

#### Health Matrix: The Journal of Law-Medicine

Volume 26 | Issue 1

2016

## First Do No Harm: Protecting Patients Through Immunizing Health Care Workers

Rene F. Najera

Dorit R. Reiss

Follow this and additional works at: https://scholarlycommons.law.case.edu/healthmatrix



Part of the Health Law and Policy Commons

#### Recommended Citation

Rene F. Najera and Dorit R. Reiss, First Do No Harm: Protecting Patients Through Immunizing Health Care Workers, 26 Health Matrix

Available at: https://scholarlycommons.law.case.edu/healthmatrix/vol26/iss1/13

This Article is brought to you for free and open access by the Student Journals at Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Health Matrix: The Journal of Law-Medicine by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

# FIRST DO NO HARM: PROTECTING PATIENTS THROUGH IMMUNIZING HEALTH CARE WORKERS

Rene F. Najera and Dorit R. Reiss<sup>†</sup>

#### Contents

Introduction	363
A. Adoption of Influenza Vaccine Mandates	365
I. WHY VACCINATE HEALTH CARE WORKERS AGAINST INFLUENZA?	369
II: Mandating Vaccines	372
A. First Steps: Voluntary Mandates in Hospitals	372
B. State Mandates	375
C. Employer-initiated Mandates: Legal Limits	380
III. Exemptions: What is Required?	383
A. Medical Exemptions	384
B. Religious Exemptions	
1. Constitutionally Required?	389
2. Legally Required Under the Civil Rights Act of 1964?	391
3. Religious Exemptions: Constitutional Limits on Content	394
4. Valent v. Board of Review	396
5. State RFRAs	399
IV. DISCUSSION: WHAT IS DESIRABLE IN VACCINE POLICY?	400
V. Congrueion	409

#### Introduction

Influenza is wrongly seen as a mild disease, but it can seriously harm and kill, especially but not exclusively within vulnerable segments of the population. One step hospitals are increasingly taking to protect vulnerable patients is requiring their employees to

<sup>†</sup> Rene F. Najera, MPH, is a Doctor of Public Health student at Bloomberg School of Public Health, John Hopkins University. Dorit R. Reiss is a Professor of Law at UC Hastings College of the Law. We are grateful to Melody Anne Butler, Karen Ernst, and Paul Offit for very, very helpful comments on previous drafts and to Mira Karageorge and Rob Taobada for excellent research work.

<sup>1.</sup> Martin G. Myers, The History of Vaccine Development and the Diseases Vaccines Prevent, in VACCINOLOGY: AN ESSENTIAL GUIDE 1, 27-28 (Greg N. Milligan & Alan D.T. Barrett eds., 2015).

get an annual influenza vaccine.<sup>2</sup> Opponents, unsurprisingly, attack this policy as harmful to employees' rights. This article examines the legal issues surrounding that policy.

During June 2014, a New Jersey Court of Appeals ruled that a hospital offering non-medical, religious exemptions from its policy of mandating influenza vaccines cannot deny unemployment benefits to a nurse whose opposition to the vaccine was based on secular reasoning.<sup>3</sup> While the case focused on unemployment benefits rather than the mandate itself, the court's reasoning in *Valent v. Board of Review, Department of Labor* suggested that if a hospital offers any non-medical exemptions from influenza vaccine mandates, it then needs to extend exemptions to any employee with concerns, and cannot limit exemptions to just those with religious objections.<sup>4</sup>

If other courts follow the *Valent* court's reasoning, hospitals wishing to impose immunization requirements may face a choice between not offering religious exemptions or not being able to enforce vaccination mandates. Even if other courts do not agree with *Valent*, hospitals should seriously consider whether it is prudent to offer any non-medical exemptions, since such exemptions are subject to abuse and are not legally or constitutionally required.

The ruling in *Valent* presents an opportunity to consider the legal issues surrounding mandatory vaccination of health care workers. We agree with Stewart and Cox that state mandates are a better choice than voluntary action by hospitals: they are more efficient, impose uniform requirements across providers, and provide more certainty to patients.<sup>5</sup> But as Stewart and Cox highlight, only a significant minority of states have adopted laws addressing this issue, and many of those laws <sup>6</sup> lack strong enforcement mechanisms and may therefore only loosely be considered vaccine mandates. Voluntary action taken by hospitals may serve as an important intermediate measure until states pass more effective legislation. Understanding the legal framework for both the statutory and the employer-based options—for example what can and cannot be done and where problems may arise—can help hospitals or legislatures better think through this issue.

<sup>2.</sup> Henry H. Bernstein & Jeffrey R. Starks, *Influenza Immunization for All Health Care Personnel: Keep it Mandatory*, 136 PEDIATRICS 809, 812 (2015).

Valent v. Board of Review, Dept. of Labor, 91 A.3d 644 (N.J. Super. Ct. App. Div. 2014).

<sup>4.</sup> *Id.* at 647-48.

Alexandra M. Stewart & Marisa A. Cox, State Law and Influenza Vaccination of Health Care Personnel, 31 VACCINE 827, 830 (2013).

<sup>6.</sup> Id. at 828.

#### A. Adoption of Influenza Vaccine Mandates

The last thing someone who is hospitalized needs is to contract another illness during their stay. Some illnesses are harder to avoid than others, but for others we have readily available vaccines. A prime example is the vaccine against seasonal influenza. Twenty states have statutes addressing influenza vaccination of health care workers, and more may follow. In states without mandatory vaccination laws, some hospitals voluntarily require employees to be vaccinated out of the laudable desire to protect vulnerable patients against a dangerous disease. Increasingly, hospitals around the country have adopted policies requiring health care workers to be vaccinated against influenza, with sanctions up to and including firing imposed against recalcitrant employees.

The influenza vaccine is not one of the most effective vaccines, <sup>10</sup> although it is not as ineffective as anti-vaccine websites like to pretend. This lack of effectiveness is not because scientists working on it are less competent than scientists working on other vaccines, but because it is objectively more difficult to produce. <sup>11</sup> The influenza virus mutates quickly, often rearranging its genes enough to trigger yearly epidemics in different regions of the world at different times. <sup>12</sup> Occasionally, the mutation will be severe enough that the whole of humanity is not immune at the same time, triggering a pandemic like the one recently seen in 2009. <sup>13</sup> Additionally, the influenza virus grows best—and slowly—in eggs rather than in tissue cultures like other viruses, though more recently some vaccines have been produced

#### 7. *Id*.

- 8. Some of these institutions can be found here: Wall of Shame, Nurses Against Mandatory Vaccines, http://www.namv.org/healthcare-organizations-that-mandate-vaccines.html (last visited Jan. 26, 2015); Influenza Vaccination Honor Roll, Immunization Action Coal., http://www.immunize.org/honor-roll/influenza-mandates/honorees.asp (last updated Feb. 11, 2016) (providing a list of institutions that mandate vaccination).
- 9. Jane M. Orient, Mandatory Influenza Vaccination for Medical Workers: A Critique, 17 J. Am. Physicians & Surgeons 111, 114 (2012).
- 10. CDC, Seasonal Influenza Vaccine Effectiveness, 2005-2015, http://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm.
- 11. CDC, Selecting the Viruses in the Seasonal Influenza (Flu) Vaccine (2015), http://www.cdc.gov/flu/professionals/vaccination/virusqa.htm.
- 12. WHO, Biologicals: Influenza, http://www.who.int/biologicals/vaccines/influenza/en/.
- 13. See F. Carrat & A. Flahault, Influenza Vaccine: The Challenge of Antigenic Drift, 25 Vaccine 6852, 6854 (2007).

using mammalian and insect cell lines.<sup>14</sup> This results in a hefty investment in eggs for growing the virus, and given the time needed to grow the virus, it means that the strain that is to be grown must be picked carefully six months ahead of the next flu season. 15 This process sometimes leads to a mismatch between the vaccine strain and the strain that actually circulates during the annual flu outbreak. 16 In spite of all that, the vaccine, although not perfect, is our best protection against influenza. In good years, its effectiveness ranges from 60-70%<sup>17</sup>—a substantial reduction in the chances of contracting the disease. In bad years, it can be much less. For example, in the 2014-2015 influenza season, one of the strains mutated after the creation of the vaccine, leading to substantially reduced effectiveness—only 23% effective in completely preventing influenza across all age groups (although effectiveness was higher in children). 18 Still, 23% effectiveness is still higher than the zero percent non-vaccination provides. Even if the vaccine fails to prevent the disease completely, it can reduce its severity. 19 Also, it's an extremely safe vaccine.20

A recent meta-analysis of twelve observational studies found that some research shows that health care workers, for the most part,

- 14. Anthony E. Fiore et al., *Inactivated Influenza Vaccines*, in VACCINES 257, 266-68 (Stanley A. Plotkin et al. eds., 6th ed. 2013).
- 15. See CDC, How Influenza (Flu) Vaccines are Made, http://www.cdc.gov/flu/protect/vaccine/how-fluvaccine-made.htm (last updated Jan. 6, 2015).
- 16. U.S. FOOD AND DRUG ADMIN., The Evolution, and Revolution, of Flu Vaccines (Jan. 18, 2013), http://www.fda.gov/forconsumers/consumerupdates/ucm336267.htm.
- CDC, Interim Estimates of 2013-14 Seasonal Influenza Vaccine 17. Effectiveness - United States. February 2014, 63 MORBIDITY & MORTALITY WKLY. Rep. 137, 141 (Feb. 21. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6307a1.htm; CDC, Estimated Influenza Illnesses and Hospitalizations Averted by Influenza Vaccine - United States, 2012-13 Influenza Season, 62 MORBIDITY & MORTALITY WKLY. Rep. 997. 999 (Dec. 13. 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6249a2.htm.
- 18. CDC, Protection from Flu Vaccination Reduced this Season (Jan. 15, 2014), http://www.cdc.gov/media/releases/2015/p0115-flu-vaccination.html.
- 19. CDC, Influenza 151, 159, http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/flu.pdf; JM Kelso, Safety of Influenza Vaccines, 12 CURRENT OPINION IN ALLERGY & CLINICAL IMMUNOLOGY 383; CDC, Key Facts About Seasonal Flu Vaccine: Benefits, http://www.cdc.gov/flu/protect/keyfacts.htm#benefits.
- $20. \quad \text{CDC}, \ \textit{Seasonal Influenza Vaccine Safety: A Summary for Clinicians}, \\ \text{http://www.cdc.gov/flu/professionals/vaccination/vaccine\_safety.htm}.$

agreed with mandates to get vaccinated as a condition of employment.<sup>21</sup> Almost all of the participants in one of the studies (96.7%) were of the opinion that being immunized protected the patients they served.<sup>22</sup> Indeed, a 1994-1995 study found that immunizing health care workers in a geriatric care facility reduced mortality from influenza in the elderly patients more than vaccinating the patients themselves.<sup>23</sup> A randomized controlled trial in 2000 found a similar effect.<sup>24</sup> With regards to patient populations other than the elderly, a 1997-2000 study of vaccine uptake and morbidity and mortality in a hospital in Virginia showed that increased vaccine uptake was associated with a lower number of nosocomial (hospital acquired) cases and deaths from influenza.<sup>25</sup>

There is a strong ethical case for requiring vaccination of health care workers against influenza. This is based on health care workers' autonomous choice to work in a profession in which they care for vulnerable individuals, they have responsibilities to patients and the community, and the resulting high costs in lives and suffering if they spread influenza because they did not receive the vaccine.<sup>26</sup>

However, while most health care workers understand and support the requirement to vaccinate against influenza,<sup>27</sup> a small minority opposes it. Some oppose it because of the opposition to mandates.<sup>28</sup>

