



# NYCLU

NEW YORK CIVIL LIBERTIES UNION

125 Broad Street, 19<sup>th</sup> Fl.  
New York, NY 10004  
212.607.3300  
212.607.3318  
www.nyclu.org

October 13, 2009

Richard F. Daines, M.D., Commissioner  
New York State Department of Health  
Corning Tower  
Empire State Plaza,  
Albany, NY 12237

**Re: Influenza Vaccination Requirements for Health Care Personnel,  
10 NYCRR Subpart 66-3 et seq.**

Dear Commissioner Daines:

We write on behalf of the New York Civil Liberties Union to register our objections to the recent emergency Department of Health (“NYSDOH”) regulation mandating, as a condition of employment, that tens of thousands of health care workers be inoculated against H1N1 and seasonal influenza. *See* 10 N.Y.C.R.R. Subpart 66-3 et seq.

The goal of protecting New Yorkers from the effects of H1N1 and seasonal influenza are undeniably important, as is the interest in ensuring that the health care workforce is healthy enough to keep our health care system functioning. But the mandatory vaccination program for health care workers violates core legal principles and public health policy. The starting point in our consideration of this matter is that individuals maintain a constitutional right of autonomy, and that competent adults have a “fundamental right” to direct the course of their medical care and treatment. Any intrusion upon a fundamental right is presumptively impermissible and can be justified only if necessary to the advancement of an important societal interest. The vaccine mandate is at odds with this principle, as well as with international and federal public health directives that call for voluntary influenza inoculation, rather than coercive measures. For these reasons we urge NYSDOH to withdraw the compulsory aspect of the regulation.

The NYCLU’s opposition to the compulsory vaccination regime of Subpart 66-3 should not be construed as opposition to the use of vaccination against the harms caused by the H1N1 virus or by seasonal influenza. Indeed, our position is consistent with well-established best practice protocols: the state should make vaccination widely available, particularly to vulnerable populations and to health care workers serving those populations. This initiative should be undertaken in conjunction with a clear, accurate,

and accessible public education effort that helps individuals understand the benefits and contraindications, if any, of vaccination against influenza.

**The Vaccine Mandate Violates Well-Established Principles of Personal Autonomy, including the Right of Competent Adults to Refuse Medical Care and Treatment by Failing to Strike the Appropriate Balance Between Individual Autonomy and the Protection of Public Health**

Mandatory vaccination violates well established principles of individual autonomy, including the right of competent adults to make decisions regarding their medical care. Long-established federal and New York law make clear that a person with decisional capacity has the fundamental right to make her or his own health care treatment decisions, including the right to refuse any treatment. *See Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278 (1990) (affirming competent adult’s “constitutionally protected liberty interest in refusing unwanted medical treatment”); *see also Schloendorff v. New York Hospital*, 211 N.Y. 125, 129-130 (1914) (same); and *Matter of Storar*, 52 N.Y. 2d 363, 377 (1981) (same). When fundamental rights are at stake, there is a strong presumption protecting those rights that can only be overcome if the burdensome measures are needed to substantially further powerful countervailing state interests.

This is not to say that there are never circumstances where the danger to the public from a communicable disease is so grave that state actions curtailing individual rights are warranted. But those circumstances are rare. The Supreme Court decision in *Cruzan* teaches that the question of whether an individual’s “constitutional right” [to refuse medication] has been violated must be determined by “balancing [the] liberty interest [at stake] against the relevant state interests.” *Cruzan, id.* at 279. The appropriateness of state action in response to a disease outbreak, therefore, must be considered on a case-by-case basis. Such a consideration must 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 called for by the state action, the likely effectiveness of the action, and the availability of less restrictive alternatives to accomplish the same goal.

It is our position that after a thorough balancing of interests, the nature of the threat at hand does not warrant the vaccination requirement for health care workers contained in the emergency regulation and therefore the state has exceeded its constitutional authority to curtail individual liberties.

