

WHEN DOCTORS BECOME “PATIENTS”: ADVOCATING  
A PATIENT-CENTERED APPROACH FOR HEALTH  
CARE WORKERS IN THE CONTEXT OF MANDATORY  
INFLUENZA VACCINATIONS AND  
INFORMED CONSENT

*Christine Nero Coughlin\**  
*Nancy M.P. King\*\**  
*Kathi Kemper\*\*\**

*“You are no longer doctors, you are hospital patients.”<sup>1</sup>*

In the 1991 movie *The Doctor*, William Hurt plays the protagonist, Dr. Jack McKee, a renowned yet callous surgeon who discovers that he has a malignant tumor in his throat.<sup>2</sup> He is suddenly transformed from “captain of the ship”<sup>3</sup> into a patient in a world where the idea of patient-centered health care<sup>4</sup> is unknown,

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\* J.D., Professor and Director, Legal Analysis, Research and Writing, Wake Forest University School of Law; Wake Forest University Center for Bioethics, Health, and Society.

\*\* J.D., Professor, Department of Social Sciences and Health Policy, Wake Forest University School of Medicine; Co-Director, Wake Forest University Center for Bioethics, Health, and Society.

\*\*\* MD, MPH, Caryl J. Guth Chair for Complementary and Integrative Medicine, Director, Center for Integrative Medicine, Professor, Pediatrics; Social Science and Health Policy; Family and Community Medicine; Wake Forest University Baptist Medical Center.

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1. THE DOCTOR (Silver Screen Partners IV 1991). The movie was based on Edward Rosebaum’s autobiography. EDWARD E. ROSENBAUM, *A TASTE OF MY OWN MEDICINE* (1988).

2. THE DOCTOR, *supra* note 1.

3. See generally THE PHYSICIAN AS CAPTAIN OF THE SHIP: A CRITICAL REAPPRAISAL (Nancy M.P. King et al. eds., 1988).

4. On April 15–16, 2010, Wake Forest University School of Law hosted the *Patient-Centered Law and Ethics Symposium*, which was designed, in part, to encourage leading scholars in “thinking more systematically and comprehensively about what patient-centeredness might mean and the

and its amorphous principles are rejected and even ridiculed. Dr. McKee's experience as a patient teaches him that practicing medicine involves more than surgical skills.<sup>5</sup>

Today's health care delivery has evolved from the physician-centered model showcased in *The Doctor* into a more patient-centered model.<sup>6</sup> Although the definition and boundaries of the patient-centered health care movement are still being developed and refined, patient-centered care is arguably distinguishable, both historically and conceptually, from public health.<sup>7</sup> Nonetheless, just as public-health concerns and individual medical choices have come together in some health care decision-making contexts for centuries,<sup>8</sup> contemporary questions such as whether hospitals should mandate annual influenza vaccinations for their health care workers involve legal and ethical principles underlying the patient-centered movement, most notably that of informed consent.

This Essay discusses some of the legal arguments addressing health care employers' mandatory influenza vaccination policies in the United States. In particular, we examine the relationship between influenza vaccination mandates imposed on health care workers by private-sector employers and informed consent to vaccination, in the absence of federal or state vaccination requirements. This Essay proposes that the practice of requiring employees to sign a consent form as a condition of continued employment when they receive the influenza vaccination conflicts with the ethical and legal doctrine of informed consent, and

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different approaches it might engender, both in health law and in bioethics.<sup>7</sup> Lois Shepherd & Mark A. Hall, *Patient-Centered Law and Ethics*, 45 WAKE FOREST L. REV. 1429, 1431 n.10 (2010).

5. Ultimately, Dr. McKee requires medical residents in his training program to spend seventy-two hours in the hospital learning the patient experience first-hand, by wearing hospital gowns, eating hospital food, and undergoing some of the medical tests and treatments they may one day prescribe. See *THE DOCTOR*, *supra* note 1.

6. See, e.g., HOWARD BRODY, *THE FUTURE OF BIOETHICS* 49–64 (2009) (discussing the history of “patient-centered care” and its three phases: medical epistemology, medical therapy, and a broad framework for policy and health care organization). Empirical studies show that the patient-centered movement has therapeutic and relational value. See Larry R. Churchill & David Schenck, *Healing Skills for Medical Practice*, 149 ANNALS INTERNAL MED. 720, 720 (2008). But see *Chaney v. Plainfield Healthcare Ctr.*, 612 F.3d 908, 913–14 (7th Cir. 2010) (holding that patient care preferences may be limited by federal civil rights laws).