- 21. See Samantha A. Pitts et al., A Systematic Review of Mandatory Influenza Vaccination in Healthcare Personnel, 47 Am. J. PREVENTATIVE MED. 330, 337 (2014).
- 22. Id.
- J. Potter et al., Influenza Vaccination of Health Care Workers in Long-Term-Care Hospitals Reduces the Mortality of Elderly Patients, 175 J. INFECTIOUS DISEASE 1, 1 (1997).
- 24. W.F. Carman et al., Effects of Influenza Vaccination of Health-Care Workers on Mortality of Elderly People in Long-Term Care: A Randomised Controlled Trial, 355 The Lancet 93, 93-97 (2000).
- 25. Cassandra D. Salgado et al., Preventing Nosocomial Influenza by Improving the Vaccine Acceptance Rate of Clinicians, 25 INFECTION CONTROL & HOSP. EPIDEMIOLOGY 923, 923-27 (2004).
- 26. See Arthur L. Caplan, Time to Mandate Influenza Vaccination in Health-care Workers, 378 The Lancet 310, 310-11 (2011); Abigale L. Ottenberg et al., Vaccinating Health Care Workers Against Influenza: The Ethical and Legal Rationale for a Mandate, 101 Am. J. Public Health 212, 212 (2011).
- 27. Kristen A. Feemster et al., Employee Designation and Health Care Worker Support of an Influenza Vaccine Mandate at a Large Pediatric Tertiary Care Hospital, 29 VACCINE 1762, 1766 (2011).
- 28. See Kinesh Patel, Resisting the Needle: Why I Won't Have the Flu Jab, BMJ (Oct. 17, 2011), http://www.bmj.com/content/343/bmj.d6554?ijkey=92b2cf3e3f35e1d441a52de965e0bf1fe9bfd69d&keytype2 =tf\_ipsecsha. But see Amy J. Behrman et al., Doctors Choosing Not to

Others oppose it because of unfounded fears or anti-vaccine views.<sup>29</sup> This viewpoint is especially troubling from a health care worker: if a health care worker cannot trust something supported by evidence as extensive as that supporting the safety of vaccines,<sup>30</sup> how can they trust the rest of the medical care they are ostensibly providing? Furthermore, like the legal field, health care is a service profession. Those who enter the field choose a job in which their role is to serve and care for people who depend on and trust them. By making that choice, a person is accepting certain limits on their conduct. If they are unwilling to take the simple, safe precaution of an influenza vaccine to protect the vulnerable patients under their care (a protection that also protects them against a dangerous disease), a health care worker is, arguably, failing that service duty.<sup>31</sup>

This Article explores the legal issues surrounding the influenza vaccine requirement for health care workers. It highlights that the requirement is in fact legitimate and legal, though collective bargaining can limit what employers facing unionized work forces can do unilaterally. We argue that while medical exemptions may be required and are arguably desirable, there is no legal or constitutional requirement to offer any other exemptions. It also highlights that if an employer wants to provide a religious exemption, they are subject to certain requirements that may make the exemption vulnerable to abuse or allow it to swallow the mandate.

Part I sets the background by providing the data behind the employers' choice to require vaccinating against influenza. It demonstrates that the vaccine is safe and can help protect patients and save lives. Part II addresses the basic legality and constitutionality behind requiring influenza vaccines, the litigation surrounding it, as it has been until now, and what we know from

Be Vaccinated is Choosing to Do Harm, BMJ (Nov. 8, 2011), http://www.bmj.com/content/343/bmj.d7198?tab=citation.

<sup>29.</sup> See, e.g., Final Thoughts on the Bashista Case, Nurses Against Mandatory Vaccines (Aug. 30, 2014), http://nursesagainstmandatoryvaccines.wordpress.com/2014/08/30/final-thoughts-on-the-bashista-case/.

<sup>30.</sup> Inst. Med. of the Nat'l Acads., Comm. on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule, The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence and Future Studies, xiv (Michael Hayes ed., 2013), http://www.nap.edu/openbook.php?record\_id=13563&page=1.

<sup>31.</sup> Kristen A. Feemster & Arthur L. Caplan, Should Flu Shots for Health Professionals Be Required?, Am. Med. News (Apr. 8, 2013), http://www.amednews.com/article/20130408/profession/130409953/5/; Behrman et al., supra note 27.

other areas of the law. Part III examines the tricky question of whether an employer is required to offer a religious exemption. It highlights that a religious exemption is not required under our Constitution;<sup>32</sup> nor is it required under the Civil Rights Act of 1964.<sup>33</sup> It also suggests that there is a strong argument that states with a Religious Freedom Restoration Act (RFRA) do not require even public hospitals to offer a religious exemption. Part III also explains the limits on and requirements of hospitals that choose to offer a religious exemption from immunization requirements. Part IV lays out our recommendations. We support state level statutory mandates, and recommend including an enforcement mechanism. Absent such mandates, we urge private employees to adopt their own mandate, and provide medical exemptions, but not other exemptions.

### I. WHY VACCINATE HEALTH CARE WORKERS AGAINST INFLUENZA?

In the United States, anywhere from 3,000 to 49,000 deaths are attributed to influenza each year.<sup>34</sup> Of those, the great majority are a result of secondary bacterial infections or exacerbations of preexisting medical conditions.<sup>35</sup> The majority of those who die during any given influenza season are very old, very young (e.g. neonates-newborns), or very sick (e.g. cancer patients).<sup>36</sup> One way to protect these populations is by immunizing them against influenza, pneumococcus, and *H. influenzae*—the latter two being common bacterial complications of an influenza infection.<sup>37</sup> However, this immunization strategy has some limits. First, the people who comprise these groups are made up mostly of persons whose immune system function is not

- 32. Kevin M. Malone & Alan R. Hinman, Vaccination Mandates: The Public Health Imperative and Individual Rights, in LAW IN PUBLIC HEALTH PRACTICE 262, 274 (Richard A. Goodman et al. eds., 2nd ed. 2007).
- 33. See discussion infra Part III.B.2.
- 34. Estimating Seasonal Influenza-Associated Deaths in the United States: CDC Study Confirms Variability of Flu, CDC, http://www.cdc.gov/flu/about/disease/us\_flu-related\_deaths.htm (last updated Sept. 12, 2013).
- 35. Id.
- 36. CDC, Estimates of Deaths Associated with Seasonal Influenza --- United States, 1976—2007, 59 MORBIDITY & MORTALITY WKLY. REP. 1057, 1057-62 (Aug. 27, 2010), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5933a1.htm.
- 37. Michael B. Rothberg et al., Complications of Viral Influenza, 121 Am. J. MED. 258, 260 (Apr. 4, 2008), http://download.thelancet.com/flatcontentassets/H1N1-flu/pathogenesis/pathogenesis-8.pdf.

normal. Neonates may not develop their own immune response to the influenza vaccine until age six months.<sup>38</sup> The elderly may not mount an efficient immune response to the vaccine because of their advanced age as well.<sup>39</sup> People on chemotherapy may be immune deficient as a side effect of their treatment.<sup>40</sup>

Even with the technical limitations of being unable to predict the next strain of influenza with 100% certainty and having to grow most of the vaccine viruses in eggs, the influenza vaccine is the best defense against influenza available in vaccine form. It is not 100% effective, nor near that, however. A meta-analysis of over 40 years of influenza vaccine studies found that the vaccine's effectiveness depended on the age of the people getting it as well as the formulation (i.e. live, attenuated intranasal vaccine versus killed injected vaccine).

The influenza vaccine has a good track record of safety.<sup>43</sup> In children, the vaccine is not associated with serious side effects.<sup>44</sup> During pregnancy, the influenza vaccine has been shown to prevent serious outcomes from influenza infection in pregnant women while

- 38. Paul A. Offit et al., Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System?. 109
  PEDIATRICS 124, 125 (2002), http://pediatrics.aappublications.org/content/109/1/124.short.
- 39. See E. Bernstein et al., Immune Response to Influenza Vaccination in a Large Healthy Elderly Population, 17 VACCINE 82, 82 (1999).
- 40. See, e.g., Leagh M. Boehmer et al., Influenza Vaccination in Patients With Cancer: An Overview, CANCER NETWORK (Nov. 15, 2010), http://www.cancernetwork.com/oncology-journal/influenza-vaccination-patients-cancer-overview.
- 41. See e.g., Vaccine Effectiveness How Well Does the Flu Vaccine Work?, CDC, http://www.cdc.gov/flu/about/qa/vaccineeffect.htm (last updated Dec. 21, 2015); CDC, Estimated Influenza Illnesses and Hospitalizations Averted by Influenza Vaccine United States, 2012-13 Influenza Season, 62 MORBIDITY & MORTALITY WKLY. REP. 993, 997 (Dec. 13, 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6249a2.htm.
- 42. See Michael T. Osterholm et al., THE COMPELLING NEED FOR GAME-CHANGING INFLUENZA VACCINES 5-6 (2012), http://www.cidrap.umn.edu/sites/default/files/public/downloads/ccivi\_report.pdf.
- 43. Influenza Vaccine Safety, CDC, http://www.cdc.gov/flu/protect/vaccine/vaccinesafety.htm (last updated Oct. 2, 2014).
- 44. See, e.g., Jason M. Glanz et al., Safety of Trivalent Inactivated Influenza Vaccine in Children Aged 24 to 59 Months in the Vaccine Safety Datalink, Arch. Pediatric Adolesc. Med. 749, 749-50 (2011); Nicholas Wood et al., Influenza Vaccine Safety in Children Less Than 5 Years Old: The 2010 and 2011 Experience in Australia, 31 Pediatric Infectious Disease J. 199, 199-202 (2012).

not being associated with serious side effects in the women or their fetuses. <sup>45</sup> Even persons with egg allergies, long believed to be ineligible for receiving the influenza vaccine because the vaccine virus is grown in eggs, can receive the vaccine safely. <sup>46</sup> While not used in the United States, vaccines with adjuvants (chemicals used to enhance the immune response) have also been shown to be safe and very effective. <sup>47</sup>

As stated previously, influenza vaccine effectiveness depends on different factors. The live, attenuated vaccine has been shown to work best in children while having decreased effectiveness in older adults. 48 On the other hand, injectable vaccines have been shown to work best in older adults. 49 Currently, high-dose vaccines are recommended for older adults because more antigens are needed in the vaccine to trigger an immune response. 50 Most health care workers will fall somewhere between children and the elderly, making them prime candidates for any vaccine formulation, albeit with the knowledge that the vaccine will not be 100% effective in any population.

In order to prevent influenza transmission in the health care setting, health care workers have different choices. They can wear masks that are not guaranteed to prevent transmission and whose proper use cannot be guaranteed.<sup>51</sup> They can wash their hands with

- 45. Glanz, supra note 44.
- 46. John M. James et al., Safe Administration of Influenza Vaccine to Patients with Egg Allergy, 133 J. PEDIATRICS 624, 624 (1998).
- 47. Murdo Ferguson et al., Safety and Long-Term Humoral Immune Response in Adults After Vaccination With an H1N1 2009 Pandemic Influenza Vaccine With or Without AS03 Adjuvant, 205 J. INFECTIOUS DISEASES 733 (2012), http://jid.oxfordjournals.org/content/205/5/733.short.
- 48. Lisa A. Grohskopf et al., Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, Morbidity & Mortality Wkly. Rep. (Aug. 15, 2014), at 691-692, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6332a3.htm.
- 49. See David Holland et al., Intradermal Influenza Vaccine Administered Using a New Microinjection System Produces Superior Immunogenicity in Elderly Adults: A Randomized Controlled Trial, 198 J. INFECTIOUS DISEASES 650, 657 (Sep. 2008).
- 50. Ann R. Falsey et al., Randomized, Double-Blind Controlled Phase 3
  Trial Comparing the Immunogenicity of High-Dose and Standard-Dose
  Influenza Vaccine in Adults 65 Years of Age and Older, 200 J.
  INFECTIOUS DISEASES 172, 172 (2009).
- 51. Mark Loeb et al., Surgical Mask vs N95 Respirator for Preventing Influenza Among Health Care Workers A Randomized Trial, 302 JAMA 1865, 1870 (2009).

every patient contact. However, guidelines about washing their hands are often not followed by health care workers for a variety of reasons.<sup>52</sup> Influenza vaccination is a passive method for reducing cases and deaths from influenza of patients and workers in health care settings. That is, it doesn't require anything more than being immunized, and especially combined with proper hand washing and use of personal protective equipment like masks, it can be part of a comprehensive and highly effective influenza outbreak mitigation strategy.