Many individuals view vaccination as a minimal intrusion on bodily integrity. To others the intrusion appears far more substantial. A vaccination involves the introduction into the body of “a preparation of a weakened or killed pathogen, such as a bacterium or virus . . . that . . . stimulates antibody production or cellular immunity against the pathogen but is incapable of causing severe infection.”<sup>1</sup> Side effects to vaccinations are

---

<sup>1</sup> Definition of “vaccine,” Dictionary.com; available at <http://dictionary.reference.com/browse/vaccine>.

often mild (slight fever, rash, or soreness at the site of injection), but there is always the possibility – however rare – of serious side effects.<sup>2</sup> That is why the CDC recommends that while “[t]he risks of serious disease from not vaccinating are far greater than the risks of serious reaction to a vaccination,” individuals should weigh those risks for themselves and determine whether or not to get vaccinated.<sup>3</sup> In our constitutional system the choice is presumptively up to the individual.

This intrusion posed by the vaccine mandate must be balanced against the public health interests to be served. At this point, the H1N1 flu itself does not appear to be more severe than a typical seasonal flu – though concededly circumstances may change. According to Centers for Disease Control and Prevention (CDC) director Thomas Frieden in early September: “The good news is that so far, everything that we’ve seen, both here and abroad, shows that the virus has not changed to become more deadly. . . . That means that although it may affect a lot of people, most people will not be severely ill.”<sup>4</sup> Moreover, while few would deny the beneficial effects of the vaccine, none have claimed that it holds out the promise of eradicating the flu altogether, or providing absolute protection against infection.<sup>5</sup>

Indeed, less coercive measures to address the threat of flu outbreak are available to the state. A strong program to encourage vaccination, combined with employee cooperation in staying home when sick can go a long way to achieve the public health goal of minimizing individual risks and reducing transmission rates. And for the relatively few health care workers who refuse vaccinations, a combination of universal

---

<sup>2</sup> The CDC has acknowledged the possibility of adverse events associated with the vaccine, and has committed to close monitoring for side effects. Statement by Thomas Frieden, CDC Commissioner, Press Conference, Sept. 3, 2009.

<sup>3</sup> Centers for Disease Control and Prevention, *Basics and Common Questions: 10 Things You Need to Know About Immunizations*, available at <http://www.cdc.gov/vaccines/vac-gen/10-shouldknow.htm>.

<sup>4</sup> See Betsy McKay & Gordon Fairclough, *Swine Flu Remains Mild as Vaccine Advances*, Wall Street Journal, Sept. 4, 2009, available electronically at <http://online.wsj.com/article/SB125198466331383281.html>. See also *Critical Care Services and 2009 H1N1 Influenza in Australia and New Zealand*, N. Engl. J. Med 2009, available in early online publication on Oct. 8, 2009 at <http://content.nejm.org/cgi/content/full/NEJMoa0908481?query=TOC>.

<sup>5</sup> Recently, the Joint Commission released a monograph titled “Providing a Safer Environment for Health Care Personnel and Patients through Influenza Vaccination: Strategies from Research and Practice,” to help health care organizations of all types improve seasonal influenza vaccination rates in health care personnel. The Joint Commission’s Division of Quality Measurement and Research authored the monograph in collaboration with the Association for Professionals in Infection Control and Epidemiology, Inc., the CDC, the National Foundation for Infectious Diseases, and the Society for Healthcare Epidemiology of America. See JCAHO’s *Strategies for Implementing Successful Influenza Immunization Programs for Health Care Personnel*, available at [http://www.jointcommission.org/NR/rdonlyres/814E02F2-1E1C-4D76-9043-DBB3E12A205A/0/Flu\\_Monograph.pdf](http://www.jointcommission.org/NR/rdonlyres/814E02F2-1E1C-4D76-9043-DBB3E12A205A/0/Flu_Monograph.pdf). The Joint Commission’s report demonstrates the magnitude of benefit attributable to the mandatory vaccination of health care workers intervention has varied from study to study and is the subject of ongoing debate. See also *AOECM Guidance Statement* available at <http://www.aoecm.org/guidelines.aspx?id=5362>, citing various studies.

precautions combined with effective face masks can sharply reduce the risks of infection and transmission rendering mandatory measures unnecessary and unwarranted.<sup>6</sup>

Consideration of the relative severity of the threat, the degree of intrusion occasioned by a vaccination (including the possibility of side effects), the fact that mandatory vaccination is likely to mitigate, but not to eradicate the threat, and the availability of alternative, less intrusive measures, leads to the conclusion that the NYSDOH has failed to strike the appropriate balance in mandating the vaccine.