7. See Shepherd & Hall, *supra* note 4, at 1434–35.

8. See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 37–39 (1905) (holding that a compulsory vaccination law did not violate the constitutional rights of an adult enjoying the general protection afforded by a local government); *O'Brien v. Cunard S. S. Co.*, 28 N.E. 266, 266–67 (Mass. 1891) (holding that a ship owner was not liable to the plaintiff for assault when the ship owner's surgeons vaccinated all emigrants who so desired and when the plaintiff did not object to the vaccination at the time of administration).

concludes that when an employer's policy effectively removes an employee's freedom to choose whether to become vaccinated, it is unethical to require that the health care worker sign a consent form. The Essay advocates that if—despite controversy over such policies—employers choose to mandate immunization, they should be required to provide an alternative form, so that health care workers who would not seek vaccination except to avoid termination of employment may acknowledge that acquiescence to vaccination is informed but not voluntary.<sup>9</sup>

As demonstrated by the recent H1N1 outbreak, there is increasing public alarm and controversy over the risks of and response to global influenza pandemics.<sup>10</sup> In the United States alone, there are between fifteen million and sixty million seasonal influenza cases per year that “result in more than 200,000 hospitalizations and 36,000 deaths.”<sup>11</sup> Advocates of mandatory health care worker vaccination policies assert that “[h]ealth-care workers . . . who have direct contact with patients present the primary source of infectious disease outbreaks in health-care facilities.”<sup>12</sup> In fact, they contend that “[d]uring an average season, 23% of [health-care workers] are infected with the [influenza] virus, show mild symptoms, and continue to work despite being

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9. This Essay does not address many interesting and related questions that are beyond its scope, including but not limited to the relative efficacy of mandatory vaccination policies as compared with systematic education about influenza and encouragement of voluntary vaccination; the efficacy and appropriateness of various sanctions and workforce alterations short of termination (e.g., fines and other penalties, temporary transfers, mandatory mask-wearing, etc.); the merit and scope of reasonable exceptions from mandates; the definition of patient contact (direct patient-care responsibilities compared with daily or occasional proximity to patient-care areas); the relative merits of various justifications that have been offered for influenza vaccination mandates (e.g., public health, business considerations like workforce maintenance, or soft paternalism directed at individual decisions); the impact of mandates on employee morale and quality of care; or medical and scientific controversies about the characterization of the recent H1N1 outbreak and the reliability of safety and efficacy statistics used by public-health officials to support influenza vaccination.

10. There are at least two flu seasons per year worldwide: one in the Northern Hemisphere and one in the Southern Hemispheres. In addition, in some tropical countries, the viruses are persistent throughout the year and peak once or twice during the rainy season. See *Influenza (Seasonal)*, WORLD HEALTH ORG. (Apr. 2009), <http://www.who.int/mediacentre/factsheets/fs211/en>.

11. Alexandra M. Stewart & Sara Rosenbaum, *Vaccinating the Health-Care Workforce: State Law vs. Institutional Requirements*, 125 PUB. HEALTH REP. 615, 615 (2010) (citing Anthony E. Fiore et. al., *Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 2008, MORBIDITY & MORTALITY WKLY. REP., Aug. 8, 2008, at 1). Worldwide, there are three to five million cases of influenza each year, with approximately 250,000 to 500,000 deaths, most of which occur in industrialized countries. *Influenza (Seasonal)*, *supra* note 10.

12. Stewart & Rosenbaum, *supra* note 11, at 615.

infectious.”<sup>13</sup> While vaccination does not eliminate the chance of contracting influenza, one frequently cited statistic provides that vaccines “can reduce morbidity by 70% to 90%.”<sup>14</sup>

Over the past fifteen years, 40% to 50% of health care workers have voluntarily elected to be vaccinated against seasonal influenza.<sup>15</sup> In the past five years, to increase the number of health care workers being vaccinated (or, more importantly, to decrease the number of unvaccinated health care workers), some private sector health care employers began to mandate<sup>16</sup> that workers be vaccinated annually as a condition of employment.<sup>17</sup> While some institutions allow health care workers to decline vaccination based on religious beliefs or physical or philosophical concerns,<sup>18</sup> many

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13. *Id.* (citing James A. Wilde et. al., *Effectiveness of Influenza Vaccine in Health Care Professionals: A Randomized Trial*, 281 JAMA 908, 908–13 (1999)).

