



# **Maintaining Civil Liberties Protections in Response to the H1N1 Flu**

An ACLU White Paper  
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November, 2009

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In April 2009, a novel influenza A (H1N1) virus appeared in Mexico. The virus soon spread to the U.S. and to other countries, and within two months, the WHO had classified the outbreak as a level 6 pandemic. While the virus is so far proving to be no more severe than a typical seasonal flu, its high rate of transmission and a concentration of severe cases in young people is cause for significant public health concern.

There is always a danger that fears aroused by a disease epidemic may encourage federal, state, and/or local governments to respond with irrational fears, discriminatory behaviors, and panicked, coercive measures. As the ACLU explained in a January 2008 Report on pandemic preparedness,<sup>1</sup> in the past such reactions have nearly always proven detrimental to the goal of limiting the spread of disease.

Such reactions also hold great potential to set bad precedents and permanently undermine our civil liberties. It is imperative that civil liberties protections are viewed as part of – rather than in conflict with – a public health mitigation effort.

This white paper provides:

1. An overview of the current state of the science on the H1N1 flu
2. An analysis of federal and state actions taken to date
3. Possible future scenarios of concern for civil liberties

## 1. Current Science on the H1N1 Virus

### **The appearance of the H1N1 virus**

The 2009 influenza A (H1N1) flu was first identified in April 2009. The outbreak began in Mexico some months prior and the first cases of infection in the U.S. were confirmed on April 15 and 17. The virus was initially referred to as the “swine flu” because laboratory testing revealed that many of the genes in this new virus were similar to influenza viruses that occur in pigs in North America. Further analysis revealed that the flu is actually “triple reassortant,” meaning it contains genes from three origins -- avian, human and swine viruses. By early May, Mexico had identified more than 11,000 suspected cases and approximately 1,000 laboratory-confirmed cases, including 42 patients who died, and the outbreak had spread to 21 additional countries.<sup>2</sup>

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<sup>1</sup> ACLU, *Pandemic Preparedness: The Need for a Public Health – Not a Law Enforcement/ National Security – Approach*, January 2008; online at <http://www.aclu.org/privacy/medical/33642pub20080114.html>.

<sup>2</sup> CDC, “Update: Novel Influenza A (H1N1) Virus Infections – Worldwide, May 6, 2009,” MMWR 58: 453-458.

On April 25, the WHO director-general convened an emergency committee and declared a “public health emergency of international concern.” The next day, the U.S. Department of Health and Human Services (HHS) issued a nationwide public health emergency declaration, allowing the federal government certain authority and flexibility in directing significant resources toward mitigation measures, including accelerated vaccine development and the stockpiling and release of antivirals. At that time, there were 20 confirmed cases of H1N1 in five states.<sup>3</sup>

By June 11, the virus had spread to 74 countries and all continents but Antarctica, and WHO raised the level of pandemic alert to “Level 6” (sustained transmission in multiple geographic regions), the highest level for a pandemic. As of September 27, approximately 340,000 confirmed laboratory cases and 4,100 deaths had been reported to WHO worldwide.<sup>4</sup>

On October 23, President Obama declared H1N1 a national emergency. White House officials emphasized that this was primarily a preemptive step that did not signify a worsening of the H1N1 situation. The declaration gives the secretary of HHS the authority to allow hospitals to set up temporary, offsite clinics in order to address patient overflows.

### **Initial overestimation of the threat**

Initial reports on the H1N1 outbreak indicated that this virus might be as or more virulent than the genetically similar 1918-19 H1N1 pandemic virus, which resulted in the death of 40-100 million people worldwide and 500,000-750,000 in the U.S. alone. These early studies, which showed alarmingly high rates of hospitalization and death as compared with seasonal flu, overestimated the severity of the virus because most mild cases had gone unreported. Since then, the Centers for Disease Control and Prevention (CDC) has greatly increased surveillance efforts of the virus, and the case-fatality ratio is now thought to be much lower, and similar to that of a typical seasonal flu (CDC estimates the case-fatality rate for H1N1 to be 0.018%, more than 100 times lower than the 2% case-fatality rate associated with the 1918-19 pandemic).<sup>5</sup>

All current clinical data on the 2009 H1N1 influenza strain suggest that it is generally mild-moderate in severity and that the vast majority of individuals who become infected will be able to recover without medical treatment. The symptoms of the H1N1 flu are similar to seasonal flu and can include fever, chills, sore throat, cough, headache, and fatigue, but can also include vomiting and diarrhea, which are not usually seen in seasonal flus.