We recognize that, in 1905, the U.S. Supreme Court found that a mandatory smallpox vaccination regime was an appropriate exercise police power in the state of Massachusetts. *See Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905). The current H1N1 threat is easily distinguished from the nature and type of public health emergency in that case. Smallpox, described by the WHO as “one of the most devastating diseases known to humanity,”<sup>7</sup> was highly communicable, as is the H1N1 virus, but the mortality rate for those contracting smallpox was as high as 30%—300 times higher than the mortality rate associated with those who seek treatment for the H1N1 virus.<sup>8</sup> 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 the disease was underway that required high vaccination rates in order to be effective. The vaccine was designed to eradicate the disease, and it was ultimately successful. The H1N1 vaccine, by contrast, is not designed to, nor can it, eradicate the flu.

The H1N1 vaccine is also different from other vaccines and medications that have been required by the state in various contexts, such as MMR (measles, mumps, and rubella),<sup>9</sup> diphtheria, polio, and tuberculosis. *See, e.g., City of New York v. Doe*, 205 A.D.2d 469, 470 (1st Dep’t 1994) (detention and mandated treatment of individual with antibiotic-resistant tuberculosis upheld where patient was unable and unwilling to comply with “repeated efforts to have her participate in voluntary forms of directly observed therapy.”). In each of those cases the vaccination or medication is known to be one hundred per cent effective in preventing the disease and/or treating it, and preventing transmission.

In sum, as a New Jersey appellate court so aptly noted in *City of Newark v. J.S.*, 652 A.2d 265 (N.J. Sup. Ct. Law Div.1993), a case which dealt with the detention and mandated treatment of an individual with antibiotic-resistant tuberculosis:

---

<sup>6</sup> *See, e.g.*, Letter from New York Committee for Occupational Safety and Health to Richard F. Daines, M.D., dated October 2, 2009, available electronically at <http://www.nycosh.org/pdfs/daines.pdf>.

<sup>7</sup> World Health Organization, *Smallpox*, available at [www.who.int/mediacentre/factsheets/smallpox/en](http://www.who.int/mediacentre/factsheets/smallpox/en).

<sup>8</sup> *Id.* *See also supra* note 4, *New Engl. J. Med.* (indicating a .01% mortality rate for those contracting the H1N1 virus among cases reported to the WHO).

<sup>9</sup> *Ritterband v. Axelrod*, 149 Misc.2d 135 (Sup. Ct. Albany Co. 1990) (affirmation of NYSDOH’s authority to require mandatory physical examinations, tuberculosis tests, and rubella vaccinations for hospital personnel).

It becomes possible to reconcile public health concerns, constitutional requirements [and] civil liberties [...] all simultaneously. Good public health practice considers human rights so there is no conflict. Since coercion is a difficult and expensive means to enforce behaviors, voluntary compliance is the public health goal. Compliance is more likely when authorities demonstrate sensitivity to human rights ... That these interests are reconcilable does not mean that any one case will be easy to reconcile. Any individualized balancing process is a challenge. But it does mean that the principles by which that process is governed can be made clear and without conflict or contradiction.

*City of Newark v. J.S.*, 652 A.2d at 276

**The Vaccine Mandate is Inconsistent with Recommendations Established by the World Health Organization (“WHO”), the Centers for Disease Control (“CDC”) and Other Respected Public Health Organizations**

New York is the only governmental entity in the United States that has adopted a mandatory vaccination requirement to address the threat of the H1N1 virus. Neither the WHO nor the CDC has mandated vaccination of health care providers against either seasonal influenza or the H1N1 influenza. These organizations have consistently taken the position that inoculation against seasonal flu, and now the pandemic variant H1N1, is strongly recommended but always voluntary.

Both the WHO and the CDC have recommended immunization of health-care workers as a first priority in order to ensure the functioning of the health care system. But in response to New York’s enactment of the emergency regulation, Thomas Frieden, the CDC’s director and the former Commissioner of the New York City Department of Health and Mental Hygiene, stated that the CDC does not think it appropriate to make influenza vaccination mandatory at this time.<sup>10</sup> And, as recently as September 25, 2009, President Obama and Kathleen Sibelius, the Secretary of the United States Department of Health and Human Services reiterated that the federal government’s public health recommendation on this matter is that vaccination against H1N1 influenza should be voluntary.<sup>11</sup>

Voluntary influenza vaccination is widely recognized as a best-practice principle. In addition to the WHO and the CDC, the following organizations endorse a voluntary approach to immunization in conjunction with comprehensive programs that protect health care workers and patients against influenza: the Joint Commission (formerly the

---

<sup>10</sup> See Donald G. McNeil & Karen Zraick, *New York Health Care Workers Resist the Flu Vaccine Rule*, N.Y. Times (Sept. 20, 2009) available at [http://www.nytimes.com/2009/09/21/nyregion/21vaccine.html?\\_r=1&ref=nyregion](http://www.nytimes.com/2009/09/21/nyregion/21vaccine.html?_r=1&ref=nyregion).