14. *Id.* at 615. This statistic, however, has not been tested in a comparative effectiveness trial.

15. Alexandra M. Stewart, *Mandatory Vaccination of Health Care Workers*, 361 NEW ENG. J. MED. 2015, 2015 (2009) (citing Press Release, Richard F. Daines, N.Y. State Health Comm’r (Sept. 24, 2009)), available at [http://www.health.state.ny.us/press/releases/2009/2009-09-24\\_health\\_care\\_worker\\_vaccine\\_daines\\_oped.htm](http://www.health.state.ny.us/press/releases/2009/2009-09-24_health_care_worker_vaccine_daines_oped.htm); Stewart & Rosenbaum, *supra* note 11, at 615 (stating that voluntary immunization rates are approximately 40%) (citing Georgia P. Dash et al., *APIC Position Paper: Improving Health Care Worker Influenza Immunization Rates*, 32 AM. J. INFECTION CONTROL 123, 123 (2004)).

16. See Stewart & Rosenbaum, *supra* note 11, at 615. The majority of private-sector lawsuits concern union employees who argue that the new requirements are unlawful because they were unilaterally added by the employer and not part of the collective bargaining agreement. See *infra* note 24 and accompanying text. Moreover, there may be a difference between accepting a position that has a known influenza vaccination requirement and facing termination of employment when a new vaccination requirement is instituted. It likely is the difference between an offer and a threat. See *infra* note 44 and accompanying text.

17. Employers have the authority to enact a vaccination policy as a condition of employment, unless a state law permitting employees to opt out of the policy applies. See KATHLEEN S. SWENDIMAN, CONG. RESEARCH SERV., RS 21414, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS 4 (2009); *Approved: New Infection Control Requirement for Offering Influenza Vaccination to Staff and Licensed Independent Practitioners*, JOINT COMMISSION PERSP., June 2006, at 10, 10–11. This does not mean, however, that the mandate will not be subject to legal challenge. See Wendy E. Parmet, *Pandemic Vaccines—The Legal Landscape*, 362 NEW ENG. J. MED. 1949, 1952 (2010).

18. In discussing state-law vaccination mandates, Professor Parmet sets forth some of the valid concerns that individuals have about receiving vaccines. As a result of public distrust of vaccines, she notes that forty-eight states provide for religious exemptions and twenty-one allow for philosophical exemptions with respect to schoolchildren vaccination requirements and that the California and Massachusetts laws allow health care workers to choose between vaccination or a written declination. Parmet, *supra* note 17, at 1951. Reasonable exemptions, such as those seen with school vaccinations or with the California options to decline without sanction helps to provide “a light enough touch so that they do not undermine the population’s willingness to bare their arms.” See *id.* at 1952.

“unvaccinated workers are subject to additional precautions, including the use of masks or respirators during the influenza season, opting for a leave of absence, accepting reassignment to non-patient-care areas, and the potential risk of job termination.”<sup>19</sup>

The legal landscape of vaccination laws is complex. Although vaccination is primarily governed by state law,<sup>20</sup> there exists a web of related federal,<sup>21</sup> military,<sup>22</sup> and emergency<sup>23</sup> legislation that can

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19. Stewart and Rosenbaum, *supra* note 11, at 616.

20. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), is the landmark case granting states authority to institute mandatory vaccination programs. Additionally, see generally SWENDIMAN, *supra* note 17, for an excellent overview of state law regarding mandatory vaccination and school vaccine requirements.

21. The federal government has jurisdiction over public health matters under the Commerce and Spending Clauses. U.S. CONST. art. I, § 8, cls. 1 & 3; see, e.g., 42 U.S.C. § 233(p) (2006) (governing procedures and liability related to the administration of smallpox countermeasures by health professionals); 42 U.S.C. § 247b (2006) (granting the Secretary of Health and Human Services the power to fund public entities to assist them in establishing and maintaining preventive health service programs, and creating procedures for the provision of such funding); 42 U.S.C. § 247d-6d, -6e (2006) (establishing liability protections for injuries caused by security countermeasures that are taken in response to pandemic and epidemic products); National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 to -34 (2006); cf. Parmet, *supra* note 17, at 1950 (noting that in 2009, Kathleen Sebelius, the Secretary of Health and Human Services, issued an emergency declaration for H1N1 influenza and that the declaration has since been updated and reissued several times under the Public Readiness and Emergency Preparedness Act).

