large percentage of the U.S. population.

IV. CREATING A FEDERAL STANDARD FOR MASS VACCINATIONS IN A MULTI-STATE EMERGENCY

A. Reasons for a Federal Law

The recent emergence of H1N1, H5N1, and SARS illustrates the rapid spread of contagious viruses in today's increasingly mobile society, and underscores that a nationwide or multiple state outbreak is a real threat to public health. Current state public health emergency laws inadequately address mass vaccination situations and leave wide-open the potential for the abrogation of individuals' rights. Amending federal law to ensure the protection of individuals seeking medical and religious exemptions in a national or multi-state vaccination emergency will preserve freedoms and enable the creation of a more coherent and coordinated strategy among the states in fighting contagious diseases.

1. Rapid Spread of Disease Across State Lines

The transmission of communicable disease in our society is facilitated by modern transportation systems and the corresponding physical contact and interaction between individuals across large geographic areas.¹⁷¹ The 2009 global outbreak of the H1N1 influenza virus strongly demonstrates that “[d]ue to continued differences in disease risks between different locations, population mobility is emerging as a

Colorado increased from 1.02% to 1.87%).

¹⁷⁰ *Id.* at 3146.

¹⁷¹ Douglas W. MacPherson & Brian D. Gushulak, *Human Mobility and Population Health: New Approaches in a Globalizing World*, 44 PERSP. BIOLOGY & MED. 390 (2001) (explaining that global disparities in access and quality of healthcare contribute to different levels of disease risks among the human population). *See also* Suzana Dragicevic & Liliana Perez, *An Agent-Based Approach for Modeling Dynamics of Contagious Disease Spread*, 8 INT'L J. HEALTH GEOGRAPHICS 50 (2009) (developing a model that simulates the spread of communicable disease in an urban environment based on individuals' interactions in a geospatial context).

major determinant of health for individuals and communities.”¹⁷² As of August 13, 2009, the World Health Organization (“WHO”) reported more than 182,000 laboratory-confirmed cases of H1N1 influenza and 1,799 related deaths in 177 countries and territories.¹⁷³ The CDC reported, as of August 20, 2009, that the number of hospitalized H1N1 cases totaled 7,983 and related deaths totaled 522 based on reporting from all fifty states, the District of Columbia, and U.S. territories.¹⁷⁴ The first confirmed H1N1 illness in the United States was on April 15, 2009. After determining that the virus was spreading from person-to-person, the federal government declared a public health emergency on April 26, 2009. By June 19, 2009, H1N1 cases had appeared in all fifty states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands.¹⁷⁵ The spread of H1N1 and the government’s response to it serves to highlight that any mass vaccination plan likely would be implemented at the direction of the federal government in response to a national emergency.

The H1N1 outbreak provides a real-time example of how contagious diseases can travel long distances in a short period of time. In addition to the mobility of the population, a disease’s incubation period and the method of its transmission determine the rate and distance over which it will spread.¹⁷⁶ For example, if a bioterrorist attack released smallpox into a community, the long incubation period of ten to seventeen days “[A]lmost ensures that some persons who were infected in the attack [would] have traveled great distances from the site of exposure before the disease is recognized.”¹⁷⁷ Absent a federal mass vaccination plan, the mobility of the population combined with a disease’s specific characteristics underscore the likelihood that a mass outbreak will overwhelm the states’ ability to adequately protect public health and safeguard patients’ rights.

¹⁷² MacPherson, *supra* note 171, at 392.

¹⁷³ World Health Organization [WHO], *Pandemic (H1N1) 2009 – Update 62* (Aug. 21, 2009), http://www.who.int/csr/don/2009_08_21/en/index.html.

¹⁷⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., 2009 H1N1 FLU SITUATION UPDATE, (2009), <http://www.cdc.gov/h1n1flu/updates/082109.htm>. Territories include American Samoa, Guam, Puerto Rico and the U.S. Virgin Islands.

¹⁷⁵ CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., NOVEL H1N1 FLU: BACKGROUND ON THE SITUATION, (2009), <http://www.cdc.gov/h1n1flu/background.htm>.

