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Eileen P. Kelly

Susan P.S. Rosenthal

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¹⁷ 462 U.S. 19, 25 (1983).

¹⁸ Coastal States Gas Corp. v. Dep't of Energy, 617 F. 2d 854, 858 (D.C. Cir. 1980). (other citations omitted by author).

¹⁹ 682 F. 2d 530, 543 (5th Cir. 1982), *cert. denied*, 66 U.S. 944 (1984).

²⁰ 134 F.2d 1194, 1202 (2d Cir. 1998).

²¹ *Id.*

²² *Supra* 4 at 38.

²³ *Supra* 4 at 65.

²⁴ Roger Russell, *Supremes Mull Textron Petition*, Accounting Today, Vol. 24, No. 4, April 19-May 9, 2010, at 10.

²⁵ *Supreme Court Nixes Textron Appeal in IRS Case*, WebCPA (by WebCPA staff), May 24, 2010, <http://www.webcpa.com>; 2010 LEXIS U.S. App. LEXIS 13226.

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²⁷ *Supra* 2.

LEGAL INSIGHTS ON MANDATORY FLU
VACCINATIONS

by

Eileen P. Kelly*
Susan P.S. Rosenthal**

INTRODUCTION

The 2009-2010 swine flu pandemic was an historic health event of global proportion. The first influenza pandemic in over 40 years affected communities in virtually every country throughout the world. Although the recent pandemic has abated, questions regarding how it was handled and the consequences from the response remain unanswered. This article first enunciates, background information about the HINI flu, its global reach and subsequent responses by government and public health agencies are discussed. Next the recent controversy over mandatory HINI flu vaccination policies for employees, particularly those in health care fields, is examined. The debate in New York State over its Department of Health flu vaccination mandate and potential legal challenges to mandatory flu vaccination policies follows. As a conclusion, managerial suggestions to avoid employee litigation are presented.

*Professor of Management, Ithaca College, School of Business, Ithaca, NY.

**Associate Professor of Management and Chairperson, Department of Management, Ithaca College, School of Business, Ithaca, NY.

THE SPREAD OF H1N1

According to the Mayo Clinic¹ H1N1, popularly known as swine flu, is a respiratory infection caused by an influenza virus. This new virus, officially called swine influenza A (H1N1), contains genetic material from human, swine, and avian flu viruses. Initial H1N1 symptoms are similar to those of seasonal flu: high fever, cough, sore throat, chills and body aches, fatigue, and the like. However, unlike the common seasonal flu virus, H1N1 spreads quickly and easily to young, otherwise healthy people, rather than to the infirm or elderly. Those particularly at risk include children, college students, pregnant women, and health care workers who provide direct patient care.

Outbreak Timeline

The first cases of H1N1 in the United States, appearing in two children, were confirmed in southern California by the Centers for Disease Control and Prevention (CDC) on April 21, 2009.² Three days later, Mexico announced that it had hundreds of cases and 68 people had died.³ Seventy-five New York City students, some of whom had recently returned from Mexico, were immediately tested for flu-like symptoms; 28 tested positive for H1N1.⁴

On April 26, the U.S. government declared a public health emergency.⁵ The CDC advised Americans to postpone nonessential trips to Mexico the next day. There were now 40 confirmed cases in the United States and, within days, H1N1 illness was confirmed in several other countries including Canada, Germany, Israel, Spain, and New Zealand.⁶

By June 1, the CDC reported that more than 10,000 cases of H1N1 were confirmed in the United States. On June 11, 2009,

with nearly 30,000 people infected in 74 countries, the World Health Organization (WHO) raised its swine flu alert to its highest level – Phase 6 – signifying widespread human infection and “community level transmission” in two or more regions of the world.⁷ This alert was not related to the severity of the illness, but to its rapid and extensive transmission. The H1N1 influenza virus was now a worldwide pandemic.

Notably, no effective vaccine to protect against the H1N1 virus existed at the time of the WHO Phase 6 alert. Simultaneously, the CDC was projecting as many as 90,000 anticipated flu-related fatalities in the United States alone.⁸ Given the potential for a pandemic, Margaret Chan, Director General of the World Health Organization, called upon flu vaccine manufacturers to “quickly prepare commercial-scale pandemic vaccine.”⁹ The H1N1 vaccine became available in October, 2009.