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<sup>3</sup> News Release: HHS Declares Public Health Emergency for Swine Flu, April 26, 2009, available at: <http://www.hhs.gov/news/press/2009pres/04/20090426a.html>

<sup>4</sup> These figures are known to underestimate that actual number of cases and deaths. Approximately ¾ of the 4100 deaths were reported by the WHO Regional Office of the Americas. See World Health Organizations, Pandemic (H1N1) 2009 – update 68, available at: [http://www.who.int/csr/don/2009\\_10\\_02/en/index.html](http://www.who.int/csr/don/2009_10_02/en/index.html)

<sup>5</sup> Centers for Disease Control and Prevention, “CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April – October 17, 2009,” November 12, 2009. Available at: [http://www.cdc.gov/h1n1flu/estimates\\_2009\\_h1n1.htm](http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm)

## Concerns remain

While the 2009 H1N1 outbreak is not as severe as some had initially feared, a number of concerns remain:

- **Severe cases among the young.** Seasonal flu tends to have the gravest impact on the elderly and very young children, but with H1N1 severe cases have occurred predominantly in relatively young individuals. Pregnant women and individuals with underlying complications, such as neurological disorders, asthma, and diabetes appear to be at particular risk. In the U.S., 90% of deaths and 91% of hospitalizations associated with the pandemic flu have occurred among individuals under the age of 65. In contrast, almost 90% of seasonal flu's deaths and 2/3 of hospitalizations are of individuals 65 and older.<sup>6</sup> Some public health experts have theorized that older people have acquired partial immunity to the pandemic flu and so are less susceptible to it than the younger population.<sup>7</sup>
- **A high transmission rate.** The rate of transmission of the virus has proven to be high, so even if it remains a "mild" disease that has a low fatality rate, the *actual* number of people who will die of it is expected to be higher than the number that typically die from the seasonal flu. Approximately 36,000 people in the U.S. die of seasonal flu each year. In contrast, a report issued in August by the President's Council of Advisors on Science and Technology projects that 30-50 percent of the American population could become infected with the H1N1 virus this fall and winter, as opposed to 5-20% for seasonal flu.<sup>8</sup> Under this scenario, they predict that up to 1.8 million people would require hospitalization and that between 30,000 and 90,000 deaths would likely result (concentrated among children and young adults).<sup>9</sup> Similarly, the CDC predicted that the H1N1 virus could reach 20 to 40 percent of the population over the next two years. They reported that the resulting deaths from such widespread infection could reach 90,000 to several hundred thousand, if efforts to contain the spread of the flu were unsuccessful.<sup>10</sup>

Estimating the actual number of cases that have occurred to date is very challenging, because many cases go unreported. The CDC estimates that between April and October 17, between 14 million and 34 million cases of H1N1 occurred in the U.S., between 63,000 and 153,000 people were hospitalized, and between

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<sup>6</sup> The President's Council of Advisors on Science and Technology Report [Hereafter "PCAST Report"] "U.S. Preparations for the 2009-H1N1 Influenza," August 7, 2009, p. 14, available at: [http://www.whitehouse.gov/assets/documents/PCAST\\_H1N1\\_Report.pdf](http://www.whitehouse.gov/assets/documents/PCAST_H1N1_Report.pdf)

<sup>7</sup> Jon Cohen, "Flu Researchers Train Sights On Novel Tricks of Novel H1N1," *Science*, Vol. 324 (14 May 2009): 870-871.

<sup>8</sup> PCAST Report, 2009.

<sup>9</sup> PCAST Report, 2009.

<sup>10</sup> <http://www.cbsnews.com/stories/2009/07/24/world/main5185843.shtml>

2,500 and 6,000 people died of H1N1-related causes.<sup>11</sup> These estimates are significantly higher than the numbers of reported cases.

- **Unpredictability.** Finally, there is considerable uncertainty and unpredictability when it comes to pandemic viruses, which tend to mutate between seasons. So far, there is no evidence to indicate that the virus has mutated significantly since its resurgence in the Northern Hemisphere.<sup>12</sup> However, the virus is likely to continue to evolve throughout the season (though it is important to remember that could evolve in *either* direction, becoming either more serious or less so). One concern is that it could evolve away from the current vaccine or that it could become resistant to the class of anti-influenza drugs that have so far been effective against H1N1 (see below).<sup>13</sup> Recent studies indicate that this may be happening.<sup>14</sup> Some have projected a particularly harrowing scenario whereby this H1N1 strain “swaps genes” with the highly pathogenic avian H5N1 virus that has an extremely low transmission rate but a mortality rate of over 60 percent in the few human cases that have occurred.<sup>15</sup>