¹⁷⁶ Joseph Barbera et al., *Large-Scale Quarantine Following Biological Terrorism in the United States: Scientific Examination, Logistic and Legal Limits, and Possible Consequences*, 286 JAMA 2711, 2714 (2001).

¹⁷⁷ *Id.*

As our history of immunization demonstrates, informed consent, exemptions, and conditional rights of refusal come in a variety of formulations, but none specifically address the unique circumstances of a large-scale, multi-state vaccination emergency. The widespread differences among the states in their common law and statutes governing vaccinations emphasize the importance of establishing a federal standard for dealing with a nationwide health emergency.

2. MSEHPA Fails to Address Mass Vaccination Situation

Post-9/11, the Model State Emergency Health Powers Act (“MSEHPA”) reflects the only effort undertaken to develop an emergency response law at the state level. The model law, drafted by The Center for Law and the Public’s Health, at Georgetown and John Hopkins Universities, seeks to “grant public health powers to state and local public health authorities to ensure strong, effective, and timely planning, prevention, and response mechanisms to public health emergencies (including bioterrorism) *while also respecting individual rights.*”¹⁷⁸ As MSEHPA is a model law designed for the benefit of state legislatures, thirty-eight states and the District of Columbia have passed bills that incorporate some portions of the Model Act.¹⁷⁹ While the Model Act may be useful in establishing a comprehensive approach to emergencies internal to states, vaccination is only a small part of MSEHPA and states are under no obligation to adopt its proposed measures. Additionally, MSEHPA fails to address the need for a consistent and coordinated nationwide approach to mass vaccination in a multi-state emergency. Finally, with respect to exemptions, MSEHPA broadly states, “To prevent the spread of contagious or possibly contagious disease the public health authority *may isolate or quarantine . . . persons who are unable or unwilling for reasons of health, religion, or conscience to undergo vaccination.*”¹⁸⁰ This language provides little guidance to states. It lacks detail and fails to address the legal standards for defining religion and conscience, and the methods for processing these exemptions. At least fifteen of the more than thirty states that have enacted some portion of MSEHPA have adopted the provisions authorizing state officials to

¹⁷⁸ The Centers for Law & the Public's Health, the Model State Emergency Health Powers Act, <http://www.publichealthlaw.net/ModelLaws/MSEHPA.php> (emphasis added).

¹⁷⁹ *Id.*

¹⁸⁰ MODEL STATE EMERGENCY HEALTH POWERS ACT § 603(a)(3) (as drafted by Ctr. for Law & Pub. Health, Dec. 21 2001), available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf> (emphasis added).

implement isolation or quarantine measures, but have not specified what exemptions, if any, they would allow in an emergency.¹⁸¹

Prior to MSEHPA, many states¹⁸² had public health and safety statutory language abrogating immunization exemptions in an emergency and imposing quarantine. It is unclear if MSEHPA has had any effect in encouraging states to revisit and amend their statutes to protect, in an emergency, those exemptions normally permitted in a non-emergency situation.¹⁸³ Although Hawaii adopted some of the MSEHPA recommendations, the state did not alter those provisions related to compulsory vaccination and quarantine in an emergency.¹⁸⁴

Under normal circumstances, Hawaii allows exemptions for religious and medical reasons. However, Hawaii's Civil Defense and Emergency Act grants the Governor authority to quarantine and immunize indiscriminately, augment already existing compulsory vaccination laws,¹⁸⁵ and carry-out any such supplemental provisions. Consequently, the emergency powers effectively rescind Hawaii's medical and religious exemptions to vaccinations. In December 2009, Hawaii County's Council, fearing the Hawaiian Governor's compulsory vaccination powers during the H1N1 outbreak, approved a resolution urging Hawaii's state legislators and congressional delegation to amend emergency vaccine laws to allow for medical, religious, and philosophical exemptions.¹⁸⁶ Supporters of the resolution claim that the Hawaiian officials are effectively running a "compulsory vaccination" program, particularly in the school.¹⁸⁷ All schoolchildren from

¹⁸¹ MSEHPA: A CHECKLIST OF ISSUES (2002) (counting the number of states that have isolation and quarantine provisions) *available at* <http://www.ncsl.org/programs/health/modelact.pdf>.