#### II: MANDATING VACCINES

Vaccine mandates can stem from one of two sources, and different legal frameworks apply to each. The first source is state statute or state regulations. The second is employers' workplace rules. The legal situation is somewhat different between the two. This section starts by describing the adoption of mandates first in the hospitals, where the idea started, then by state legislatures. Then it separates out a discussion of the legal issues, first for states and then for hospitals.

#### A. First Steps: Voluntary Mandates in Hospitals

The first hospitals to adopt mandatory immunizations policies were Bronson Methodist Hospital in Kalamazoo, Michigan and Virginia Mason Medical Center in Seattle, Washington, in 2005.<sup>53</sup> By 2009, twenty-five other institutions did the same.<sup>54</sup> Hundreds more followed, but the number of health care institutions doing so remained minute compared to the number of existing health care providers.<sup>55</sup>

In addition, twenty states passed laws addressing vaccination of health care workers, though not all of them actually mandate vaccination, and only three address sanctions for non-compliance.<sup>56</sup>

Let's consider one example of a hospital-initiated mandate. In a detailed PowerPoint, Dr. Susan Coffin from the Children's Hospital of Philadelphia described the hospital's experience with an influenza

<sup>52.</sup> Sile A. Creedon, Healthcare Workers' Hand Decontamination Practices: Compliance With Recommended Guidelines, 51 J. ADVANCED NURSING 208, 208 (Aug. 2005).

<sup>53.</sup> Alexandra M. Stewart & Sara Rosenbaum, Vaccinating the Health-Care Workforce: State Law vs. Institutional Requirements, 125 Pub. Health Rep. 615, 615 (2010).

<sup>54.</sup> *Id.* 

<sup>55.</sup> See Stewart & Cox, supra note 5, at 830.

<sup>56.</sup> *Id.* at 829 (stating that the three states addressing compliance are Maine, Arkansas, and Rhode Island).

vaccination mandate.<sup>57</sup> In July 2009, the hospital's Patient Safety Committee recommended requiring vaccination for all employees working with patients or in buildings where patient care was provided.<sup>58</sup> The main reason given was concern over the harm not vaccinating could pose to the patients. Dr. Coffin provided information about adverse outcomes—up to and including death—that had occurred to patients from influenza contracted in the hospital pre-mandate.<sup>59</sup>

The hospital offered a medical and a religious exemption, but if an employee refused to be vaccinated without obtaining one of those, they were furloughed for two weeks and if they persisted, they were terminated. On Paul Offit, Chief of Infectious Diseases in the Children's Hospital in Philadelphia, explained:

We actually mandated the vaccine, not only for health care workers, but for all employees, and the deal was that if you didn't want to get the vaccine, you had 2 weeks of unpaid leave to think about it. If you still didn't want to get the vaccine, then you were asked to step down from your position. 62

In terms of implementing the exemptions, fifty employees obtained a medical exemption from 2009 to 2010.<sup>63</sup> Dr. Offit explained that initially, he was responsible for enforcing the religious exemption.<sup>64</sup> When that was the case, he required the person requesting an exemption to provide a letter from their religious leader pointing out where, exactly, in that person's religious texts there was a prohibition on vaccination.<sup>65</sup> Under that strict approach, the

- 57. Susan Coffin, Carrots and Sticks: Influenza Vaccination of Healthcare Workers (2010), http://pahcwfluvaxdotorg.files.wordpress.com/2011/06/coffin\_flu-vax-of-hcw-chop\_june-20101.pdf.
- 58. Id.
- 59. Id.
- 60. Id.
- 61. Id.
- 62. Paul A. Offit, Mandating Influenza Vaccine: One Hospital's Experience (Sept. 13, 2010), http://www.medscape.com/viewarticle/728352?src=sttwit.
- 63. Coffin, supra note 57.
- 64. Telephone Interview with Dr. Paul Offit, Director of the Vaccine Education Center, at The Children's Hospital of Philadelphia (June 12, 2014).
- 65. As will be discussed later, if this had gone to court, that approach would probably have been found unconstitutional. See notes 186-188 and accompanying text.

number of religious exemptions was extremely limited (only two such exemptions were granted).  $^{66}$ 

In subsequent years, the hospital transferred the decision making to a former federal judge, who adopted a more lenient approach, and the number of religious exemptions became higher.<sup>67</sup> Still, the vast majority of employees complied. This is in line with the experience in other hospitals, where mandating vaccination led to very high rates of employees being vaccinated.<sup>68</sup>

The accommodation offered to those who received a medical or religious exemption was wearing a facemask during influenza season, which Dr. Offit noted is not as effective in preventing transmission of influenza. <sup>69</sup> Still, as explained above, the number of employees taking advantage of the accommodation in the first years was very, very small.

We asked Dr. Offit why the hospital provides a religious accommodation at all, and he explained that it was not because the hospital thought it was legally required to provide it, but rather it was out of respect for religious values.<sup>70</sup>

In Valent v. Board of Review, a New Jersey Court of Appeals described the way the mandate was implemented by Hackettstown Community Hospital:

Effective September 21, 2010, Adventist Health Care, Inc., the corporate owners of HCH, issued a policy in its "Corporate Policy Manual" titled "Health Care Worker Flu Prevention Plan." The purpose of the policy was to enhance "health care worker vaccination rates and prevent[] the spread of the flu during the flu season or pandemic, to patients, residents, [health care workers] and their families, as well as the community."

Participation with the flu vaccination directive was mandatory "unless there [was] a documented medical or *religious* exemption. For those with an exemption, a declination form

<sup>66.</sup> Coffin, supra note 57.

<sup>67.</sup> Telephone Interview with Dr. Paul Offit, supra note 64.

<sup>68.</sup> Bridget A. Gaughan, The Successful Implementation of Mandatory Seasonal Influenza Vaccination for Health Care Workers at an Academic Medical Center, 38 Am. J. Infection Control e51, e51 (2010); R.M. Rakita et al., Mandatory Influenza Vaccination of Healthcare Workers: A 5-Year Study, 31 Infection Control Hosp. Epidemiology 881, 881 (2010).

<sup>69.</sup> Telephone Interview with Dr. Paul Offit, Director of the Vaccine Education Center, at The Children's Hospital of Philadelphia (June 12, 2014). And see discussion near footnotes 144-147.

<sup>70.</sup> Id.

must be signed and accompanied with an appropriate note each year. In addition, regardless of where [employees] work, for those who must decline the flu vaccine, it will be mandatory to properly wear a facemask (available at the facility) during the entire flu season, to be determined by [employer] based on [Center for Disease Control] guidelines. Failure to comply with this policy will result in progressive discipline up to and including termination."<sup>71</sup>

Again, the hospital chose a policy that requires immunization and offered a medical and religious exemption. The fate of its religious exemption is discussed in Section III.b.

#### B. State Mandates

Another potential source for mandates is state-wide legislation or regulation. Stewart and Cox reviewed state laws related to influenza vaccination of health care workers in 2012.<sup>72</sup> They found that twenty states had laws on the issue, though none of them matched the model statute Stewart and Cox proposed.<sup>73</sup> These statutes generally required immunization and documenting the practice, though relatively few of them required employers to cover the cost.<sup>74</sup>

Enforcement provisions were scarce: most statutes did not require that employees be dismissed for non-compliance or have other sanctions, suggesting that the statutes were not exactly full mandates.<sup>75</sup> Only three of those states actually addressed handling non-compliance.

In Arkansas, employers not in compliance with the vaccination requirements will be sanctioned. Maine public health officials, on the other hand, will exclude an HCP from work if they pose a "clear danger to the health of others." An exempted HCP may receive immunization or be tested to determine their immune status. Those who are shown to not be immune "must be excluded from the work site during one incubation period."<sup>76</sup>

Rhode Island differs:

Rhode Island requires HCP who are exempt from the vaccination requirement to wear a surgical face mask when the

Valent v. Bd. of Review, Dept. of Labor, 91 A.3d 644, 644-645 (N.J. Super. Ct. App. Div. 2014).

<sup>72.</sup> See generally Stewart & Cox, supra note 5.

<sup>73.</sup> See id. at 829 (Table 2).

<sup>74.</sup> *Id*.

<sup>75.</sup> See id.

<sup>76.</sup> Id. at 829.

Department of Health declares influenza is widespread and when the HCP is engaged in direct contact with patients. HCP who refuse to comply are subject to a \$100 fine for each act. The HCP may be disciplined by the licensing board for unprofessional conduct. $^{77}$ 

Others described Rhode Island as the only state with a real mandate.<sup>78</sup>

There have been several recent additions to states that issue mandates via regulations. In 2012, the Colorado Board of Health enacted rules that require licensed facilities to meet a specified threshold of immunized workers by a set date.<sup>79</sup> The licensing requirements provide that:

10.6 If a licensed healthcare entity demonstrates that it has vaccinated a targeted percentage of its employees in a given year, using its own methodology, it shall be exempt from the requirements of sections 10.7 through 10.12 of this Part for the following year as long as it continues to use the same or more stringent methodology.

- (A) The minimum targets required for this exemption are:
  - (1) 60 percent of employees vaccinated by December 31, 2012:
  - (2) 75 percent of employees vaccinated by December 31, 2013; and
  - (3) 90 percent of employees vaccinated by December 31, 2014; and by December 31 of each year thereafter.<sup>80</sup>

Requirements 10.7-10.12 include a requirement to offer the vaccine and document meeting the proposed set.<sup>81</sup> Colorado offered a medical exemption.<sup>82</sup> The Colorado approach was to use a licensing tool to raise immunization rates. This approach may be especially promising: states have substantial leeway in setting health and safety requirements as license conditions for health care facilities. The topic, however, deserves its own treatment, and is somewhat beyond the scope of this article.

<sup>77.</sup> Id.

<sup>78.</sup> Lisa H. Randall et al., Legal Considerations Surrounding Mandatory Influenza Vaccination for Healthcare Workers in the United States, 31 VACCINE 1771, 1771 (2013).

<sup>79.</sup> Colo. Code Regs § 6 C.C.R. 1011-1 (2014).

<sup>80.</sup> Id.

<sup>81.</sup> Id.

<sup>82.</sup> Colo. Code Regs. § 1011-1-10.8(A)(2) (2013).

On August 12, 2014, South Dakota's Governor signed an executive order requiring all state-employed health care workers to vaccinate against influenza, unless they obtain one of the exemptions offered—medical or religious.<sup>83</sup> The order did not, however, mention any sanction for non-compliance.<sup>84</sup>

In states without clear enforcement provisions, compliance is a real issue. On July 16, 2014, Massachusetts' Department of Public Health released a report showing that the program, while not inconsequential, was not as effective as hoped. 85 Many hospitals failed to comply with the target of having over 90% of the workforce vaccinated against influenza, and many hospitals did not even meet the reporting requirements properly. 86 State officials considered taking action by citing non-compliant hospitals. 87

Note, however, that most hospitals had over 80% of workers vaccinated—an increase compared to before the statute.<sup>88</sup> This example suggests that a statute—even without a direct enforcement mechanism—helps, but more powerful enforcement provisions would probably help more. There is evidence that hospital mandates can lead to 98% compliance,<sup>89</sup> and there is no reason states should not achieve similar results.