### **Vaccination and antivirals**

The federal government has spent more than \$2 billion to buy at least 250 million doses of vaccine from five manufacturers and pledged to buy enough to vaccinate the entire population for free. The CDC recommended that the vaccine be made available first to five high-priority categories of individuals who are thought to be at greatest risk. These groups together comprise approximately 159 million people and include the following:

- Pregnant women
- Caregivers of infants under 6 months of age
- Everyone between 6 months and 24 years of age
- Individuals ages 25-64 with underlying conditions
- Healthcare workers and emergency personnel

Vaccination can reduce disease burden both by protecting individuals, directly, and decreasing transmission, reducing the infection risk even for those who have not been vaccinated. Flu vaccines are never 100% effective, in part because flu strains tend to evolve quickly and because the vaccine has to be developed prior to the onset (or at least

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<sup>11</sup> Centers for Disease Control and Prevention, “CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April – October 17, 2009,” November 12, 2009. Available at: [http://www.cdc.gov/h1n1flu/estimates\\_2009\\_h1n1.htm](http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm)

<sup>12</sup> Statement by Thomas Frieden, CDC Commissioner, Press Conference, September 3, 2009.

<sup>13</sup> Jon Cohen, “Flu Researchers Train Sights On Novel Tricks of Novel H1N1,” *Science*, Vol. 324 (15 May 2009).

<sup>14</sup> “H1N1 Evolution Outpacing Vaccine and Host Defenses,” *Recombinomics Commentary* 13:32, November 30, 2009. Available at: [http://www.recombinomics.com/News/11300901/225\\_Evolution.html](http://www.recombinomics.com/News/11300901/225_Evolution.html) See also: WHO, “Public health significance of virus mutation detected in Norway,” Pandemic (H1N1) Briefing Note 17, November 20, 2009. See also: Michelle Fay Cortez and Marianne Stigset, “Mutated Swine Flu Strains Block Drugs, Worsen Illness,” *Bloomberg.com*, November 20, 2009.

<sup>15</sup> Michael Torrice, “China First to Vaccinate Against Novel H1N1 Virus,” *Science*, Vol. 325 (18 September 2009).

the peak) of the flu season if it is going to have any mitigating effect. Effectiveness tends to range from 30%-70%. Clinical trials involving 4,600 people revealed that the H1N1 vaccine is a good match to the current H1N1 virus and that one dose of the vaccine (as opposed to two) may be sufficient to stimulate a robust immune response to the virus in adults and children ages 10 and older.

Where the vaccine is not received or fails to protect, H1N1 has thus far been susceptible to one of two classes of antiviral medications that are used for the treatment of seasonal influenza. These are the neuraminidase inhibitors (oseltamivir [Tamiflu] and zanamivir [Relenza]). These drugs have been stockpiled by HHS and allocated to the states on a population basis.

### *Vaccine shortage*

The government projected that an initial batch of approximately 40 million doses of the vaccine would be made available around the country by the middle of October, enough to cover ¼ of high-risk individuals. Instead, the speed of manufacturing has been far slower than initially estimated and significant vaccine shortages have resulted. As of the end of October, there were approximately 27 million doses available for ordering. At a November 4 hearing before the U.S. House Appropriations Subcommittee on Labor, Health and Human Services, Commissioner Tom Frieden predicted that the current wave of H1N1 will likely “peak, crest, and begin to decline” before ample supplies of the vaccine become available.<sup>16</sup> Similarly, an Alabama health official testified that there may not be enough vaccine to immunize people outside of the priority groups until late December.<sup>17</sup>

### *Adverse effects*

The CDC has acknowledged the possibility of adverse events associated with the vaccine, and has committed to close monitoring for side effects.<sup>18</sup> There are no particular reasons to anticipate that this vaccine will prove to be less safe than any other flu vaccine, since the H1N1 vaccine was produced in the same way that the seasonal flu vaccine is produced (although on an accelerated schedule). To date, reports of adverse events have been similar to those seen with seasonal flu and not unexpected.<sup>19</sup>

One concern that has been raised is around whether people who receive flu shots are at an increased risk of developing Guillain-Barre syndrome (GBS), a rare autoimmune syndrome that often leads to temporary paralysis and sometimes permanent nerve damage or death. The Institute of Medicine found that people who received the 1976 swine flu vaccine had a slight increased risk of developing GBS. Two additional studies

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<sup>16</sup> R. Roos, “CDC says vaccine shortage likely to outlast current H1N1 wave,” *CIDRAP*, November 4, 2009.

<sup>17</sup> Testimony of Donald E. Williamson, M.D., Alabama State Health Officer, Before the U.S. House Appropriations Subcommittee on Labor, Health and Human Services, November 4, 2009.