CONTROVERSY OVER MANDATORY VACCINATION POLICIES

Considerable controversy erupted when some health officials sought mandatory vaccination of health care workers. In light of the declared pandemic, the resistance of the H1N1 virus to Tamiflu (the most frequently prescribed medicine for flu treatment), and the widespread exposure that health care workers would face in the event of contagion, some public officials and health administrators felt mandatory vaccination of health care workers was a first line of defense.¹⁰

New York State became the first state to require that all health care workers be vaccinated. On August 13, 2009, the State Hospital Review and Planning Council adopted an emergency regulation, recommended by the New York State Health Department, requiring seasonal influenza vaccination

and H1N1 vaccination, when available, of health care workers in hospitals, outpatient clinics, and home care services.¹¹ Some hospitals in other states also required vaccination as a condition of employment. MedStar Health system, located in the Washington-Baltimore region, required all its 26,000 employees to get the seasonal flu shot. For the past five years, Virginia Mason Medical Center in Seattle mandated seasonal flu vaccines and subsequently also the H1N1 vaccine.¹² Legal challenges arose in New York, Washington State, and across the nation as health care workers sued over mandatory flu vaccinations.¹³ As discussed below, both proponents and opponents of mandatory vaccination policies had reasonable grounds for their respective positions.

Proponents of Mandatory Vaccination

With the onslaught of H1N1 cases, public health officials and employers had good reason to be concerned about its rapid spread. The Centers for Disease Control and Prevention (CDC) estimated that between 34 million and 67 million cases of H1N1 occurred between April and November 14, 2009.¹⁴ In contrast to the typical seasonal influenza, the CDC estimates that on average about 36,000 people die of flu-related causes each year, with 90 percent of deaths usually occurring in people age 65 and older.¹⁵

Proponents of mandatory vaccination believed such a policy would not only prevent health care workers from contracting the flu, with its associated absenteeism and lost productivity, it would also help prevent health care workers from transmitting flu to patients. Even prior to the H1N1 outbreak, some public health officials were calling for mandatory seasonal influenza vaccination of health care workers as a precautionary measure to protect both health care workers and patients.¹⁶ Only 49 percent of all health care workers in the United States

voluntarily take the flu shot each year.¹⁷ A recent study of a large Midwestern health care organization with 26,000 employees found voluntary immunization plans led to low immunization rates while a mandatory vaccination policy increased immunization rates to ninety-eight percent among health care workers.¹⁸

Opponents of Mandatory Vaccination

On the other hand, opponents cited a number of reasons why they were against mandatory vaccinations. Foremost among these were concerns about the safety of the new H1N1 vaccine.¹⁹ In concert with this view, the Czech Defense Ministry retreated on compulsory vaccination of all armed forces personnel for swine flu after President Václav Klaus condemned the policy. In a widely publicized statement, President Klaus stated,

It would be justifiable in an acute epidemic situation, but we are clearly not in such a situation. My civic opinion is enforced by the health risks of being vaccinated, which have led to public disagreement among our health professionals. Soldiers cannot be regarded as an experimental sample upon whom vaccinations tests can be practiced without their consent. Therefore, I call on the defense minister and the chief of general staff of the army to consider whether the decision on vaccination should not be left up to individual soldiers.²⁰

Other concerns raised were the deaths and incidences of Guillane-Barre syndrome associated with the flu vaccine in 1976 as well as violation of personal freedom.²¹

NEW YORK STATE'S MANDATORY VACCINATION

The June 24, 2009 New York State Register noted that the Department of Health was considering regulatory action requiring health care workers to be vaccinated for influenza. On July 23, the State Hospital Review and Planning Council met to discuss emergency adoption of the immunization requirement.²² On August 13, 2009, New York State became the first state to require that all health care workers be vaccinated when the State Hospital Review and Planning Council subsequently adopted an emergency regulation recommended by the New York State Health Department. The emergency regulation consisted of the addition of Subpart 66-3 entitled "Health Care Facility Personnel-Influenza Vaccination Requirements" to Title 10 of the New York Codes, Rules and Regulations.²³

66-3 Immunization - Amend the regulations to add Subpart 66-3 to Title 10 to require certain regulated facilities to document as a precondition of employment and annually, immunizations for influenza virus for specified health care personnel employed or affiliated with a health care facility. The requirement is subject to the availability of an adequate supply of the necessary vaccine and exemptions for medical contraindications. In addition, parallel regulatory changes are proposed to Sections 405.3 (hospitals), 751.6 (diagnostic and treatment facilities), 763.13 and 766.11 (home health agencies and programs), and 793.5 (hospices) of Title 10. Any facility defined as a hospital or diagnostic and treatment centers pursuant to PHL Article 28, home care agency within PHL Article 36, or hospice within PHL

Article 40 will be required to comply with the referenced requirements detailed in Subpart 66-3.²⁴