¹⁸² *See* ARIZ. REV. STAT. ANN. § 36-787 (C) (West 2008) (stating "In addition to the authority provided in subsections A and B, during a state of emergency or state of war emergency in which there is an occurrence or the imminent threat of smallpox, plague, viral hemorrhagic fevers or a highly contagious and highly fatal disease with transmission characteristics similar to smallpox, the governor, in consultation with the director of the department of health services, may issue orders that: 1. Mandate treatment or vaccination of persons who are diagnosed with illness resulting from exposure or who are reasonably believed to have been exposed or who may reasonably be expected to be exposed. 2. Isolate and quarantine persons"). Arizona has not adopted any portions of the MSEHPA.

¹⁸³ *E.g.*, HAW. REV. STAT. ANN. § 325-34 (West 2009).

¹⁸⁴ MSEHPA: A CHECKLIST OF ISSUES 33 (2002) *available at* <http://www.ncsl.org/programs/health/modelact.pdf>.

¹⁸⁵ HAW. REV. STAT. ANN. § 128-8 (2) (West 2009) (The Governor has the power under state emergency laws to increase the penalties for non-vaccination imposed by § 325-37.).

¹⁸⁶ John Burnett, *Flu Mist Is Better than No Vaccine*, HAWAII TRIBUNE HERALD (Dec. 4, 2009).

¹⁸⁷ *Id.*

kindergarten to eighth grade are being vaccinated, and supporters of the resolution argue that parents have insufficient information in order to provide the proper informed consent.¹⁸⁸ Although this resolution also advocates for philosophical exemptions, it serves as an example of how citizens are unwilling to support vaccination laws that deny them all options and abrogate basic freedoms. Moreover, the complaints that parents and others lack sufficient information about the H1N1 vaccine underscore the importance of clear and honest communication between citizens and the government in an emergency vaccination situation.

3. Divergent State Practices Undermine Public Health and Patients' Rights

The effectiveness of compulsory school vaccination programs varies widely among states and within states because school districts and public officials and state courts fail to apply, interpret, or enforce exemption provisions in a consistent manner.¹⁸⁹ In addition, the procedural requirements differ among states for claiming exemptions. For example, Nebraska and Montana require a signed affidavit,¹⁹⁰ whereas Wyoming only requires "submission of written evidence of religious objection."¹⁹¹ In states that require affidavits, the affidavits are maintained in the student's immunization records and any false claim of a religious exemption is subject to a penalty for falsely swearing.¹⁹² Indeed, the Wyoming standard is less strict than states such as Nebraska and Montana, because in *In re LePage*, the Wyoming Supreme Court held that once the paperwork is submitted, the state may not inquire into the sincerity of one's religious objection.¹⁹³ Besides the potential for significant variations in the actual processing of exemptions in an emergency, it is foreseeable that some states would implement either: (1) no exemptions; (2) some exemptions, but contingent on isolation or quarantine; or (3) too many exemptions, placing at risk the public health.

¹⁸⁸ *Id.*

¹⁸⁹ Ross D. Silverman, *No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions to Ensure Public Health Protection*, 12 ANNALS HEALTH L. 277, 282-85 (2003).

¹⁹⁰ NEB. REV. STAT. § 79-221 (West 2008); MONT. CODE ANN. § 79-221 (2) (2009).

¹⁹¹ WYO. STAT. ANN. § 21-4-309(a) (West 2009).

¹⁹² MONT. CODE ANN. § 79-221 (2) (2009); NEB. REV. STAT. § 79-221 (West 2008).

¹⁹³ *In re LePage*, 18 P.3d 1177, 1180-81 (Wyo. 2001).