<sup>18</sup> Statement by Thomas Frieden, CDC Commissioner, Press Conference, September 3, 2009.

<sup>19</sup> Testimony of Thomas Frieden, CDC Commissioner, Before the U.S. House Appropriations Subcommittee on Labor, Health and Human Services, November 4, 2009.

have shown that approximately one additional person out of 1,000,000 who receive a seasonal flu vaccine may be at risk.<sup>20</sup>

Many have vocalized concerns about a possible relationship between vaccines and autism, but studies that have looked at this issue to date have consistently failed to show an association.<sup>21</sup>

## 2. Government Responses to H1N1

When the H1N1 flu broke, there was considerable concern in both the civil liberties and public health communities that overreactions on the part of the federal and state governments would result in serious infringements on civil liberties and panicked, less-than-effective public health strategies. Many state emergency flu preparedness plans currently on the books were modeled after the “Model State Emergency Health Powers Act” that was drafted at the request of the Bush Administration’s CDC following the anthrax letter scare in 2001. Designed to address a “worst case” scenario, the Model Act provided state officials with extensive, unchecked powers to curtail individual autonomy and privacy in the face of an emergency, including powers to surveil the public’s health and to compel vaccination, testing, treatment, isolation, and quarantine. The Model Act lacked checks and balances and privacy protections while it emphasized an ineffective, coercive approach to pandemic response rather than a public health response.<sup>22</sup> Some states also amended their pandemic planning laws in response to the 2005 H5N1 avian flu scare, again adopting highly draconian measures that are inappropriate for the vast majority of flu situations.

### Federal response

Fortunately, the Obama Administration has so far acted appropriately in response to the outbreak and has helped to establish and maintain a sense of calm throughout the country:

- Unlike President Bush, who suggested that he would call in the military to quarantine large sections of the United States in the face of a pandemic, President Obama responded calmly and rationally to the outbreak by encouraging people to wash their hands and stay home when sick.
- When Senator McCain and a handful of other U.S. legislators<sup>23</sup> suggested that closing the U.S.-Mexico border should be an option in combating the H1N1 flu strain, Obama responded appropriately that this “would be akin to closing

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<sup>20</sup> CDC, “General questions and answers on Guillain-Barre syndrome,” September 14, 2009. Available at: [http://www.cdc.gov/h1n1flu/vaccination/gbs\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/gbs_qa.htm)

<sup>21</sup> <http://www.cdc.gov/ncbddd/autism/research.html#vaccines>

<sup>22</sup> See ACLU, “Q&A On the Model State Emergency health Powers Act,” online at <http://www.aclu.org/privacy/medical/14857res20020101.html>.

<sup>23</sup> Mike Sunnucks, “McCain: Closing Mexican border should be option to hold back swine flu,” *Phoenix Business Journal*, April 29, 2009, available at: <http://phoenix.bizjournals.com/phoenix/stories/2009/04/27/daily40.html>

the barn door after the horses are out because we already have cases here in the United States.”<sup>24</sup>

- The Administration has since directed the use of its emergency powers towards tracking and assessing the severity and transmission of the flu, speeding up vaccine development, stockpiling and deploying anti-virals, and improving coordination among federal and state health agencies.<sup>25</sup>
- The Obama CDC, through its weekly public call-in updates, has taken great care to communicate openly the potential health risks associated with the virus and the steps being taken to mitigate its effects, while also acknowledging the unknowns.
- The Administration also helped to minimize stigma and discrimination associated with the flu by using the term “2009 H1N1 influenza” and discouraging the use of “Mexican flu,” as well as misunderstandings about the flu’s origin and false claims that people could get the flu from eating infected pork.

Response at the international level has also helped to set the tone globally. When the outbreak first occurred, the WHO director-general, Margaret Chan, moved quickly to recommend that “all countries intensify surveillance for unusual outbreaks of influenza-like illness and severe pneumonia.” Chan recommended against travel restrictions and border closures. She also held off on raising the pandemic alert from phase 5 to 6 in response to several warnings that calling the outbreak a pandemic would create panic about a virus that did not cause serious disease and could trigger draconian measures. Regardless of these efforts, some Asian countries previously affected by a 2002-2003 outbreak of Severe Acute Respiratory Syndrome (SARS) were quick to implement quarantines for travelers from Mexico, Canada and the U.S. during the early days of the outbreak.<sup>26</sup>

### **Overreaction at the state level**

Some state governments have unfortunately strayed from the example set by the federal government and have used the H1N1 outbreak to enact misguided policies. In perhaps the most sweeping state action to date, the New York State Department of Health in