States also varied in terms of the exemptions offered. Some offered none, some offered only medical exemptions, and two—Maine and New Hampshire—offered a philosophical exemption.  $^{90}$ 

Several suits were brought challenging statutes and regulations related to influenza vaccines.<sup>91</sup> While no court actually struck down a

- 83. Exec. Order No. 2014-11, Office of the Governor, South Dakota (Aug. 12, 2014), http://doh.sd.gov/documents/order2014-11.pdf.
- 84. Id. Summary of CDPHE Rule on Influenza Immunization of Healthcare Workers, https://www.colorado.gov/pacific/sites/default/files/PW\_Imm\_Summary-of-Board-of-Health-ruling-regarding-influenza-vaccination-of-health-care-workers.pdf (last visited Jan. 28, 2015).
- 85. See Chelsea Rice, Mass. Hospital Workers' Flu Vaccination Rates Fall Below Target, BOSTON GLOBE (July 16, 2014), http://www.boston.com/health/2014/07/16/mass-hospital-workers-flu-vaccination-rates-fall-belowtarget/RUftxAYxnNIfBhWoJqHMNO/story.html.
- 86. Id.
- 87. Id.
- 88. Id.
- 89. See Randall et al., supra note 78, at 1772.
- 90. Stewart & Cox, supra note 5, at 829.
- 91. Stewart & Rosenbaum, supra note 53, at 616-17; Wendy J. Parmet, Pandemic Vaccines The Legal Landscape, 362 NEW ENG. J. MED. 1949, 1951 (2010).

statute addressing influenza vaccination, a court in New York, where the requirement was in regulations, issued a temporary restraining order against the mandate in response to a case. <sup>92</sup> Citing vaccine shortages, the state withdrew the regulation and the case was dismissed. <sup>93</sup> Possibly because of this setback, <sup>94</sup> New York changed its regulation: now the regulation requires documentation of vaccination status, and for those workers with no documentation, that they "wear a surgical or procedure [sic] mask while in areas where patients or residents may be present." <sup>95</sup>

It's unlikely that a mandate would be found unconstitutional if a court had to rule on it. Since Jacobson v. Massachusetts, 6 which found that fining an individual who refuses to vaccinate is constitutional, every state or federal court that ruled on the issue gave states dramatic leeway to require immunization, without requiring any non-medical exemptions. 7 It's been a long time since Jacobson, and in those years, patient autonomy acquired substantial importance. Substantial debate rages around the continued validity of the case. Nevertheless, much of the logic holds: as important as

- 92. See id. (discussing the challenge to the New York emergency regulation).
- 93. Id.
- 94. James T. Mulder, New Ultimatum for CNY Health Care Workers this Flu Season: Get a Shot or Wear a Mask, SYRACUSE POST STANDARD (Oct. 22, 2013), http://www.syracuse.com/news/index.ssf/2013/10/new\_ultimatum\_for\_cny\_health\_care\_workers\_this\_flu\_season\_get\_a\_shot\_or\_wear\_a\_m.html.
- 95. Nirav R. Shah, DAL: DAL-NH-13-04: Flu Mask Requirements, N.Y. DEP'T OF HEALTH (July 17, 2013), https://www.health.ny.gov/professionals/nursing\_home\_administrator/dal\_nh\_13-04 flu mask requirement.htm.
- 96. Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11, 31-32 (1905).
- 97. Dorit R. Reiss, Thou Shalt Not Take the Name of the Lord Thy God in Vain: Use and Abuse of Religious Exemptions from School Immunization Requirements, 65 HASTINGS L.J. 1551, 1558-60 (2014).
- 98. Jaime S. King & Benjamin Moulton, Rethinking Informed Consent: The Case for Shared Medical Decision- Making, 32 Am. J. LAW & MED. 429, 429-30 (2006).
- See, e.g., Michael H. Shapiro, Updating Constitutional Doctrine: An Extended Response to the Critique of Compulsory Vaccination, 12 Yale J. Health Pol'y, L. & Ethics 87, 95-96 (2012); Ben Horowitz, A Shot in the Arm: What a Modern Approach to Jacobson v. Massachusetts Means for Mandatory Vaccinations During a Public Health Emergency, 60 Am. U. L. Rev. 1715, 1730-31 (2011); Christopher Richins, J.D., Ll.M., Jacobson Revisited an Argument for Strict Judicial Scrutiny of Compulsory Vaccination, 32 J. Legal Med. 409, 410 (2011); Lawrence O. Gostin, Jacobson v. Massachusetts at 100 Years: Police Power and

individual liberty is, sometimes it must be put aside for the public good. For example, we still have laws allowing quarantining of individuals in certain circumstances. <sup>100</sup> If we apply the rational basis test to the question of mandatory immunization, upholding influenza requirements is an easy question: it's rational to aim to reduce morbidity and mortality from a disease like influenza. <sup>101</sup>

We can argue that a person's autonomy to choose or reject a medical procedure is part of the liberty protected by the Fourteenth Amendment, subject to a strict scrutiny standard. But even under a strict scrutiny standard, a state would have a powerful argument supporting the statute. Protecting vulnerable patients from a disease that can kill or severely hurt them is a compelling interest. In Workman v. Mingo Board of Education, the Fourth Circuit found that a "state's wish to prevent the spread of communicable diseases clearly constitutes a compelling interest." And as discussed more in depth in Section III, there really is no good substitute to vaccination for preventing influenza. Masks, though they have been used in the past, are of limited effectiveness. 40

Civil Liberties in Tension, 95 Am. J. Pub. Health 576, 580 (2005); James Colgrove & Ronald Bayer, Manifold Restraints: Liberty, Public Health and the Legacy of Jacobson v. Massachusetts, 95 Am. J. Pub. Health, 571, 575 (2005); Wendy K. Mariner et al., Jacobson v. Massachusetts: It's Not your Great-Great-Grandfather's Public Health Law, 95 Am. J. Pub. Health 581, 586 (2005); Note, Toward a Twenty-First-Century Jacobson v. Massachusetts, 121 Harv. L. Rev. 1820, 1821-22 (2008); Wendy E. Parmet et al., Plenary Program: Jacobson v. Massachusetts, 33 J. L. Med. & Ethics 24, 26 (2005).

- 100. Jason W. Sapsin, Center for Law & the Public's Health at Georgetown and Johns Hopkins Universities, Public Health Legal Preparedness Briefing Memorandum #41: Overview of Federal and State Quarantine Authority, Center for Law and the Public's Health, http://www.publichealthlaw.net/Resources/ResourcesPDFs/4quarantine.pdf
- 101. Ottenberg et al, supra note 26, at 214.
- 102. Dorit Reiss & Lois Weithorn, Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal, 63 Buff. L. Rev. 881, 897 (2015).
- 103. Workman v. Mingo Cnty. Bd. Of Educ., 419 F. App'x 348, 353–54 (4th Cir. 2011) (per curiam).
- 104. B.J. Cowling et al., Face Masks to Prevent Transmission of Influenza Virus: A Systematic Review, 138 EPIDEMIOLOGY AND INFECTION 449, 449 (2010); Allison E. Aiello et al., Mask Use, Hand Hygiene, and Seasonal Influenza-Like Illness Among Young Adults: A Randomized Intervention Trial, 201 J. INFECTIOUS DISEASES 491, 491 (2010); Chandini R. MacIntyre et al., A Cluster Randomized Clinical Trial Comparing FitTested and Non-Fit-Tested N95 Respirators to Medical Masks to Prevent Respiratory Virus Infection in Health Care Workers, 5 J.

hospitals tried other ways to increase vaccination rates, including education and declination forms. <sup>105</sup> While not completely ineffective, those methods only led to a very modest increase in immunization rates. <sup>106</sup> It appears that there really is no good substitute to vaccine mandates in this context. Even under strict scrutiny review, therefore, there is a strong argument that a mandate is constitutional. <sup>107</sup> Patients in a hospital are not just any person on the street; they are vulnerable individuals placing themselves literally in the hands of health care workers, relying on their care. <sup>108</sup> Acting to protect them is even more imperative than acting to protect citizens' lives generally—and protection of life is already a powerful argument.

#### C. Employer-initiated Mandates: Legal Limits

The situation for mandates is somewhat different for an employer. Employment in the United States is generally at-will, which means that employers have quite a bit of leeway to set work conditions and to dismiss workers who refuse to meet those conditions and requirements. Specifically, every state except Montana has a presumption of at-will employment, which means the employee can be fired for any reason or no reason at all. This presumption can be overcome if there is an implied-in-fact contract, for example, a handbook with employment contracts that set limits on firing. But the majority rule is that if there is such a contract, the employer can unilaterally change the policy as long as they give the employees notice and it doesn't interfere with vested interests.

INFLUENZA AND OTHER RESPIRATORY VIRUSES 170, 170 (2011); Faisal bin-Reza et al., The Use of Masks and Respirators to Prevent Transmission of Influenza: A Systematic Review of the Scientific Evidence, 6 J. INFLUENZA & OTHER RESPIRATORY VIRUSES 257, 257 (2011).

- 105. K.A. Bryant et al., Improving Influenza Immunization Rates Among Healthcare Workers Caring for High-Risk Pediatric Patients, 25 INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 912, 912 (2004); Tehri Tapiainen et al., Influenza Vaccination Among Healthcare Workers in a University Children's Hospital, 26 INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 855, 855 (2005).
- 106. Bryant, supra note 105, at 912. See also Coffin, supra note 60.
- 107. Stewart & Rosenbaum, supra note 53, at 616-17.
- 108. Caplan, supra note 26.
- 109. See, e.g., Cal. Lab. Code § 2922 (West); Payne v. Western & Atl. R.R. Co., 81 Tenn. 507, 519-20 (1884) (an employer could fire his employees for a good reason, a bad reason, or no reason at all, including firing employees for shopping at a non-company owned store).
- 110. Asmus v. Pac. Bell, 999 P.2d 71, 81 (Cal. 2000) ("As discussed, our employment cases support application of contract principles in the

Employers may not discriminate in hiring, promotion or retention because of disability or because of one of the bases included in Title VII of the Civil Rights Act of 1964—"race, color, religion, sex, or national origin." Aside from those restrictions, an employer has substantial leeway to require that employees adhere to conditions set.

Non-unionized workers, therefore, cannot attack influenza mandates set by a private employer except through the lens of the Americans with Disabilities Act<sup>112</sup> or The Civil Rights Act, 1964.<sup>113</sup> Neither law directly prevents mandates, although employees will probably argue they mandate exemptions (see Section III for that discussion).

The situation may be different for unionized workers. The question is whether immunization requirements are subject to collective bargaining. At least one court answered in the affirmative. In 2004, after a voluntary immunization program still left the staff immunization rate at 55%, Virginia Mason Hospital circulated a memo announcing a mandatory influenza immunization program. Under the policy, anyone who did not have a religious objection or documented vaccine allergy would have to show proof of vaccination by January 1, 2005, or face termination "unless he or she agreed to

decision whether an employer may unilaterally terminate employment security policy that has become an implied-in-fact unilateral contract. Under contract theory, an employer may terminate a unilateral contract of indefinite duration, as long as its action occurs after a reasonable time, and is subject to prescribed or implied limitations, including reasonable notice and preservation of vested benefits. The facts clearly show that employees enjoyed the benefits of the MESP for a reasonable time period, and that Pacific Bell gave its employees reasonable and ample notice of its intent to terminate the MESP. The company also did not at any time interfere with employees' vested benefits in effecting the MESP termination. In addition, the employees accepted the company's modified policy by continuing to work in light of the modification. Therefore, in response to the Ninth Circuit's certification request, we conclude that we should answer as follows: An employer may terminate a written employment security policy that contains a specified condition, if the condition is one of indefinite duration and the employer makes the change after a reasonable time, on reasonable notice, and without interfering with the employees' vested benefits.") (citations omitted).