<sup>11</sup> See Rob Stein, *Mandatory Flu Shots Hit Resistance*, Wash. Post (Sept. 26, 2009) available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/09/25/AR2009092503854.html>.

Joint Commission on the Accreditation of Healthcare Organizations), the Society for Healthcare Epidemiology of America, the Federal Drug Administration, the Occupational Safety and Health Administration, the American College of Physicians, the American Nurses Association, the American College of Occupational and Environmental Medicine, as well as many other private organizations and local governmental agencies, including the New York City Department of Health and Mental Hygiene.

### **The Vaccine Mandate is Contrary to Sound Public Health Policy and Undermines Trust in the Public Health System**

Sound health policy promotes trust and cooperation between and among the government policy makers, health care workers and the general public. When public trust is established, public education is more effective, and compliance with recommendations regarding health and safety recommendations is far more likely. Sweeping government mandates that carry harsh penalties for non-compliance are fundamentally at odds with effective public health policy and practice.

Indeed there is evidence of this in the hundreds of complaints received by the NYCLU and in those publicly reported. These complaints indicate that the NYSDOH's vaccination mandate for health care workers is creating conflict between health care administrators, who must enforce the mandate, and their employees, who risk loss of employment for refusing the vaccination.<sup>12</sup> Conflict of this nature can create confusion and inefficiency; it can also jeopardize public safety. If significant numbers of health care workers refuse to be inoculated and are fired, health care facilities could be seriously understaffed at the very moment H1N1 is expected to cause a surge in hospital visits.

It should evoke little surprise that many health care workers object to the compulsory vaccination regime. Health care workers are trained to recognize and respect the right of competent adults to refuse medical treatment. Their training teaches them that no competent adult may receive medical treatment without informed consent. Now they learn that this basic principle is suspended when it comes to their own medical treatment -- and not just with regard to the new H1N1 flu vaccine, but for the seasonal flu that poses the same medical issues today that it has for years.

And if health care workers are confused and upset about compulsory vaccinations, what are their patients to think? As reports of health care workers refusing vaccinations become public, confusion and worry will grow in the general population. And even if vaccination is the appropriate medical option for individuals, people may become increasingly reluctant to choose that option.

---

<sup>12</sup> Health care workers who cannot demonstrate compliance with the vaccination mandate contained in Subpart 66-3 are to be terminated from service and, further, may not be employed at any other New York health care facility that is subject to Subpart 66-3. Under this regulatory regime health care workers could be denied the right to practice their profession -- rendering null their license to practice without the rudimentary protections of due process.

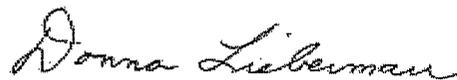
Effective mitigation of H1N1 influenza will require the cooperation of the public regarding vaccination, social distancing, sick leave from work, and other measures. But such cooperation will occur only if the public trusts health officials. NYSDOH's efforts to increase the numbers of persons inoculated against H1N1 would be more effective if the agency works with medical and nursing organizations to persuade them, based on scientific evidence, that vaccination is the appropriate medical treatment for them and their patients.

\* \* \* \* \*

In conclusion, the NYCLU takes the position, consistent with longstanding principles of law and public policy, that the State of New York should respond to the H1N1 influenza epidemic and concerns about the seasonal flu with a comprehensive and coordinated strategy that educates the public and engages its voluntary participation in vaccination programs and infection control practices.

We ask that you give serious consideration to the issues we have raised. We note, however, that this letter is not intended as a complete or exhaustive analysis of the relevant legal issues. If you would be interested in a further elaboration of the NYCLU's analysis, we would be pleased to provide it.

Sincerely,



Donna Lieberman, Executive Director



Robert Perry, Legislative Director