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<sup>24</sup> Obama news conference: President says swine flu no reason to close border with Mexico, *L.A. Times*, April 29, 2009, available at: <http://latimesblogs.latimes.com/washington/2009/04/obama-news-conference-president-says-swine-flu-is-not-reason-to-close-border-with-mexico-.html>

<sup>25</sup> Under the Public Health Service Act, the Secretary of Health and Human Services may declare a public health emergency and respond by making grants, providing awards for expenses, entering into contracts, and conducting investigations into the cause, treatment, or prevention of a disease (42 U.S.C. § 247d (a)). The FDA, in conjunction with the CDC, may issue Emergency Use Authorizations to make available to public health and medical personnel important diagnostic and therapeutic tools to identify and respond to a disease (42 U.S.C. § 247d-6b).

<sup>26</sup> In July, 65 American and 52 British students and their teachers were quarantined in Beijing after 4 students tested positive for H1N1. BBC News, July 19, 2009. In Changchun, a city in northeastern China, 22 Canadian students with no apparent symptoms were held in a hotel. Three hundred guests in a hotel were confined for a week in Hong Kong under police guard, after an infected man who had stayed there was isolated. Gostin, 2009.



September 2009 put into effect an emergency rule requiring all health care personnel to be vaccinated against influenza.<sup>27</sup> The rule required the following:

- More than 525,000 New York health care workers at hospitals, in home health care agencies, and in hospice care were to be immunized as a precondition to employment and on an annual basis, or risk losing their jobs.
- Vaccination was required not only for H1N1 but also for *any flu for which a vaccine is available*, including future seasonal flus of unknown severity.
- No opt out provision; the only narrow exception made was for individuals for whom the vaccine was determined to be “medically contraindicated.”

The rule resulted in significant conflict between health care workers and the state Department of Health. The New York Civil Liberties Union (NYCLU) received hundreds of complaints from doctors, nurses and other healthcare workers, and moved quickly to oppose the regulation. In a letter to Commissioner Richard Daines, the NYCLU urged the health department to withdraw the compulsory aspect of the regulation, stating that the mandate is contrary to an individual’s fundamental right to direct the course of his or her medical treatment as well as to sound public health policy.<sup>28</sup> The New York Committee for Occupational Safety and Health, the Public Employees Federation and several other unions also formally opposed the regulation.

Two lawsuits were filed in state court in opposition to the regulation, and on October 13, a state judge issued a temporary restraining order on the mandate and scheduled a hearing for October 30. On October 22, Governor Paterson suspended the regulation, stating that the change in policy was not in response to the litigation, but rather to the CDC’s announcement that the vaccine was in far shorter supply than previously anticipated.

To date New York is the only state to have attempted to mandate flu vaccination for healthcare workers. Similar programs have been implemented at some hospital chains and private healthcare systems, including MedStar Health, whose facilities include 7 hospitals and more than 100 physicians offices, hospices, rehabilitation centers and outpatient clinics in Washington, DC and Baltimore. A number of individual hospitals around the country have implemented similar programs.<sup>29</sup>

Some states have proposed problematic legislation in response to the H1N1 outbreak. In Massachusetts, legislators reactivated a bill reminiscent of the Model State Emergency Health Powers Act that quickly passed the state senate with little review.<sup>30</sup> The legislation sought to remove important due process protections and grant the commissioner excessive power in responding to a public health emergency. However, as of this writing a calm and rational approach appears to be prevailing and state lawmakers

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<sup>27</sup> NYCRR Subpart 66-3 et seq. (NYS Register, September 2, 2009).

<sup>28</sup> New York Civil Liberties Union, Letter to Commissioner Richard F. Daines Re: Influenza Vaccination Requirements for Health Care Personnel, 10 NYCRR Subpart 66-3 et seq., October 13, 2009. Available at: [http://www.nyclu.org/files/Flu\\_Letter\\_DOH\\_10.13.09.pdf](http://www.nyclu.org/files/Flu_Letter_DOH_10.13.09.pdf)

<sup>29</sup> Rob Stein, “Mandatory flu shots hit resistance,” *Washington Post*, September 26, 2009.

<sup>30</sup> Massachusetts Senate Bill S. 2028, “An Act Relative to Pandemic and Disaster Preparation and Response in the Commonwealth.”

appear to be moving toward a public health-oriented house bill that is devoid of these problems.