4. Additional Benefits of a Federal Law

Additional benefits derived from a federal mass vaccination policy would include: (1) the government's ability to exert greater control over the distribution and application of a vaccine, helping to reduce tort liability; (2) the standardization of patients' rights in a vaccine emergency; (3) enhanced transparency with respect to the communication of all risks and benefits of treatment; and (4) the potential for the federal government to engage with state governments sooner to identify pathogens and contain the spread of disease.

B. Recommendations for Amending the Public Health Service Act

I propose amending the Public Health Service Act ("PHS Act"). Such an amendment would build upon recent legislation, allowing for medical and religious exemptions and a conditional right of refusal during a federal mass vaccination campaign.¹⁹⁴ Currently, the PHS Act does not authorize any mandatory vaccination programs, but it does have several provisions related to vaccines and emergency preparedness.¹⁹⁵ The Pandemic and All-Hazards Preparedness Act ("PAHPA") of 2006 specifically authorizes the Secretary for the Department of Health and Human Services ("HHS") to grant vaccination waivers in an emergency.¹⁹⁶ Therefore, the Secretary of HHS's existing powers justify the amendment proposed in this Note. In addition, Congress could draft as an amendment to existing federal quarantine regulations the right of refusal, conditioned on a discretionary requirement of quarantine.¹⁹⁷

¹⁹⁴ Public Health Service Act, 42 U.S.C. §§ 201-300 (2006).

¹⁹⁵ *Id.*

¹⁹⁶ Pandemic and All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417, § 203A(4)(A), 120 Stat. 2831 (2006) ("The Secretary may waive one or more of the requirements under paragraph (1) for an individual who is not able to meet such requirements because of—(i) a disability; (ii) a temporary medical condition; or (3) any other extraordinary limitation as determined by the Secretary.").

¹⁹⁷ 42 C.F.R. § 70 (2008) (implementing the provisions of the Public Health Service Act ("PHS Act") to prevent the introduction, transmission, or spread of communicable diseases from one State or possession into any other State or possession, and granting the CDC authority for interstate quarantine over persons); 42 U.S.C. § 264(d)(1) (2006) (granting the federal government authority to control the interstate spread of communicable disease, including the reasonable apprehension and detention of "any individual reasonably believed to be infected with a communicable disease in a qualifying state and (A) to be moving or about to be moving from a State to another State; or (B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State.").

The Public Health Emergency Medical Countermeasures Enterprise (“PHEMCE”)¹⁹⁸ is likely the most appropriate government body to be in charge of implementing the new informed consent requirements, the medical and religious exemptions, and the right of refusal conditioned on a discretionary requirement of isolation or quarantine. The PHEMCE is a coordinated interagency effort by the Office of the Assistant Secretary for Preparedness and Response and includes three primary HHS internal agencies: CDC, the Food and Drug Administration (“FDA”), and the National Institutes of Health (“NIH”). In addition to being in charge of the deployment and use strategies for medical countermeasures – i.e., the vaccine supply held in the Strategic National Stockpile (“SNS”) – the mission of the PHEMCE is to define and prioritize requirements for public health emergency medical countermeasures, and to integrate and coordinate research, early- and late-stage product development, and procurement activities addressing these requirements.

The PHEMCE also considers medical countermeasures to address chemical, biological, radiological, and nuclear (CBRN) attacks, as well as naturally emerging infectious diseases and pandemic threats. In short, PHEMCE has lead responsibility within the federal government to protect the civilian population during mass public health emergencies.¹⁹⁹

Prior to the onset of an emergency, the National Vaccine Program (“NVP”),²⁰⁰ created in 1986 by the Public Health Service Act, could help with training and sensitizing state and local health professionals to the exemption procedures. HHS officials assigned to the NVP could work closely with states to review the religious exemption checklist, which I discussed earlier, and establish an effective strategy for conducting interviews of exemptors. In addition to the NVP, CDC representatives, who are assigned to state health boards, could serve as another resource in implementing these recommendations.²⁰¹

¹⁹⁸ See U.S. DEPT. OF HEALTH & HUMAN SERVICES, PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE (PHEMCE), <http://www.hhs.gov/aspr/bard/phemce/index.html> (last visited Oct. 10, 2009).