22. The Constitution provides Congress with war powers to raise and support the military. See U.S. CONST. art. 1, § 8, cls. 12–14. In 2008, the Department of Defense (“DoD”) implemented a policy directive requiring that “all civilian [health care personnel] who provide direct patient care in DoD [military treatment facilities] be immunized against seasonal influenza infection each year as a condition of employment, unless there is a documented medical or religious reason not to be immunized.” Memorandum from S. Ward Casscells, Assistant Sec’y of Def. (Health Affairs) to Gen. Counsel of the Dep’t of Def. 2 (Apr. 4, 2008), available at <http://www.mhs.osd.mil/Content/docs/pdfs/policies/2008/08-005.pdf>.

23. See 42 U.S.C. § 247d-6d(b) (2006) (authorizing the Secretary of Health and Human Services to make determinations regarding public health emergencies related to communicable diseases and to establish countermeasures related to such diseases); THE CTR. FOR LAW & THE PUB.’S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIVS., THE MODEL STATE EMERGENCY HEALTH POWERS ACT (Draft for Discussion Dec. 21, 2001), available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA.pdf>. In August 2009, the State of New York issued an emergency regulation requiring that all health care workers with direct patient contact be immunized against H1N1 and seasonal influenza. Parmet, *supra* note 17, at 1951. The regulation resulted in a spate of lawsuits being filed. *Id.* (outlining cases filed challenging mandates for health care workers to receive these vaccines). In October 2009, New York’s health department suspended the regulation due to a reported diminished H1N1 vaccine supply. *Id.* In February 2010, a New York trial court dismissed the health care workers’ claims. Stewart & Rosenbaum, *supra* note 11, at 616. In examining the effectiveness of such emergency mandates, however, Professor Parmet notes, “Indeed, during the peak of the outbreak, vaccine was either non-

affect state law. Within the private sector, litigation has primarily focused on whether employers violated labor laws by unilaterally implementing mandatory vaccination policies that apply to union-represented health care workers without engaging in the collective bargaining process.<sup>24</sup> In these lawsuits, health care employers, in defending their right to require vaccinations, have advanced the following arguments as justification: (1) influenza vaccines are the most effective means of disease prevention, according to the Centers for Disease Control and Prevention (“CDC”) and the Joint Commission on Accreditation of Health Care Organizations (“JCAHCO”);<sup>25</sup> (2) influenza vaccines are no more invasive than other required vaccinations (e.g., measles, mumps, rubella), tuberculosis tests, mask and respirator requirements, and safety procedures already in place;<sup>26</sup> (3) the interests of public safety and the protection of those most vulnerable—such as children, pregnant women, the elderly, and individuals with compromised immune systems—outweigh the interests of health care workers in refusing mandatory vaccination, particularly given the high rate of infection among unvaccinated health care workers;<sup>27</sup> and (4) hospitals and other health care employers have a significant interest in avoiding liability for negligence in infection control under the doctrines of respondeat superior, corporate negligence, and other theories of liability.<sup>28</sup>

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existent or in short supply, and many people who wanted to be vaccinated could not be. Under such circumstances, which are likely to exist during any pandemic, *mandates are bound to be ineffective.*” Parmet, *supra* note 17, at 1951 (emphasis added).

24. See e.g., *Va. Mason Hosp. v. Wash. State Nurses Ass’n*, 511 F.3d 908 (9th Cir. 2007); *Serv. Emps. Int’l Union, Local 121RN v. Los Robles Reg’l Med. Ctr.*, No. C09-05065 JF, 2009 WL 3872138 (N.D. Cal. Nov. 17, 2009); *United Nurses of Children’s Hosp. v. Rady Children’s Hosp.*, No. 3:09-cv-02633-MMA-CAB (S.D. Cal. filed Nov. 20, 2009); *Serv. Emps. Int’l Union, Local 1107 v. Healthcare Corp. of Am.*, No. 2:09-cv-02094-RCJ-PAL (D. Nev. filed Oct. 29, 2009); *Plaintiff’s Complaint for Injunctive Relief Pending Arbitration, Wash. State Nurses Ass’n v. Multicare Health Sys.*, No. 3:09-cv-05614-RJB (W.D. Wash. Oct. 1, 2009) [hereinafter *Plaintiff’s Complaint*]; see also Susan R. Hobbs, *With Flu Season Under Way, Mandatory Vaccination Policies Meet with Resistance*, [2009] *Human Res. Rep. (BNA)* No. 27, at 1097 (Oct. 19, 2009).