- 111. 42 U.S.C. § 2000e-2 (1964) ("The Civil Rights Act").
- 112. See 42 U.S.C. § 12101, et seq. (1990).
- 113. 42 U.S.C. §2000e-2 (1964).
- 114. Stewart & Rosenbaum, supra note 53, at 616.
- Va. Mason Hosp. v. Wash. Nurses Ass'n, 511 F.3d 908, 912 (9th Cir. 2007).

take flu prophylaxis medication at his or her own expense."<sup>116</sup> The Washington State Nurses Association, a union, filed a grievance that went to an arbitrator.<sup>117</sup> The arbitrator interpreted the Collective Bargaining Agreement as requiring the employer to negotiate with the union on this issue and the federal district court upheld the arbitrator's interpretation.<sup>118</sup> The Ninth Circuit Court of Appeals, in turn, upheld the District Court's decision.<sup>119</sup> Note, however, that the basis for the Ninth Circuit's decision was the high level of deference due to the arbitrator's interpretation of the specific collective bargaining agreement at issue, not a decision about mandatory immunization policies and collective bargaining in general.<sup>120</sup>

After the Ninth Circuit decision, the hospital adopted, apparently still unilaterally, a policy requiring extensive mask use from non-vaccinated employees, and the union appealed that policy, this time to the National Labor Relations Board (NLRB), as an unfair labor practice. 121 After somewhat complex proceedings, the NLRB rejected the hospital's claim that it did not have to negotiate on masks because the issue was part of its core purposes under the Peerless standard and remanded the decision to the Administrative Law Judge (ALJ) to decide on the rest of the hospital's claims. 122 The ALJ decided—and the NLRB affirmed—that the union waived the requirement of collective bargaining by agreeing to a specific clause—the management-rights clause—in the collective bargaining agreement. 123

- 116. Id.
- 117. Id.
- 118. Va. Mason Hosp. v. Wash. Nurses Ass'n, No. C05-1434MJP, 2006 WL 27203, at \*7 (W.D. Wash. Jan. 5, 2006), aff'd, 511 F.3d 908 (9th Cir. 2007).
- 119. Va. Mason Hosp., 511 F.3d at 917-18.
- 120. Va. Mason Hosp., 2006 WL 27203 at \*7.
- 121. WSNA Leads Fight for Nurses' Rights on Flu Policies (July 27, 2012), http://www.wsna.org/labor/Victories/Mandatory-Immunization/documents/VMMC-2012-07.pdf.
- 122. Va. Mason Hosp. (a Div. of Va. Mason Hosp. Ctr.) and Wash. Nurses Ass'n, 357 N.L.R.B. No. 53, 5 (Aug. 23, 2011); Peerless Publ'ns, Inc. & Newspaper Guild of Greater Phila. Local 10, 283 N.L.R.B. 334, 335-336 (1987) (setting a test under which some decisions are exempt from collective bargaining, if the subject matter goes to "the protection of the core purposes of the enterprise," the rule is "narrowly tailored" to meet that objective, and appropriately limited to relevant employees to achieve the objectives).
- 123. Supplemental Decision and Order, Va. Mason Hosp. (a Div. of Va. Mason Hosp. Ctr.) and Wash. Nurses Ass'n, 357 N.L.R.B. No. 53, 1-2 (June 25, 2012).

We do not know what, exactly, happened. It could be that the union was not amenable to accepting a flu mandate—Washington is a state with relatively high rates of exemptions from school immunization requirements, 124 suggesting a relatively sizable antivaccine contingency (still a small minority, but larger than in other states). It could be that the management acted in a heavy-handed manner and the contentious issue was really the power to decide rather than the influenza vaccine mandate itself.

So, what is the takeaway from *Virginia Mason Hospital?* We believe it is that a hospital facing a unionized workforce may be limited in its ability to impose a mandatory immunization policy without bargaining with the union. A hospital cannot assume that its mandatory immunization policies will be upheld against unionized workers if they were not reached via collective bargaining. The specific limits will heavily depend on the collective bargaining agreement's contents. The safe course for a hospital faced with a unionized workforce is to bargain about influenza immunization policies and try to get the union on board. If the union will not bargain, or if an agreement cannot be reached, whether a court will uphold the hospital's policy will depend on the specifics of the collective bargaining agreement as interpreted by the decision maker.

Other struggles around unionized workers also showed that an employer may face trouble applying a mandatory immunization policy to the unionized workers without bargaining with the union first, though the result is uncertain. However, even in Virginia Mason Hospital, "vaccination coverage among unionized inpatient nurses in this medical center increased from 85.9% to 95.8% between 2005 and 2010, potentially indicating that mandatory vaccination increased facility-wide coverage, even among exempted union workers." In other words, even after the court's initial decision that unionized workers were not required to vaccinate, the mandatory policy still in place for non-unionized workers continued to achieve high rates of immunization.

#### III. Exemptions: What is Required?

This subsection analyzes what is required once a state or employer decides to impose a mandatory influenza immunization

<sup>124.</sup> See Ranee Seither et al., Vaccination Coverage Among Children in Kindergarten, Morbidity & Mortality Wkly. Rep. 607, 610-11 (August 2, 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6230a3.htm.

<sup>125.</sup> Randall, et al., supra note 78, at 1773.

<sup>126.</sup> Id.

policy. An employer or a state may choose to offer certain exemptions from the requirements. Experience suggests that the exemptions used in the health care worker context mimic those of school immunization requirements, including medical, religious, and in a minority of cases philosophical exemptions.<sup>127</sup> This section explores what the options and limits in terms of exemptions are. Are any exemptions required? If so, which? And what are the limits on the content of an exemption?

#### A. Medical Exemptions

The first type of exemption is a medical exemption. The CDC recognizes that some individuals with specific medical problems should not be vaccinated. <sup>128</sup> For the injected influenza vaccine, which contains inactivated viruses, a "[s]evere allergic reaction (e.g., anaphylaxis) after a previous dose of any IIV or LAIV or to a vaccine component, including egg protein" is a contraindication, and the CDC lists it as a reason not to get the vaccine. <sup>129</sup> For the nasal mist, which contains attenuated viruses, contraindications are a "[s]evere allergic reaction (e.g., anaphylaxis) after a previous dose of IIV or LAIV or to a vaccine component, including egg protein" and "[c]onditions for which the ACIP recommends against use, but which are not contraindications in vaccine package insert: immune suppression, certain chronic medical conditions such as asthma, diabetes, heart or kidney disease, and pregnancy." <sup>130</sup>

Should a state passing a statute, or an employer mandating vaccination, offer a medical exemption? Let's begin with  $Jacobson\ v.$   $Massachusetts.^{131}$  The statute challenged in Jacobson included an exemption from vaccination for "children certified by a registered physician to be unfit subjects for vaccination," but had no equivalent exception for adults.  $^{132}$  In response, the Court said,

<sup>127.</sup> See Stewart & Cox, supra note 5, at 831; Randall et al., supra note 78, at 1772.

<sup>128.</sup> Chart of Contraindications and Precautions to Commonly Used Vaccines, CDC, http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm (last updated Mar. 6, 2014).

<sup>129.</sup> Id. However, it's not clear that egg allergy is, in fact, a bar to getting the influenza vaccine. See Jonathan Spergel, Vaccines and Egg Allergies: Can People With Egg Allergies Get Vaccines?, CHILDREN'S HOSPITAL OF PHILADELPHIA, http://www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients/egg-products#.VvMyw-IrJpg ("Advances in technology have allowed the quantities in current influenza vaccines given as shots to be so minimal that people with egg allergies can now receive the influenza shot.").

<sup>130.</sup> Chart of Contraindications, supra note 128.

<sup>131.</sup> Jacobson v. Commonwealth of Mass., 197 U.S. 11 (1905).

<sup>132.</sup> Id. at 30.

[T]his cannot be deemed a denial of the equal protection of the laws to adults; for the statute is applicable equally to all in like condition, and there are obviously reasons why regulations may be appropriate for adults which could not be safely applied to persons of tender years.<sup>133</sup>

In other words, applying a medical exemption only to children and not to adults is not a constitutional problem because there are real differences between adults and children.

But that's not all the case said. Rejecting Jacobson's claim of medical risk, apparently based on an adverse reaction as a child, the Court highlighted that Jacobson did not substantiate his argument:

[D]efendant did not offer to prove that, by reason of his then condition, he was in fact not a fit subject of vaccination at the time he was informed of the requirement of the regulation adopted by the board of health. It is entirely consistent with his offer of proof that, after reaching full age, he had become, so far as medical skill could discover, and when informed of the regulation of the board of health was, a fit subject of vaccination. 134

While the Court did not expressly rule on what would have happened had Jacobson proven a specific medical problem, it at least implies that such a problem would impact the result. This suggests that it may at least be unconstitutional to require vaccinations for people with medical conditions that make vaccinating dangerous—such as people with contraindications.

This is probably an appropriate result, and should be kept today: the rationale behind contraindications is that those individuals are put at risk by being vaccinated. Requiring them to sacrifice their health or worse for vaccinating is probably asking too much. Rather, those people will be protected by herd immunity. Since such reactions are extremely rare, the number of people with contraindications is probably small enough to keep rates of vaccination in hospitals very, very high.

On the other hand, one could ask whether it's appropriate to allow people who cannot be vaccinated for medical reasons to have

<sup>133.</sup> Id.

<sup>134.</sup> Id. at 36-37.

<sup>135.</sup> David S. Stephens, Vaccines for the Unvaccinated: Protecting the Herd, 197 J. INFECTIOUS DISEASES 643, 645 (2008).

<sup>136.</sup> Seasonal Influenza Vaccine Safety: A Summary for Clinicians, CDC, http://www.cdc.gov/flu/professionals/vaccination/vaccine\_safety.htm (last updated Dec. 12, 2014).

access to vulnerable patients. The discussion is not, after all, whether it's appropriate to tie people with contraindications down and force vaccinate them or to penalize them criminally for not vaccinating. If the reason for not vaccinating is medical, there is no fault in not doing so, but there may still be good reason to deny people with those conditions access to vulnerable patients to whom they might transmit influenza. It's not a matter of penalty nor is it a matter of blame: the patient's interest in being protected against influenza stands in opposition to the health care worker's interest in working in the medical field and to the public's need for qualified and caring health care professionals.

Legislatively, it seems close enough that the state should have some leeway to decide if, in that state's specific circumstances, the existence of a medical exemption too seriously undermines the protection of patients' right to health and life, which as discussed, is a compelling state interest. There is, however, at least a potential argument that a medical exemption is constitutionally required under Jacobson. 137

There is an additional factor for both public and private employers to consider. In addition to constitutional requirements that may force a public employer to offer a medical exemption, the Americans with Disabilities Act<sup>138</sup> may impose requirements. Sections 12112(a) and (b) of the ADA require employers not to discriminate against disabled workers—a category that is broad enough to include contraindications—if  $_{
m thev}$ can, with with reasonable accommodation, still do the job. 139 Generally, this means that an should accommodate workers with employer contraindications, as the EEOC explained in a memo on the topic. 140

There is an exemption in the ADA if the employer can demonstrate "undue hardship" on its operation <sup>141</sup> or, under our jurisprudence, on fellow employees. <sup>142</sup> This is a fairly high bar requiring "significant" difficulty or expense. <sup>143</sup> Factors to consider include the cost of the

<sup>137.</sup> See Jacobson, 197 U.S. at 36-37. See also Reiss & Weithorn, supra note 102, at 920.

<sup>138.</sup> See 42 U.S.C § 12101 et seq. (1990).

<sup>139. 42</sup> U.S.C. § 12112(a)-(b).

<sup>140.</sup> U.S. Equal Employment Opportunity Commission, PANDEMIC PREPAREDNESS IN THE WORKPLACE AND THE AMERICANS WITH DISABILITIES ACT, http://www.eeoc.gov/facts/pandemic\_flu.html (last modified Oct. 9, 2009).