¹⁹⁹ *Id.*

²⁰⁰ Public Health Service Act, 42 U.S.C. § 300aa-1 (2006) (creating the National Vaccine Program).

²⁰¹ See MICHAEL HUGHES, CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., THE CDC PORTFOLIO MANAGEMENT PROJECT & FY2008 FUNDING TO CALIFORNIA GRANTEES, http://www.cdph.ca.gov/services/boards/phac/Documents/CDC_Portfolio_Mgmt_%20012309.pdf (last visited on Oct. 10, 2009).

V. IMPLEMENTATION OF INFORMED CONSENT, OPT-OUT PROVISIONS, AND RIGHT TO REFUSAL MEASURES IN AN EMERGENCY VACCINATION CLINIC

A. The Emergency Clinics in Action

As of January 2007, the CDC provided state and local authorities with access to the Maxi-Vac program.²⁰² The program simulates a vaccination clinic and consists of “stations” or activities that a patient may rotate through during the vaccination process. By assigning personnel to various responsibilities within the clinic, the simulation program maximizes the number of people who can be vaccinated within a twenty-four hour period. The estimated average time that an individual spends in the clinic is at most ninety minutes.²⁰³ The simulation includes the following stations: triage; orientation; medical forms; referral; medical screening; physical evaluation; vaccination/witness; and exit review.²⁰⁴ The challenge will be to integrate into the process a sufficient flow of information between patients and health care personnel in this ninety-minute period.

Although the model has a “medical forms” station, the model would need to be bolstered with a greater emphasis on communication between the health care providers and the patients. The reasonable risks and benefits would need to be conveyed using a number of methods, such as a five- or ten-minute video, pamphlets, and a short conversation with a state health officer or health care provider. In addition, individuals would need to understand that besides immunization they had three options: (1) an exemption based on sincerely held religious beliefs; (2) an exemption for medical reasons; and (3) a right of refusal conditioned on the possibility of the federal government, at its discretion, choosing to place the individual in isolation or quarantine.²⁰⁵ Individuals also would need to understand the requirements necessary to satisfy each option.

²⁰² CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., DOWNLOAD MAXI-VAC VERSION 1.0 AND MAXI-VAC ALTERNATIVE, <http://www.bt.cdc.gov/agent/smallpox/vaccination/mini-vac/> (last visited on Oct. 10, 2009).

²⁰³ Description of Maxi-Vac Programs, <http://www.bt.cdc.gov/agent/smallpox/vaccination/mini-vac/desc.asp> (last visited Oct. 10, 2009).

²⁰⁴ Michael L. Washington et al., *Maxi-Vac: Planning Mass Smallpox Vaccination Clinics*, 11 J. PUB. HEALTH MGMT. PRAC. 542, 543 (2005).

²⁰⁵ Quarantine is defined as “compulsory physical separation, including restriction of movement, of populations or groups of healthy people who have been

B. Personal Interviews for Religious Exemptors

While the case law demonstrates that some individuals may go to great lengths to abuse the system, the government can take several steps to minimize the number of fraudulent exemption claims. While individuals claiming a medical exemption will need to provide some proof of a medical condition (e.g., an allergic reaction to a vaccine component or an immune system disorder) that precludes them from vaccination, religious exemptors will not *per se* need to provide official documentation from their clergy or religious organization. However, such individuals will need to submit a brief signed written statement and attend an approximately ten-minute interview with two state officials. I suggest one public health officer, who is familiar with handling immunization exemption requests, and a law enforcement officer of some kind. The state officials' presence should convey the message that the government is taking exemptions very seriously and will not permit people to circumvent the rules.