The emergency regulation required seasonal influenza vaccinations by November 30th and H1N1 vaccinations, when available, as a condition of employment for health care workers in hospitals, outpatient clinics, and home care services.²⁵ Exceptions were allowed where medically contraindicated when a physician determined that vaccination would be detrimental to the health of the individual. The New York State Department of Health followed up with a letter dated August 26, 2009, accompanied by a Question and Answer attachment to all health care administrators informing their health facilities of the particulars of the mandate.²⁶

Immediately upon announcement of the emergency regulation, New York health care workers and their unions began to protest and commence litigation. The New York State Public Employees Federation (PEF) requested a temporary restraining order against implementation of the emergency regulation. On October 16, 2009, Judge Thomas McNamara, of the State Supreme Court in Albany, granted a temporary restraining order. Judge McNamara scheduled a hearing for October 30th to determine whether or not to make the restraining order permanent.²⁷

In addition to PEF, Suzanne Field, a registered nurse in Dutchess County, filed a petition for a temporary restraining order against the emergency regulation with the Supreme Court of New York, New York County on October 6, 2009.²⁸ Similar lawsuits were filed by four nurses in Albany and the New York State United Teachers Union.²⁹

On October 23, 2009, New York State Health Commissioner Richard Daines announced the suspension of the flu vaccine mandate for health care workers. Citing the shortage of both H1N1 and seasonal flu vaccine, the Commissioner contended that:

...these circumstances set up a dynamic where health care personnel covered under the regulation might compete for vaccine with persons with underlying risk factors for adverse outcome of influenza infection. In a situation where the choice to vaccinate is between health care personnel and persons at risk, I have always held that patients take precedence. Maintaining the health care personnel vaccination requirement would delay persons in need from being vaccinated. For these reasons, I have determined that there will not be sufficient supplies of either vaccine to meet the intent of the regulation in the 2009-2010 influenza seasons.³⁰

LEGAL ISSUES WITH MANDATORY VACCINATIONS

Employers can legally require employees to get vaccinated provided their policy permits medical and religious exemptions. The New York Department of Health pointed out that state courts previously held that health care workers could be required to be vaccinated against rubella and tuberculosis.³¹ Despite the legality of mandatory vaccination policies, prudence would dictate that an employer tread carefully and seek legal counsel before instituting one. Mandatory vaccination policies can be challenged on a variety of bases which make such policies a legal mine field. These challenges are discussed below.

Religious Discrimination Claims

Under Title VII of the Civil Rights Act of 1964, employers are legally required to accommodate the sincerely held religious beliefs and practices of their employees. All 50 states also prohibit religious discrimination in employment, as well as many municipalities.³²

Notably, some religions have objections to the use of modern medicine.³³ Christian Scientists, for example, may choose to rely on prayer rather than medicine as a remedy to health problems. While the church's official position is that their adherents are free to take vaccinations, it nonetheless appears that choosing not to be vaccinated may be equally acceptable to church authorities. As noted on the church's website:

Generally, a Christian Scientist's first choice is to rely on prayer for healing, and in most cases, this means that a medical remedy is unnecessary. There is no biblical or church mandate to forgo medical intervention, nor do Christian Scientists believe that it's God's will that anyone suffer or die. A Christian Scientist's decision to rely on prayer comes from trust, not blind faith, in God, and from a conviction that God's care continues under every circumstance..... Christian Scientists care about their neighbors and fellow community members and gladly abide by city and state laws or mandates regarding quarantines, vaccinations, and the like. The Christian Science Journal, Christian Science Sentinel, and The Herald of Christian Science also contain

documented healings of communicable diseases and show the role prayer can play, not just in protecting and healing individuals, but in helping communities as well...³⁴

Employees who have strong religious beliefs barring them from taking vaccinations may seek a religious exemption to avoid vaccination. Note that the employee does not have to belong to an organized religion to be accorded legal protection. The Supreme Court expanded the test for defining religious belief in its decision in *Welsh v. United States*.³⁵ In that decision, Justice Black held that deeply and sincerely held beliefs that are purely ethical or moral in source and content but that nevertheless impose a duty of conscience meet the statutory definition of a religious belief. The EEOC further elaborated on this issue in its 1980 Guidelines on Discrimination because of Religion in which the EEOC stated that "The fact that no religious group espouses such beliefs or the fact that the religious group to which the individual professes to belong may not accept such belief will not determine whether the belief is a religious belief of the employee or prospective employee."³⁶

Thus employees confronted with a mandatory vaccination policy have the legal right to ask the employer for an accommodation for their religious beliefs. Once an employer is put on notice, they have the legal duty to reasonably accommodate the employee to the extent that it does not create undue hardship. The definition of undue hardship is essentially any accommodation that would be unduly costly, extensive, substantial, disruptive, or that would fundamentally alter the nature or operation of the business. Furthermore, the Supreme Court ruled in *TWA v. Hardison*³⁷ that the obligation to accommodate religious beliefs and practices is a *de minimis* one.³⁸ Note that the *de minimis* standard is a lower one than

that under the Americans with Disability Act. As noted in *Ansonia Board of Education v. Philbrook*,³⁹ when an employer offers an employee a reasonable accommodation, it has discharged its statutory duty. Undue hardship only becomes an issue when the employer is not able to offer any accommodation.