<sup>141. 42</sup> U.S.C §12112(b)(5)(A) (1990).

<sup>142.</sup> US Airways, Inc. v. Barnett, 535 U.S. 391, 400 (2002).

<sup>143. 29</sup> C.F.R. § 1630.2(p)(1) (1991).

accommodation, which includes sources available to offset it; the resources of the facility, size and numbers of employees; the type of operations; and the impact of the accommodation on the facility's operations and on other employees.<sup>144</sup>

The most commonly used accommodation for employees with contraindications is a facemask. Its effectiveness in preventing influenza, however, has been challenged, with some claiming that by itself it is not particularly effective. 145 As discussed above in Section III(B), if a regular mask does not properly protect—or if there's not good evidence that it does, in fact, protect—then it's not a reasonable accommodation. A reasonable accommodation is one that allows an employee to fill her essential functions without violating her religious beliefs. 146 Something that does not prevent influenza is not a substitute for something that does, and risking a patient's health in the absence of good evidence that masks work is asking quite a bit. A heavier mask such as an N95 respirator may be more effective, though even there the evidence is mixed, 147 but getting them, especially if they are not used regularly, and making sure they are being used properly at all times may be a significant expense. 148 While this may mean that those masks are a reasonable accommodation, the cost may be seen as an undue burden. That will be a question of fact.

Furthermore, there is an additional problem for both masks and N95 respirators. Vaccination is a passive precaution: get it one time and you're done, and receipt of a vaccine is relatively easy to monitor. All the employer needs to check is that the employee received his or her annual influenza vaccine. Alternatives such as masks are continuous precautions: they need to be used constantly to work. It is very human to forget or to not properly use a mask, so using masks as an alternative may require employers to invest more in monitoring, potentially making the precaution an undue burden.

Because of this, masks may not be a reasonable accommodation.

<sup>144. 29</sup> C.F.R. §1630.2(p)(2) (1991).

<sup>145.</sup> Loeb, *supra* note 51, at 1870 (noting the concerns over reduced efficacy).

<sup>146.</sup> See generally Michelle A. Travis, Leveling the Playing Field or Stacking the Deck?: The "Unfair Advantage" Critique of Perceived Disability Claims, 78 N.C. L. Rev. 901, 913 (2000).

<sup>147.</sup> See Loeb, supra note 51, at 1870; C. Raina MacIntyre et al., Efficacy of Face Masks and Respirators in Preventing Upper Respiratory Tract Bacterial Colonization and Co-Infection in Hospital Healthcare Workers, 62 Preventive Med. 1, 5 (2014).

<sup>148.</sup> See Gio Baracco et al., Comparative Cost of Stockpiling Various Types of Respiratory Protective Devices to Protect the Health Care Workforce During an Influenza Pandemic, 9 DISASTER MED. & PUB. HEALTH PREPAREDNESS 313 (2015).

The potential for loss of life from patients infected by non-vaccinated personnel is a substantial burden—few burdens can be higher than unnecessary, preventable deaths—which would allow employers not to provide this accommodation. Nevertheless, employers can still choose to provide the alternative anyway. There is an argument they're not required to; but because masks may be at least somewhat effective, there is also an argument that the burden is not high enough to exempt employers from the ADA.

Another possible accommodation is reassignment: workers with medical contraindications can be reassigned, at least during flu season, so as not to work with patients. This raises two problems: it can lead to staffing shortages in areas that require patient care, undermining the hospitals operations; and it can harm other workers. Reassignment raises issues such as where the reassigned personnel will work. Will reassigned employees have to be assigned jobs that are, from their point of view, less desirable?

Finally, some argue that that non-vaccinated employees can be seen as a direct threat, and hence the ADA would support vaccine mandates—though proponents acknowledge this has not yet been done. The direct threat doctrine is embodied in § 12113(b). The provision is vague, and courts have not given it much more substance. However, one area in which it had been applied is to health care workers that may endanger patients in contexts that included, among others, HIV infection or alcoholism. In those cases, courts, while attempting to evaluate the scientific and medical evidence, offered a high level of deference to the employer's assessment of the level of threat. Here, too, courts are very likely to defer to employers' judgment that an unvaccinated health care worker poses a direct threat to patients, especially those from vulnerable categories.

<sup>149.</sup> Andrew T. Pavia, Mandate to Protect Patients from Health Care-Associated Influenza, 50 Clinical Infectious Diseases 465, 465 (2010).

<sup>150.</sup> Befort, Stephan, The Most Difficult ADA Reasonable Accommodation Issues: Reassignment and Leave of Absence, 37 Wake Forest L. Rev. 439, 441-442 (2002).

<sup>151.</sup> See Randall et al., supra note 78, at 1773-74.

<sup>152. 42</sup> U.S.C. §12113(b) (2009) (stating that qualification standards "may include a requirement that an individual shall not pose a direct threat to the health or safety of other individuals in the workplace").

<sup>153.</sup> See Jeffrey A. Van Detta, "Typhoid Mary" Meets the ADA: A Case Study of the 'Direct Threat' Standard Under The Americans With Disabilities Act, 22 Harv. J.L. & Pub. Pol'y 849, 863-67 (1999).

<sup>154.</sup> Id. at 869.

<sup>155.</sup> Id. at 871.

Still, because the bar is relatively high under the ADA, hospitals may be required to provide a medical exemption and accommodations to workers with medical contraindications, though it will be a case-by-case, situation-dependent question.

#### B. Religious Exemptions

In considering religious exemptions, the first two questions to consider are whether they are required in the first place and, if they are adopted, whether there are requirements as to the content. The answer to these questions affects the choice of whether to provide religious exemptions.

#### 1. Constitutionally Required?

The Constitution binds state actors. This includes not only states passing statutes requiring vaccination of health care workers, but also public hospitals. The Equal Employment Opportunity Commission (EEOC), which monitors the application of the Civil Rights Act of 1964 by employers (see below), also adheres to our First Amendment jurisprudence in implementing the act. Understanding the way our courts interpret the First Amendment in this context is therefore critical.

The First Amendment says, in the relevant part, that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." Both the establishment of religion 157 and the free exercise of it 158 were incorporated—applied to the states—via the due process clause of the Fourteenth Amendment. The question is whether the First Amendment requires state actors to offer a religious exemption to vaccines. *Jacobson* predates the incorporation of the First Amendment towards the states, but subsequent jurisprudence strongly suggests that the answer is no.

Prince v. Massachusetts addressed whether religious freedom trumps child labor laws, and answered in the negative. <sup>159</sup> In dicta, the court in Prince went on to say that a parent "cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death." <sup>160</sup> Prince came after Cantwell, so the free exercise clause already applied to the state, and the Prince

<sup>156.</sup> U.S. Const. amend. I.

<sup>157.</sup> Everson v. Bd. of Educ. of Ewing Twp., 330 U.S. 1, 5 (1947).

<sup>158.</sup> Cantwell v. Connecticut, 310 U.S. 296, 303 (1940).

<sup>159.</sup> Prince v. Massachusetts, 321 U.S. 158, 168-69 (1944).

<sup>160.</sup> Id. at 166-67.

court acknowledged the weight of it. But this dicta in *Prince* reaffirmed that the state has the power to require immunization to protect the public health.

This interpretation had been relied on in subsequent state and federal cases. For example, in 2011 the Fourth Circuit Court of Appeals in *Workman v. Mingo Board of Education* rejected a challenge to West Virginia's lack of religious exemption. <sup>161</sup> The Court said:

[T]he state's wish to prevent the spread of communicable diseases clearly constitutes a compelling interest. In sum, following the reasoning of Jacobson and Prince, we conclude that the West Virginia statute requiring vaccinations as a condition of admission to school does not unconstitutionally infringe Workman's right to free exercise. This conclusion is buttressed by the opinions of numerous federal and state courts that have reached similar conclusions in comparable cases.  $^{162}$ 

Still, we could raise a question on whether *Prince* does, indeed, definitively address the issue. *Prince* addressed a situation of parental rights over children. In addition to the public health, another important interest came into play there: the rights of the child. The *Prince* dicta addressed both. There is an argument that *Prince* does not allow states to overcome religious freedoms where there is not a similar compilation of interests, such as a mixture of both children's rights and public health. In the context of health care workers and flu, we do not have such a circumstance; the tension—assuming the religious opposition is sincere<sup>163</sup>—is between the freedom of religion for health workers and public health, including the welfare of patients, some of whom may be children.

Later Supreme Court jurisprudence addressed this kind of tension, though not in the context of vaccination. The most important case is  $Employment\ Division,\ Department\ of\ Human\ Resources\ of\ Oregon\ v.$   $Smith.^{164}$  In Smith, the Supreme Court overturned previous precedents by ruling that a state can apply a "neutral law of general applicability" to those with religious objections, except in cases where another Constitutional right besides freedom of religion was

<sup>161.</sup> Workman v. Mingo Cty. Bd. of Educ., 419 F. App'x 348, 353-54 (4th Cir. 2011).

<sup>162.</sup> *Id.* (citations omitted).

<sup>163.</sup> See footnotes 192-196 and the accompanying text.

<sup>164. 494</sup> U.S. 872 (1990).

<sup>165.</sup> Id. at 878-79.

implicated.  $^{166}$  As recently explained by the Supreme Court in Hobby Lobby, "The Court therefore held that, under the First Amendment, "neutral, generally applicable laws may be applied to religious practices even when not supported by a compelling governmental interest."  $^{167}$ The Hobby Lobby majority treated Smith as the starting point for a First Amendment analysis and based its decision on RFRA's deviation from Smith, clearly leaving Smith untouched.  $^{168}$  The dissent expressed even stronger support for Smith.  $^{169}$ 

Under this jurisprudence, a general requirement of mandatory influenza vaccination with no religious exemption does not violate the First Amendment even without a showing of compelling interest.

Of course, protecting the life of vulnerable patients from influenza can be seen as a compelling interest. Under the compelling interest analysis, however, one must show that mandatory influenza vaccination is the least restrictive means of achieving the goal—a high standard, as *Hobby Lobby* demonstrates. That said, as discussed more in detail above in relation to accommodations, it's not clear that there is a viable alternative for protecting vulnerable patients: hand washing and masks reduce the infection rate, but vaccination on top of them reduces it even more. Without vaccination, there will be a cost in life. The CDC recommends both hand washing and vaccinating. The CDC recommends both hand washing and vaccinating. As also discussed, hospitals have tried education and other means before moving to mandates—and those were not sufficiently effective. This suggests that a mandate is, in fact, the least restrictive means.

The best conclusion, therefore, is that states enacting statutes mandating influenza vaccinations and public hospitals requiring its employees to vaccinate are not required to offer a religious exemption under our jurisprudence.

#### 2. Legally Required Under the Civil Rights Act of 1964?

Both public and private employers have to take into account the limits on employment discrimination embedded in Title VII of the

<sup>166.</sup> Id. at 877.

Burwell v. Hobby Lobby Stores, Inc. 134 S. Ct. 2751, 2761 (2014)
 (citing City of Boerne v. Flores, 521 U.S. 507, 514 (1997)).

<sup>168.</sup> Id. at 2761-62.

<sup>169.</sup> Id, at 2790 (Ginsburg, J., dissenting).

<sup>170.</sup> Id. at 2780.

<sup>171.</sup> CDC, CDC Says "Take 3" Actions To Fight The Flu, http://www.cdc.gov/flu/protect/preventing.htm (last updated Sept. 9, 2014).