C. Meeting the Needs of Multi-Lingual, Multi-Cultural, and Literacy-Challenged Patients

Finally, during an emergency, it is imperative that public health officials communicate clearly with patients. Because the CDC produces a VIS in English and Spanish only, the CDC depends on outside groups, like the nonprofit organization Immunization Action Coalition ("IAC"), to translate the VIS information into more than thirty languages.²⁰⁶ IAC acknowledges on its website that most of the translations it publishes are received from volunteer translators.²⁰⁷ I recommend that the federal government should assume the duty of translating a VIS and any other pertinent medical information provided to patients by health personnel in an emergency. Federal oversight provides an extra layer of assurance for accuracy of the in-

potentially exposed to a contagious disease, or to efforts to segregate these persons within specified geographic areas." Isolation is defined as "the separation and confinement of individuals known or suspected (via signs, symptoms, or laboratory criteria) to be infected with a contagious disease to prevent them from transmitting disease to others." Barbera et al., *supra* note 176, at 2712 (explaining the key considerations necessary in deciding to undertake quarantine actions).

²⁰⁶ See Immunization Action Coalition, <http://www.immunize.org/> (noting that the organization receives financial support from the CDC for specific projects and from pharmaceutical companies for educational grants under strict guidelines) (last visited Dec. 20, 2009).

²⁰⁷ Immunization Action Coalition, *Vaccine Information Statements: Translate for IAC*, http://www.immunize.org/vis/vis_translate.asp (last visited Dec. 20, 2009).

formation being conveyed, and places the responsibility on the government if a mistake in translation results in physical injury because an individual received misinformation. Separately, the CDC states that effective communication depends on conveying information in “a culturally appropriate manner and in an easy-to-understand language.”²⁰⁸ Informed consent paperwork and the dialogue exchange between the patient and medical professional must be sensitive to the cultural background of the patient, who may be reluctant to discuss personal medical history.

The average reading level of a VIS, applying the Flesch-Kincaid Grade Level indicator, is tenth grade.²⁰⁹ Yet, the average reading level of American parents of young children is at a seventh or eighth grade level.²¹⁰ Based on several studies, in order to communicate with a general audience, reading materials should be geared towards a sixth to eighth grade reading level.²¹¹ It is critical that the medical information on a vaccination informed consent form match as closely as possible the comprehension level of the general public.

CONCLUSION

Amending the Public Health Service Act to allow for informed consent, exemption for sincerely held religious beliefs, and a conditional right of refusal, can be achieved in a manner consistent with past court rulings. The proposed establishment of a federal emergency vaccination law builds upon the existing authority given to the HHS Secretary to declare a public health emergency, issue waivers in the course of a mass vaccination campaign, and oversee entities such as PHEMCE, NVP, and CDC, that coordinate and implement mass vaccination practices.

Proactive use of HHS resources to train Maxi-Vac teams to effectively screen patients, and issue vaccinations should begin well before

²⁰⁸ CTRS. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., STANDARDS FOR IMMUNIZATION PRACTICES, <http://www.cdc.gov/vaccines/recs/vac-admin/rev-immz-stds.htm>.

²⁰⁹ According to the U.S. Department of Education, “The Flesch-Kincaid Grade Level indicator is a commonly-used readability measure based primarily on the average number of words per sentence and the average number of syllables per word.” OFFICE OF PLANNING, EVALUATION AND POLICY DEV., U.S. DEP'T OF EDUCATION, NATIONAL ASSESSMENT OF TITLE I, FINAL REPORT: VOLUME I. CTRS. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., FACT SHEET FOR VACCINE INFORMATION STATEMENTS, <http://www.cdc.gov/vaccines/pubs/vis/vis-facts.htm>. (last visited Oct. 10, 2009).

²¹⁰ The Informatics Review, Comprehension and Reading Level, <http://www.informatics-review.com/FAQ/reading.html>.

²¹¹ *Id.*

an actual event. The need for a federal response is rooted in the twin realities that in a highly mobile society, future disease outbreaks are likely to jump state lines and that state emergency laws vary widely, abrogating First Amendment protections in emergencies. Furthermore, public concern about state emergency laws and mass vaccination is likely to grow as bioterrorism threats increase and new infectious diseases emerge. This proposal for a federal emergency vaccination law hopes to contribute to preserving individual choice without sacrificing public health in an emergency.