To establish a *prima facie* religious accommodation claim, an employee must establish that: (1) they had a bona fide religious belief that conflicts with an employment requirement; (2) they informed the employer of this belief and requested accommodation; and (3) they were disciplined for failure to comply with the conflicting employment requirement.⁴⁰ If the employee establishes a *prima facie* case, the burden then shifts to the employer to show that: (1) it did offer a reasonable accommodation or (2) it could not accommodate the plaintiff's religious needs without undue hardship.

Americans with Disability Act (ADA) Claims

The EEOC recently issued a guidance on Pandemic Preparedness in the Workplace and the Americans with Disabilities Act.⁴¹ The guidance notes that the ADA protects workers from disability discrimination in at least three ways:

1. It regulates disability related inquiries and medical examinations, including those who do not have a statutorily defined disability.
2. An employer may not exclude an individual from employment for safety and health reasons unless they pose a "direct threat" to themselves or others, with or without reasonable accommodation.
3. The ADA requires employers to reasonably accommodate individuals with disabilities to the extent that it does not create an undue hardship.

Clearly the ADA provides strong protections for employees who do not wish to be vaccinated. Employers are not permitted to ask general questions of an applicant concerning whether they have a disability or about the severity of their disability. This would preclude asking workers to disclose a chronic health condition that would make a vaccination dangerous to a worker. Additionally, if a vaccination was medically contraindicated, such as an employee having an allergic reaction to eggs, the employee would have sound legal grounds to ask for a reasonable accommodation.

In its guidance on pandemic preparedness, the EEOC addresses head on whether an employer has the right under the ADA and Title VII to compel all workers to take the influenza vaccine regardless of their medical conditions or religious beliefs. The EEOC's response was a resounding "no."

An employee may be entitled to an exemption from a mandatory vaccination requirement based on an ADA disability that prevents him from taking the influenza vaccine. This would be a reasonable accommodation barring undue hardship (significant difficulty or expense). Similarly, under Title VII of the Civil Rights Act of 1964, once an employer receives notice that an employee's sincerely held religious belief, practice, or observance prevents him from taking the influenza vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship as defined by Title VII ("more than de minimis cost" to the operation of the employer's business, which is a lower standard than under the ADA). Generally, ADA-covered employers should consider simply encouraging employees to get the influenza vaccine rather than requiring them to take it.⁴²

Furthermore, if adverse action were taken against an employee who refused to be vaccinated, the employee could also conceivably bring a claim that they were discharged because they were regarded as disabled. In 2008, the amendments to the Americans with Disabilities Act greatly expanded the definition of disability in favor of broad coverage of individuals.⁴³

Other Legal Claims

Other legal avenues remain open to workers who oppose mandatory vaccinations. If the employee is a public employee, they also enjoy constitutional protections in their employer-employee relationship. Employees retain a privacy interest in their own body.⁴⁴ It is possible for an objecting state or local public employee to conceivably bring a Fourth Amendment Claim for unwarranted search and seizure.⁴⁵ Additionally, they could possibly bring a Fourteenth Amendment claim. Section one of the Fourteenth Amendment states that:

All persons born or naturalized in the United States and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.⁴⁶

Absent a decree by public health authorities mandating vaccination of all citizens during a pandemic, it is conceivable

that a public employee could claim violation of their liberty with a mandatory vaccination policy.

Worker's compensation claims are yet another potential legal recourse for workers subjected to mandatory vaccinations. If the employee suffers an adverse reaction from the vaccine such as a fever, rash or other side effect, they may be able to file a worker's compensation claim.

Common law tort claims are another possible legal recourse. Tort claims such as invasion of privacy or intentional infliction of emotional distress could be filed against the employer.

CONCLUSION

Employers may legally require their employees to take influenza vaccinations if they provide exemptions for religious objections and medical contraindications.⁴⁷ If the employer chooses to mandate vaccinations, having employees sign a release prior to vaccination would be advisable.⁴⁸ Prudence, however, may recommend not mandating vaccinations given the many possible causes of action for which an employer could be held liable.

A less legally fraught course of action may be to have a voluntary vaccination program with inducements for employees to participate. Employers may undertake such incentives as free or low-cost vaccinations, easy access to flu clinics at the work site, flexible vaccination hours, and education about the advisability of taking the vaccine.

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