### **Federal government supports voluntary H1N1 vaccination**

The New York emergency regulation sparked considerable concern and confusion around the country as to the federal government's H1N1 vaccination program. However, the federal government's position on this matter has been clear:

- The White House, the Centers for Disease Control (CDC), the U.S. Department of Health and Human Services (HHS), and the Occupational Safety and Health Administration (OSHA) have all recommended that health care workers be among those who receive first priority for H1N1 vaccine, but that vaccination remain voluntary.
- HHS Secretary Kathleen Sibelius and CDC Commissioner Tom Frieden have reiterated this position on multiple occasions.<sup>31</sup>
- On September 28<sup>th</sup>, the federal government's website on the flu posted a notice reiterating that "the federal vaccination program for H1N1 flu is VOLUNTARY" and that, while the government will ensure that the vaccine is available to anyone who wants it, the decision to get vaccinated is up to each individual.<sup>32</sup>

## **3. Looking Forward: Potential Civil Liberties Concerns**

As a general rule, the flu is highly unpredictable. It is especially so in cases of a pandemic, where broad distribution of the disease around the world contributes to its ability to persist and mutate. It is not possible to anticipate with any precision the possible directions in which the flu could evolve – and the responses that such evolution could provoke.

### **Mandatory flu vaccination**

The issue of mandatory flu vaccination is one that will undoubtedly continue to play out, regardless of the evolution of this particular virus. While the federal government has stated repeatedly and emphatically that it does not endorse mandatory H1N1 vaccination, in a recent press conference, CDC Commissioner Tom Frieden suggested the federal government might explore it for future flu seasons. The Public Health Service Act, which authorizes the federal government to use quarantine and isolation measures to halt the spread of communicable diseases, does not specifically authorize mandatory vaccination. As a recent report by the Congressional Research Service (CRS) noted, any federal program would likely to be limited to areas of existing federal jurisdiction, such as interstate and foreign commerce.<sup>33</sup>

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<sup>31</sup> Stein, 2009. See also "New York health care workers resist flu vaccine rule," *New York Times*, September 21, 2009.

<sup>32</sup> See: <http://www.flu.gov/news/blogs/vaccinevoluntary.html>

<sup>33</sup> Congressional Research Service [CRS], *Mandatory Vaccinations: Precedent and Current Laws*, September 8, 2009, pg 6-7

State and local governments have primary responsibility for issuing vaccination requirements, and we may see more laws and regulations regarding the mandatory vaccination of healthcare workers. Flu vaccination could also be mandated for children through the expansion of existing public school immunization requirements. All states currently require a prescribed set of immunizations, but provide an exemption for individuals with medical contraindications to vaccines. Most states also provide an exemption for those with religious objections, and many also allow individuals to opt-out of mandatory vaccinations for philosophical or moral reasons.<sup>34</sup> Employers may generally mandate vaccinations for their employees, unless state law provides an opportunity for them to opt-out.<sup>35</sup>

### *The problem with mandatory flu vaccination*

While vaccination is an effective strategy for mitigating the effects caused by annual seasonal flu as well as the current H1N1 pandemic, a mandatory vaccination scheme to apply to all healthcare workers, all school children, or the general population is not warranted for the current H1N1 situation or for future seasonal flus of unknown severity. Especially problematic are mandates (such as that issued and subsequently rescinded in New York) that do not provide individuals an opportunity to opt out for religious or philosophical reasons and that are tied to sanctions such as job loss.

Certainly there are circumstances where the danger to the public from a communicable disease is so grave that state actions curtailing individual rights are warranted. The appropriateness of state actions in response to a disease outbreak have to be considered on a case-by-case basis. Such a consideration should weigh the nature of the disease in question, including: the gravity of the harm, the means of transmission, the degree of intrusion on personal autonomy, the likely effectiveness of the action, and the availability of less restrictive alternatives to accomplish the same goal.

With these factors in mind, the following are some of the problems with mandating flu vaccination:

- **Counterproductive from a public health perspective.** Sound public policy promotes trust and cooperation between and among government policy makers, health care workers and the general public. Government mandates, especially where accompanied by harsh penalties for non-compliance, are fundamentally at odds with this model. Incidences where individuals refuse to be vaccinated are likely to breed confusion and distrust among the general public at a time when trust in public health officials is critical, and may result in an increasing reluctance to be vaccinated.
- **Violates well established principles of individual autonomy.** Long-established federal law makes it clear that a person with decisional capacity has the fundamental right to make her or his own health care decisions, including the right to refuse any treatment.<sup>36</sup> When fundamental rights are at

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<sup>34</sup> CRS, 2009, p. 3.

<sup>35</sup> CRS, 2009, p. 4.