Civil Rights Act of 1964.<sup>172</sup> Title VII prohibits discrimination based on religion (and other attributes not relevant to this paper) in hiring, firing, compensating and promoting employees.<sup>173</sup> For religion, an employer is required to "reasonably accommodate" an employee's "religious observance or practice" unless doing so will be an "undue hardship on the conduct of the employer's business."<sup>174</sup>

Does Title VII require employers to accommodate employees' opposition to influenza vaccination if it is based on sincere religious objection? In practice, as discussed above, employers have offered exemptions and required facemask usage with varying requirements as accommodation. Another potential accommodation employers to reassign employees with religious objections to a role that does not involve working with patients or with those that work with patients—for example, in a separate building. However, there is an extremely strong case that neither accommodation is required under the Civil Rights Act as interpreted by our courts. To begin, as explained above, a mask is not effective in preventing transmission. A reasonable accommodation is a question of fact, 175 and the question of what is reasonable accommodation in the context of influenza vaccine mandates has not been directly addressed by the courts, to the best of our knowledge. But, if the mask does not prevent infection, the goal of the policy—to prevent infecting patients—will not be achieved. An accommodation that undermines the goal of the rule is not an accommodation an employer is reasonably required to offer. 176

This claim can be challenged by highlighting that an employee has a duty to offer reasonable accommodation of some kind unless such accommodation causes undue hardship.<sup>177</sup> But both suggested accommodations—wearing a mask and reassignment during flu season—are not required under the undue hardship analysis, either. Courts have interpreted the undue hardship standard to impose a very low bar. An accommodation imposes an undue hardship if it imposes "more than *de minimis* cost" on the operation of the employer's business.<sup>178</sup>

<sup>172. 42</sup> U.S.C. § 2000e-2(a) (1964).

<sup>173.</sup> Id.

<sup>174. 42</sup> U.S.C. § 2000e(j) (1964).

<sup>175.</sup> Smith v. Pyro Mining Co., 827 F.2d 1081, 1085 (6th Cir. 1987).

<sup>176.</sup> See EEOC v. Oak-Rite Mfg. Corp., No. IP99–1962–C–H/G, 2001 WL 1168156, at \*9 (S.D. Ind. Aug 27, 2001); Ansonia Bd. of Educ. v. Philbrook, 479 U.S. 60, 68-69 (1986).

<sup>177.</sup> Id.

<sup>178.</sup> Trans World Airlines, Inc. v. Hardison, 432 U.S. 63, 84 (1977) ("To require TWA to bear more than a de minimis cost in order to give Hardison Saturdays off is an undue hardship.").

As already discussed, a mask is a continuous precaution, like washing hands. This kind of precaution is much more vulnerable to employees forgetting, neglecting, or otherwise ignoring requirement to wear a mask. It's much harder to enforce than a onetime precaution, like installing seatbelts or getting a shot. Moreover, as explained above, the mask's effectiveness is debatable, and likely low: it may well not prevent transmission. Given the ineffectiveness of masks and the difficulties of enforcing their use, the cost of allowing them could be more sick or dead patients. That's a substantial burden for the operation of a business. In a previous case, a court found that an employer was not required to accommodate an employee's religious opposition to wearing pants because there was evidence that wearing other clothes created a safety hazard. 179 While that case focused on the safety of the employee, the safety of patients is no less valuable. Experimenting with patients' safety—or sacrificing it—is an undue burden. While the N-95 respirator may be more effective, as discussed, requiring employers to provide them when they do not normally carry enough to cover constant use is more than a de minimis burden.

Reassigning will also often be a substantial burden: it can deprive the hospital of trained workers available to work with patients, leading to those areas being understaffed and patients being underserved. It can also be a burden on other employees— either those who will have to shoulder additional tasks because of reassignment, or those without religious objections that will have to be reassigned in turn to make room for the objecting employee. Employers are not required to reassign employees if doing so will impose a burden on other employees. <sup>180</sup> Nor is an employer required to reassign an employee if that will violate seniority. <sup>181</sup> While the burden of reassignment is a factual question, in many circumstances reassignment would be a burden either on the employer or on other employees. Even more, reassigning in the same building may not solve the problem—the employee may still infect others who may then infect patients.

In short, Title VII of the Civil Rights Act does not require

<sup>179.</sup> E.E.O.C. v. Oak-Rite Mfg. Corp., 2001 WL 1168156at \*1 ("The accommodation that the EEOC suggests—'a reasonably close-fitting, denim or canvas dress/skirt that extends to within two or three inches above the ankle'...would impose an undue hardship on Oak—Rite by requiring it to experiment with employee safety...No evidence shows that the proposed solution has worked safely in any comparable manufacturing setting.").

<sup>180.</sup> See Trans World Airlines, Inc., 432 U.S. at 81.

Id. at 82-83. See also Stolley v. Lockheed Martin Aeronautics Co., 228
 F. App'x 379, 382 (5th Cir. 2007).

employers to offer a religious exemption. Even if we see wearing a mask or reassignment as potential reasonable accommodations, these accommodations impose an undue burden on employers and may create too high a risk for patients' health and life.

#### 3. Religious Exemptions: Constitutional Limits on Content

If a state or an employer chooses to offer a religious accommodation even though it is not required—which is possible given the high place religious values occupy in the United States society<sup>182</sup>—Constitutional jurisprudence, mostly decided in the context of school immunization requirements, imposes some important limits on the content of such an accommodation.<sup>183</sup>

First, in terms of content, our jurisprudence defines religious beliefs very broadly to include "moral, ethical, or religious beliefs about what is right and wrong ...[that are] held with the strength of traditional religious convictions." <sup>184</sup> The EEOC adopts a similarly broad approach in its interpretation of title VII. <sup>185</sup> The definition is not limitless—it does not extend to political opinions or safety concerns, for example—but it is broad. <sup>186</sup>

Part of this broad definition is the idea that the exemption cannot be limited to organized religions.<sup>187</sup> Nor can those implementing a religious exemption deny one to someone on the grounds that the

- 182. Pew Research Center, "Nones" on the Rise: One-in-Five Adults Have No Religious Affiliation,at1, 17(Oct. http://www.pewforum.org/files/2012/10/NonesOnTheRise-full.pdf (stating that the number of Americans who say religion is important in their lives is 58%, as compared to Britain at 17%, France at 13%, Germany at 21%, and Spain at 22%); see also Kenneth D. Wald & Allison Calhoun-Brown, Religion and Politics in the United STATES 11-16 (5th ed. 2007). As already mentioned, Dr. Paul Offit explained CHOP's decision to offer a religious exemption out of recognition of the importance of religion in the United States rather than any fears of legal liability. Offit, supra note 69.
- 183. See Reiss, supra note 97, at 1558-60.
- 184. Welsh v. United States, 398 U.S. 333, 340 (1970).
- 185. EEOC COMPLIANCE MANUAL 6-7 (Jul. 22, 2008), http://www.eeoc.gov/policy/docs/religion.pdf. While the EEOC's guidance document is not law, since in this case it simply encapsulates the Supreme Court's jurisprudence and the principle of non-discrimination between religious beliefs, it probably holds.
- 186. Slater v. King Soopers, 809 F. Supp. 809, 810 (D. Colo. Dec. 31, 1992) (explaining that a Ku Klux Klan member fired for participating in a rally was not discriminated against on religious grounds because "the KKK is not a religion for purposes of Title VII. Rather the KKK is political and social in nature.").
- 187. See, e.g., Dalli v. Bd. of Educ., 267 N.E.2d 219, 222-23 (Mass. 1971).

official position of that person's religion does not oppose vaccines. A person is permitted to have her or his own interpretation of religious requirements, even if that interpretation is in tension with the official religion's position.<sup>188</sup> Nor can an exemption be denied because a belief appears to the employer irrational or non-credible.<sup>189</sup> This is because state actors should not have the power to act as "conscience police" evaluating religious beliefs.<sup>190</sup> The meaning of this, however, is that these kinds of exemptions, if offered, are vulnerable to abuse.<sup>191</sup>

States or employers may require a showing of sincerity as a condition for an exemption. In fact, under some interpretations, Title VII could require such a showing.<sup>192</sup> Note that for state statutes, in the context of school exemptions, states have found that officials may not impose such a requirement unless the statute itself requires sincerity—i.e., it cannot be read in by the administrators applying the statute.<sup>193</sup> For example, in order to evaluate sincerity, New York engages in a detailed process to examine what the person seeking an exemption said and potentially also interrogating the applicant.<sup>194</sup>

There is quite some leeway to evaluate sincerity under Title VII.

- Berg v. Glen Cove City Sch. Dist., 853 F. Supp. 651, 655 (E.D.N.Y. June 1, 1994).
- 189. Dettmer v. Landon, 799 F.2d 929, 932 (4th Cir. 1986) (rejecting the argument that witchcraft was a "conglomeration" of "various aspects of the occult" rather than a religion, stating that religious beliefs need not be "acceptable, logical, consistent or comprehensible to others" to be protected) (internal quotation marks omitted).
- 190. Reiss, *supra* note 97, at 1558.
- 191. Id. at 1588.
- 192. United States v. Seeger, 380 U.S. 163, 185 (1965) ("the threshold question of sincerity ... must be resolved in every case."). See also Bushouse v. Local Union 2209, United Auto., Aerospace & Agric. Implement Workers of Am., 164 F. Supp. 2d 1066, 1075 (N.D. Ind. 2001) ("Given the purpose of the protections and special accommodations afforded by Title VII, the court concludes that Title VII does permit an inquiry into the sincerity and religious nature of an employee or member's purported beliefs before the duty to accommodate such a belief arises").
- 193. In re LePage, 18 P.3d 1177, 1180 (Wyo. 2001) ("[T]he statutory language lacks any mention of an inquiry by the state into the sincerity of religious beliefs. As a result, the Department of Health exceeded its legislative authority when it conducted a further inquiry into the sincerity of Mrs. LePage's religious beliefs."). For a detailed analysis of this, see Dep't of Health v. Curry, 722 So. 2d 874, 878–79 (Fla. Dist. Ct. App. 1998).
- 194. See, e.g., Check ex rel. MC, No. 13-cv-791 (SLT)(LB), 2013 WL 2181045, at \*7-8 (E.D.N.Y. May 20, 2013); Farina v. Bd. of Educ., 116 F. Supp. 2d 503, 510-11 (S.D.N.Y. 2000).

The EEOC explains the criteria that can be used to assess an employee's sincerity in the context of a Title VII claim:

Factors that—either alone or in combination—might undermine an employee's assertion that he sincerely holds the religious belief at issue include: whether the employee has behaved in a manner markedly inconsistent with the professed belief; whether the accommodation sought is a particularly desirable benefit that is likely to be sought for secular reasons; whether the timing of the request renders it suspect (e.g., it follows an earlier request by the employee for the same benefit for secular reasons); and whether the employer otherwise has reason to believe the accommodation is not sought for religious reasons. However, none of these factors is dispositive. 195

The ability to demand a show of sincerity reduces, but does not eliminate, the concerns about abuse.  $^{196}$ 

#### 4. Valent v. Board of Review

As previously discussed, a New Jersey Court of Appeal recently ruled that a hospital offering religious exemptions from influenza immunization cannot deny them to those with secular objections to vaccination. $^{197}$ 

June Valent began working for Hackettstown Community Hospital, New Jersey, in 2009. In 2010 the hospital adopted a policy requiring workers to be vaccinated against influenza and offered medical or religious exemptions. Employees who qualified for an exemption were required to wear a mask. $^{198}$ 

Ms. Valent refused the vaccine, even though she had no medical reason, and vaccinating would have reduced her chances of contracting influenza and transmitting it to vulnerable patients. She was not, however, willing to pretend her reasons for refusing the vaccine were religious. She clearly stated that her reasons were secular. She did agree to wear a facemask, as any vaccine exempt worker would.

The hospital fired Ms. Valent for violating the policy. The issue under consideration was whether she was entitled to unemployment benefits. Under New Jersey law, an employer may deny unemployment benefits if the employee engaged in misconduct, which

<sup>195.</sup> EEOC COMPLIANCE MANUAL, supra note 185, at 13.

<sup>196.</sup> Reiss, supra note 97, at 1559-90.