25. See, e.g., *Defendants’ Opposition to Plaintiff’s Motion for Injunction Pending Arbitration at 3–4, Los Robles Reg’l Med. Ctr.*, 2009 WL 3872138 (No. C09-05065-JF), 2009 WL 5018507 [hereinafter *Defendants’ Opposition*].

26. *Id.* at 5–6, 15.

27. See *Va. Mason Hosp.*, 511 F.3d at 911; *Defendants’ Opposition*, *supra* note 25, at 3–4, 19–20; *Stewart & Rosenbaum*, *supra* note 11, at 615.

28. See *Hobbs*, *supra* note 24, at 1097 (discussing a 2009 interview by the Bureau of National Affairs with David LaGrande, director of occupational safety and health at Communications Workers of America, in which LaGrande “expressed his belief that the New York mandatory vaccination policy is driven more by concerns about hospitals’ potential liability than by public safety”). However, even if health care workers are forced to become vaccinated against the seasonal influenza or H1N1 virus, some critics argue that this mandate is

On the other hand, opponents of private sector mandatory influenza vaccination policies typically argue that: (1) the CDC and JCAHCO reports recommend voluntary vaccination programs rather than mandatory ones for ethical reasons;<sup>29</sup> (2) mandatory vaccinations subject employees to hazardous work conditions and may be detrimental to employees' physical health;<sup>30</sup> (3) many hospitals distinguish those who cannot be—or choose not to be—vaccinated by providing them with different-colored badges or labels, or different employment assignments, all of which might stigmatize the employees or violate HIPAA confidentiality and employees' right to privacy;<sup>31</sup> (4) mandatory vaccinations arguably violate employees' rights to the free exercise of religion under the

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insufficient unless other measures—such as sick or other leave benefits and workers' compensation benefits for health care workers who become ill or suffer side effects from the vaccine—are guaranteed. *Id.*

29. Note that the private sector cases that rely on the CDC and JCAHCO reports have not, to date, questioned whether vaccines are the most effective transmission deterrent. However, the adequacy of the evidentiary basis for the CDC's and JCAHCO's current infection-control policies may be questioned, as their consideration of the effectiveness of alternatives to vaccination may not have been based on adequately sized comparative-effectiveness trials. *See, e.g.*, Plaintiffs' First Amended Complaint for Injunctive Relief Pending Arbitration at paras. 2.25–27, *Los Robles Reg'l Med. Ctr.*, 2009 WL 3872138 (No. 09-05065-JF), 2009 WL 5018680 at \*7–8 [hereinafter Plaintiffs' First Amended Complaint]; Plaintiff's Complaint, *supra* note 24, at paras. 2.16–17.

30. Plaintiffs' First Amended Complaint, *supra* note 29, at para. 2.17; Plaintiffs' Reply Brief in Support of Motion for Injunctive Relief Pending Arbitration at 9–10, *Los Robles Reg'l Med. Ctr.*, 2009 WL 3872138 (No. C09-05065-JF), 2009 WL 5018516 [hereinafter Plaintiffs' Reply Brief]; Plaintiffs' Complaint, *supra* note 24, at 8. Common side effects of the seasonal flu vaccine include soreness, cough, runny nose, flu-like symptoms, and rare possible allergic reactions. IMMUNIZATION ACTION COAL., SEASONAL INFLUENZA: QUESTIONS AND ANSWERS 4–5 (2009), available at <http://www.immunize.org/catg.d/p4208.pdf>. There have also been some reports of a link between the influenza vaccination and Guillain-Barré syndrome. *Id.* In addition, despite many publicized empirical studies to the contrary, many individuals are still concerned that due to the inclusion in some vaccines of mercury-based thimerosal, vaccines can cause mercury-related complications. *See* Parmet, *supra* note 18, at 1950–51. Interestingly, as far as the H1N1 vaccine is concerned, safety studies were not completed prior to introduction of the vaccine and in many cases were being done concurrently with the implementation of mandatory immunization policies. *See* Declan McCullagh, *Health Care Workers Protest Mandatory H1N1 Vaccination*, CBS NEWS (Sept. 29, 2009), [http://www.cbsnews.com/8301-504383\\_162-5349581-504383.html?tag=mncol](http://www.cbsnews.com/8301-504383_162-5349581-504383.html?tag=mncol); 1. Following the two peaks in H1N1 flu in 2009, there were sixty reported deaths attributed to the H1N1 vaccination and 11,180 adverse events following monovalent H1N1 vaccination. *See* CDC, DEP'T OF HEALTH & HUMAN SERVS., SUMMARY OF 2009 MONOVALENT H1N1 INFLUENZA VACCINE DATA—VACCINE ADVERSE EVENT REPORTING SYSTEM 1 (2010), available at [http://vaers.hhs.gov/resources/2010H1N1Summary\\_June03.pdf](http://vaers.hhs.gov/resources/2010H1N1Summary_June03.pdf).