<sup>36</sup> The ACLU has a long history of opposing forced treatment in various contexts, including reproductive freedom, mental health treatment (both out and in-patient), treatment of prisoners, and the forced enrollment of individuals into medical research programs.

stake, there is a strong presumption protecting those rights. It is a significant thing for the government to use coercion to require individuals to be injected with a foreign biological material (on an annual basis, in the case of a seasonal flu mandate). And while side effects are generally mild, there is always the possibility – however rare – of serious adverse effects. Individuals should weigh those risks for themselves and determine whether or not to get vaccinated. Compulsory vaccination or treatment should be reserved for only the most severe situations.

- **Availability of less coercive measures.** A well-planned and well-executed voluntary vaccination program can go a long way to achieving the public health goal of minimizing individuals' risks of disease and reducing transmission rates, especially where it is combined with efforts to encourage people to stay home when sick (e.g. ensuring reasonable sick leave and worker compensation policies in the workplace). Effective public education combined with ensuring that the flu vaccine is free and widely accessible has been shown to achieve high rates of seasonal flu vaccination in high risk populations as well as among health care workers.
- **Effectiveness.** One of the primary reasons to initiate a mandatory vaccination program would be to attempt to eradicate the disease, but unlike smallpox or polio, influenza is not a disease that can be eradicated. At the same time, as discussed above, the effectiveness of seasonal flu vaccines varies widely from season to season. Mandating influenza shots hardly seems warranted when the efficacy of the vaccine some years may be as low as 30-50%. In comparison, the full dose of the measles vaccine produces immunity in 99% of cases, and a single shot is 95-98% effective.

For these and other reasons, many health policy experts have argued against the implementation of mandatory influenza vaccination regimes.<sup>37</sup>

#### *Legal status of mandatory vaccination*

In 1905, the U.S. Supreme Court found that a mandatory smallpox vaccination program in the state of Massachusetts was an appropriate exercise of police power (*Jacobson v. Massachusetts*, 197 U.S. 11, 25). But it is important to note that the H1N1 situation differs in several key ways from the nature and type of public health emergency confronted in that case.<sup>38</sup>

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<sup>37</sup> See for example, O. Anikeeva, A. Braunack-Mayer, W. Rogers, "Requiring influenza vaccination for health care workers," *American Journal of Public Health* 99:24-29, January 2009. See also: M. Finch, "Point: Mandatory influenza vaccination for all health care workers? Seven reasons to say 'no,'" *Clin Infect Dis* 42: 1141-1143, April 15, 2006. See also: D. Isaacs and J. Leask, "Should influenza immunization be mandatory for healthcare workers? No." *British Medical Journal* 227:2140, Oct 28, 2008. See also: G. Annas, "Opinion: Don't force medical pros to get H1N1 vaccine," *Newsday.com*, October 2, 2009.

<sup>38</sup> It should also be noted that "mandatory" in *Jacobson* did not mean that anyone was actually forced to get the vaccine – instead, those who objected either had to leave town or pay a fine (\$5, equivalent to \$100 today). Furthermore, this case was decided long before the court ever began to take individual rights (e.g. the right to refuse treatment) seriously. Mariner et al., *Jacobson v. Massachusetts: It's not your Great-Grandfather's Public Health Law*, *American Journal of Public Health*, 95 (2005): 581-589.

- Smallpox, described by the WHO as “one of the most devastating diseases known to humanity,” is both highly communicable and highly fatal. At the time *Jacobson* was decided, repeated epidemics of smallpox had occurred for centuries around the world, killing thirty percent or more of its victims and leaving most of its survivors blind and/or disfigured.
- A global effort to eradicate smallpox was underway at the time that required high vaccination rates in order to be effective. Not only is the flu far less deadly than smallpox, there is no prospect of eradicating it.
- H1N1 and seasonal flu can similarly be distinguished from other diseases, such as measles, diphtheria, and polio, where vaccination has been required for school enrollment and other contexts. Seasonal flu vaccines are far more variable in their efficacy, for example, and need to be taken on an annual basis.

### **Shortages of medical resources**

As discussed above, vaccine shortages are likely to persist. Current estimates are that the first wave of H1N1 will have peaked and be well along its decline by the time that the vaccine is made available to large segments of the general population. Current delays in vaccine production mean that if the flu were to worsen suddenly, or if the demand for the vaccine were to surge (for example, as a result of reports that the flu was becoming more severe) there could be further shortages and the need for additional rationing.

Due to the unpredictable nature of the flu, it is not possible to anticipate whether the current vaccine will be well-matched with the next wave of H1N1, or whether it might emerge as an entirely new strain. If the virus were to mutate to the point where the vaccine is no longer effective, the resulting increase in severe cases could lead to shortages of anti-viral vaccines, respirators, and hospital beds. Decisions about who should be granted priority access to care under these scenarios and who should not could lead to significant conflict.