Valent v. Bd. of Review, Dept. of Labor, 91 A.3d 644, 648 (N.J. Super. App. Div. 2014).

<sup>198.</sup> Id. at 645.

includes violating a reasonable rule of the employer.<sup>199</sup> After somewhat complex proceedings, the Appeal Tribunal of the Board of Review of the Department Of Labor decided to deny her the benefits because the employer's requirements were "not unreasonable."<sup>200</sup>

The New Jersey Appellate Division reversed, reinstating the benefits. The court ruled that firing Ms. Valent "unconstitutionally violated [her] freedom of expression by endorsing the employer's religion-based exemption to its flu vaccination policy." <sup>201</sup> The policy "discriminates against an employee's right to refuse to be vaccinated based only on purely secular reasons." <sup>202</sup> It also determined that because the employer offered a non-medical exemption, the policy was clearly not driven only by health concerns. <sup>203</sup>

This decision is problematic in several ways. The result is probably correct: first, the requirement that those with religious objections "have a letter from a spiritual leader" discriminates against those whose religious opposition does not stem from organized religion, and therefore is likely unconstitutional. We are not as comfortable commenting on the employment law issues, but denial of seven weeks of unemployment—when the employee has already lost her job—seems severe. Refusing the vaccine does not seem to be the kind of deliberate misconduct that would justify such a sanction. Although, the counter argument is that a health care worker who violates the employer's rules by refusing a simple, safe precaution like a vaccine is showing a high level of disregard for the safety of patients. We would still lean away from denying unemployment benefits; on top of firing, it seems petty.

That said, the decision is extremely problematic in its analysis and implication, and should not stand. Let's start with the legal problems, and then address the policy issues. The court found the main issue to be that denying Ms. Valent benefits "unconstitutionally violated [her] freedom of expression by endorsing the employer's religion-based exemption to its flu vaccination policy"<sup>204</sup> and the hospital's policy "discriminates against an employee's right to refuse to be vaccinated based only on purely secular reasons."<sup>205</sup> Neither part can stand. First, basing this on freedom of expression rather than the

<sup>199.</sup> N.J. Stat. Ann. § 43:21-5(b) (West 2010); N.J. Admin. Code § 12:17-10.6 (2003).

<sup>200.</sup> Valent, 91 A.3d at 646 (internal quotation marks omitted).

<sup>201.</sup> Id. (internal quotation marks omitted).

<sup>202.</sup> Id. at 648.

<sup>203.</sup> Id. at 646-647.

<sup>204.</sup> Id. at 644.

<sup>205.</sup> Id. at 648.

Free Exercise Clause (of the First Amendment to the United States Constitution) is strange. Vaccinating is an act, not an expression. So is taking an exemption. The best argument we can suggest in support of this ruling is that to qualify for an exemption, Ms. Valent had to express a reason. Making the exemption religious restricted her freedom of speech by only allowing her to make certain explanations. But that's a strange way to use freedom of speech, and not the way it is usually applied. An explanation of why one fits the requirements of a waiver is not the same as expressing an opinion. This looks like an issue of freedom of conscience, not of expression.

Similarly, our laws very clearly distinguish between religious beliefs and other beliefs. Title VII of the Civil Rights Act of 1964 prohibits discrimination against religion, not against every opinion, and requires accommodation of religious beliefs, not every whim. The Constitution, too, treats religion differently. It's true that the definition of religious beliefs, as already discussed, is broad;<sup>206</sup> but it's not limitless. It does not extend to political beliefs, and it does not extend to safety concerns about vaccines. Distinguishing between religious and non-religious reasons is not discrimination: it's treating differently two different types of reasons that are already subject to different treatment in our legal system.

Legally speaking, the decision is very problematic. It is also problematic policy-wise. Broadly applied, it would abolish the distinction between religious beliefs and philosophical exemptions, allowing anyone in a state that offers a religious exemption to opt out, even if the state requires show of sincerity, even if the applicant's sole reason is safety concerns. Our jurisprudence surrounding exemptions was never applied that way—and states offering only a religious exemption seem to seek to apply it to a certain set of reasons only.

Further, in *Valent*, the court found that the religious exemption undermined the declared goal of the policy, which is to protect patients' health, because the employees with such exemptions will still be putting patients at risk.<sup>207</sup> By offering a religious exemption, the court said, the hospital admitted that it was not focusing solely on health considerations.<sup>208</sup> The court concluded that if the hospital is willing to put the values some employees hold above patients' health, the hospital should not discriminate among such values.<sup>209</sup>

That, too, is problematic. First, a hospital's willingness to

<sup>206.</sup> See Welsh v. United States, 398 U.S. 333, 340 (1970); see also notes 182-183 and accompanying text.

<sup>207.</sup> Valent, 91 A.3d at 647-48.

<sup>208.</sup> Id.

<sup>209.</sup> Id.

accommodate those with religious opposition does not imply insincerity in its health concerns or that it's willing to put them aside. It can easily suggest that a hospital thinks religious concerns are very important and that it should make an attempt to accommodate, as much as possible, both health concerns (by a mandatory policy) and religious concerns (via an exemption). A hospital can also legitimately anticipate, since most religions do not oppose vaccines, 210 that the number of religious exemptions will be small, and the harm to health less with the policy and exemption than without the policy.

Forced to extend the exemption to those with secular objections, too, a hospital will likely find the health goals undermined. *Valent* is wrong on the law and problematic on policy grounds.

#### 5. State RFRAs

After Smith, Congress enacted the Religious Freedom Restoration Act (RFRA), <sup>211</sup> attempting to reinstate the strict scrutiny of statutes that interfere with religious observances. The Court struck down RFRA's application to the states, <sup>212</sup> though it still applies to the federal government. <sup>213</sup> Subsequently, several states passed their own RFRAs. <sup>214</sup>

Generally, RFRAs revert back to applying strict scrutiny to examine statutes that interfere with religious freedom. This means those statutes must use the least restrictive means to achieve a compelling government interest—a high burden. Note that in states where the requirement derives from a RFRA, a new statute can deviate from the RFRA—subject to cannons of statutory interpretation (for example, the deviation has to be explicit). In states where applying strict scrutiny to freedom of religion claims is based on an interpretation of the state's Constitution, a new statute cannot deviate from the RFRA.

How would this affect vaccine mandates? They should not affect a

<sup>210.</sup> Reiss, *supra* note 97, at 1569.

<sup>211. 42</sup> U.S.C. §§2000bb-1(a), (b).

<sup>212.</sup> City of Boerne v. Flores, 521 U.S. 507, 536 (1997). Congress reenacted a more limited, subject specific statute protecting religious freedoms in certain contexts—Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA), 114 Stat. 803, 42 U. S. C. §2000cc et seq.—but in this context, RFRA still does not apply to the states. See Hobby Lobby Stores, Inc., 134 S. Ct. at 2761-62.

<sup>213.</sup> Hobby Lobby Stores, Inc., 134 S. Ct. at 2761.

<sup>214.</sup> See Eugene Volokh, What Is the Religious Freedom Restoration Act?, VOLOKH CONSPIRACY (Dec. 2, 2013 7:43 AM), http://www.volokh.com/2013/12/02/1a-religious-freedom-restoration-act/ (providing a map of states with RFRA statutes).

private employer's freedom to impose workplace requirements. They may affect state statutes, and they may be seen as requiring public employers to offer a religious exemption, but not necessarily. As explained above, there is at least a strong argument that mandatory vaccination programs serve a compelling interest—the lives and health of vulnerable patients. If there is no good alternative, then they can be seen as the least restrictive means. However, this is a higher bar, and it may mean that reassignment, even if burdensome, will be required.

#### IV. DISCUSSION: WHAT IS DESIRABLE IN VACCINE POLICY?

Personal autonomy is important. Our system particularly values a person's freedom to refuse medical treatment.<sup>215</sup> Our system, under Schloendorf and even Jacobson, would almost certainly disallow forcible vaccinating of an adult in sound mind. But personal autonomy is not limitless. For example, an individual can be quarantined if they have an infectious disease and are a risk to others. 216 As Jacobson highlighted, refusing to comply with reasonable public policy can lead to criminal sanctions.<sup>217</sup> Our discussion here involves a lower level of coercion. It would be untrue to say that a risk of losing your job does not limit a person's options, and hence the threat of termination can exert influence or even feel like coercion. But an individual's choice to work in a given field generally comes with the understanding that the individual will have to comply with some rules and regulations in the work place, and those may change over time. This is even truer for an individual that chooses to enter a profession as heavily regulated as the health care field. An individual making the choice to work in health care should be aware that they are entering a profession subject to rules addressing ethics as well as health and safety. It is also a service profession, no less than the legal field, and an individual should expect to be subject to limits and rules to protect the patients that put their trust in the professional. An individual is not giving up their complete freedoms, of course, but implicit in the autonomous choice of profession is agreement to reasonable health and safety regulation—including regulation for the health and safety of the patient. Refusing a precaution as simple and safe as a vaccine against influenza is refusing a reasonable regulation.

<sup>215.</sup> Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body").

City of Newark v. J.S., 652 A.2d 265, 274 (N.J. Super. Ct. L. Div. 1993).

<sup>217.</sup> Jacobson v. Commonwealth of Mass., 197 U.S. 11, 25 (1905).

It would not justify tying an employee down and force-vaccinating them, but it does suggest the employer is justified in taking lesser steps, up to and including dismissing the employee. The employee's rights and interests are not the only ones at stake: patients have rights and interests as well, including the right not to be put at higher risk of a dangerous disease.

When we are talking about a private employer, it's important to remember there is a third set of rights involved: the rights of the private employer to run their operation according to the standards they support. It's not clear why an employee's right not to protect themselves and others against a dangerous disease should trump an employer's freedom to act to increase the health and safety of patients and to have a safer and healthier facility.

Mandatory immunization policies protect vulnerable patients against infection, prevent absenteeism of workers, and therefore serve important interests. They are desirable. We agree with Cox and Stewart that the most cost-effective way to impose mandatory immunization policies is via state statutes. Going through the democratic process can provide the policy with legitimacy, and the legislature has, under our Constitution, substantial leeway to balance the public health with other considerations. But to be effective, statutes need to address implementation—to condition continuing work on receiving the vaccine.

If a legislature is unable or unwilling to pass a mandate, there is no reason for a private employer not to do so, and there are many good reasons to offer it. However, in a unionized workforce, employers may face challenges in applying such a policy without bargaining with the union.

We believe both statutes and employer policies should offer medical exemptions to those who have acknowledged contraindications, under the assumption that those exemptions would be limited enough to not create a severe risk and that people should not be penalized because they have the misfortune of being allergic to a vaccine. Nevertheless, we acknowledge the counter argument, the need to protect patients.

We would argue against offering a religious exemption. The constitutional limitations on religious exemptions make preventing their abuse extremely hard—and they are not required under the First Amendment or under the Civil Rights Act of 1964 for employers. The one exception is when a state RFRA is interpreted to require one.

<sup>218.</sup> Randall et al., supra note 78, at 1772.

<sup>219.</sup> See Caplan, supra note 26, at 311.

<sup>220.</sup> See Stewart & Cox, supra note 5, at 830.

#### V. Conclusion

When a person chooses to go into health care, that person makes an autonomous choice to work in a service profession, serving the interests of vulnerable patients. With such choices come certain obligations. Among those is the obligation to take basic precautions to protect vulnerable patients against infections. It is uncontroversial that requiring hand washing is perfectly appropriate. It should be uncontroversial that requiring the simple, safe precaution of an influenza vaccine is also appropriate. The vaccine would protect both the worker and the patients. If a health care worker is not willing to take it, he or she is failing in his or her duty to the patients.

Furthermore, if a health care worker is unwilling to trust a medical intervention as well supported by research as vaccines, how can he or she trust the rest of the medical science they ostensibly provide?