### **Social distancing measures**

Social distancing measures, such as school closures and voluntary home quarantines, could continue to occur this season or during a future wave of influenza. Generally these do not raise significant civil liberties concerns, although long-term school closures could cause social problems such as considerable disruption for working parents – especially single parents and those with fewer resources – who will need to stay at home to care for their children. If large numbers of individuals are required to or voluntarily stay at home under the advice of medical or public health personnel, the government may need to distribute food, medicine and other necessities.

### **Quarantine and isolation**

At this stage, we have moved well beyond the reach of the most coercive non-pharmaceutical interventions that could be employed during a pandemic, such as quarantine and isolation. It is widely acknowledged that these measures will not be effective in containing the disease, since it is already widespread. However, if the flu mutates significantly in the direction of increased severity, panicked calls for actions, as

well as renewed calls for border closures and travel restrictions, could arise despite their lack of effectiveness.

While public health protection has traditionally been viewed as within the states' police powers, Congress also has authority under the commerce clause to impose non-pharmaceutical interventions, including isolation and quarantine, within the states.<sup>39</sup> Section 361 of the Public Health Services Act authorizes the CDC to develop regulations to apprehend, detain, and forcibly examine persons in order to prevent a disease listed by the President from entering the country or crossing state lines. In 2005, President Bush amended the list of quarantineable diseases to include "influenza caused by novel or reemergent influenza viruses that have the potential to cause a pandemic."

At the state level, the implications of a shift in the pandemic's severity for individual liberty will depend further on the state or states in which they are occurring and how that state chooses to exercise its authority. As discussed above and in the ACLU Report *Pandemic Preparedness*<sup>40</sup>, some states have adopted highly flawed flu plans that have replaced sound public health approaches to disease prevention and mitigation with a national security approach. In Alabama, for example, the Governor or the State Board of Health may institute quarantine measures whenever they deem it necessary.<sup>41</sup> Violation of a health or quarantine law is a criminal offense, and a police officer carrying out a quarantine order may arrest and detain without warrant anyone who attempts to interfere with these duties. In Ohio, an employer of an illegal alien with an infectious disease is held responsible for "any expense caused by the contagious or infectious disease." Ohio also allows city boards of health to "employ as many persons as are necessary to execute its orders," grants those new employees police powers, and authorizes the use of "all necessary force" to enforce a quarantine.<sup>42</sup>

Another danger is that the current pandemic, and news of a worsening pandemic, could prompt states that have retained more positive and effective public health approaches in their emergency power statutes to shift toward a national security approach, as we are currently seeing in Massachusetts. Several states, for example, currently only allow quarantines to be declared if they are the least intrusive means of protecting public health. In Hawaii, the Department of Health is required to petition the court for a quarantine order, and if they are granted one, they are required to "respect the dignity" of quarantine subjects and in confine them in "the least restrictive environment dictated by public health requirements."<sup>43</sup> Quarantine subjects also have the right to contest their quarantine order in court.

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<sup>39</sup> Department of Health and Human Services and the Centers for Disease Control and Prevention "Legal Authorities for Isolation and Quarantine" December 2007. Available at: <http://www.cdc.gov/ncidod/dq/facts2.htm>

<sup>40</sup> ACLU, *Pandemic Preparedness*, <http://www.aclu.org/privacy/medical/33642pub20080114.html>.

<sup>41</sup> National Conference of State Legislatures (NCSL), "State Quarantine and Isolation Statutes (Updated April 2009)," Available at: <http://www.ncsl.org/default.aspx?tabid=17104>

<sup>42</sup> NCSL, 2009.

<sup>43</sup> NCSL, 2009.

## Conclusion

History has shown that too often, fear about the spread of a communicable disease has resulted in panicked responses on the part of the government and unnecessary restrictions on individual rights and autonomy. Currently, levels of public fear are not so high as to allow for such overreactions. Nevertheless, it is imperative that the nation engage now in conversation about appropriate responses to the current outbreak so that civil liberties concerns are considered part of – and not contrary to -- a public health mitigation effort. Safeguarding privacy and liberty in the face of a pandemic is crucial for maintaining public trust in public health authorities and encouraging public cooperation in efforts to mitigate disease. Coercive measures such as quarantine, travel bans, and forced vaccination and treatment clearly are not warranted for the current H1N1 flu situation, and should be imposed only in the most severe of cases and where there is a sound scientific and constitutional basis for doing so.