31. Plaintiffs' First Amended Complaint, *supra* note 30, at paras. 2.28–29; Plaintiffs' Reply Brief, *supra* note 30, at 11; Plaintiff's Complaint, *supra* note 24, at para. 2.18.

First Amendment;<sup>32</sup> (5) mandatory vaccination policies restrict employees' personal freedom and autonomy by not allowing employees to refuse vaccination for religious, cultural, or philosophical reasons;<sup>33</sup> and (6) hospitals and other employers should instead implement evidence-based effective infection-control policies that address the spread of the virus in treatment and waiting areas, provide for personal protective equipment to health care workers, and abolish harsh absentee and sick-leave policies that "encourage employees to work when sick."<sup>34</sup>

While scientists, scholars, and courts continue to debate and weigh the merits of these arguments,<sup>35</sup> this Essay addresses another problem created by mandatory vaccinations, which has received less attention to date: the tension between mandatory vaccination and the doctrine of informed consent. Informed consent is a bedrock principle of patient care, particularly within the patient-centered health care movement.<sup>36</sup> The rationale underlying informed consent was articulated by Justice Benjamin Cardozo in 1914: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . ."<sup>37</sup> Moreover, the doctrine of informed consent provides that "it is wrong to force another to act against his or her will."<sup>38</sup> Informed consent serves, inter alia, to increase patient trust, protect patient autonomy, and foster rational decision making.<sup>39</sup> In fact, the doctrine has been called "[t]he most prominent legal tool used by those seeking to reform the physician-patient relationship."<sup>40</sup>

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32. Plaintiffs' Reply Brief, *supra* note 30, at 10–11; Hobbs, *supra* note 24, at 1097. *But see* Stewart & Rosenbaum, *supra* note 11, at 617 ("[C]ourts have ruled that religious exemptions to vaccination requirements . . . are not constitutionally required.")

33. Hobbs, *supra* note 24, at 1097.

34. *Id.*

35. *See generally* Parmet, *supra* note 17; Stewart, *supra* note 15; Stewart & Rosenbaum, *supra* note 11. These articles set forth additional legal arguments asserted in lawsuits in which state law imposed vaccination mandates on health care workers.

36. There is a significant amount of scholarly literature on the issue of informed consent, much too voluminous to set forth here. However, a sampling of literature from conference participants includes CARL E. SCHNEIDER, *THE PRACTICE OF AUTONOMY* (1998); Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261 (1999); and William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999).

37. *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), *superseded by statute on other grounds*, N.Y. PUB. HEALTH LAW § 2805-d (McKinney 2007).

38. BARRY R. FURROW ET AL., *LIABILITY AND QUALITY ISSUES IN HEALTH CARE* 187 (6th ed. 2008).

39. *Id.* at 188 (citing Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 365–76 (1974)).

40. MARK A. HALL, MARY ANNE BOBINSKI & DAVID ORENTLICHER, *BIOETHICS*

In order to be valid, however, consent must be not only informed, but also voluntarily given.<sup>41</sup> Voluntariness is a complex and challenging concept, as there are many influences on individuals' health care decisions, only some of which can be described as "undue." Coercion, however, is somewhat easier to define: "Coercion occurs if one party intentionally and successfully influences another by presenting a credible threat of unwanted and avoidable harm so severe that the person is unable to resist acting to avoid it."<sup>42</sup> When patients face health problems and undergo medical treatment, so-called "situational coercion" is often a problem, as many patients feel powerless and vulnerable.<sup>43</sup> Situational coercion is not true coercion, however; true coercion requires that one party have the capacity to threaten another.<sup>44</sup>

It is important to recognize that to describe a decision as coerced is only to state that it is not voluntary: it is not the decision maker's own autonomous choice. Depending on the circumstances, coercion may be beneficial and praiseworthy, unethical, or morally neutral. Certainly, public-health legislation—indeed, much law relating to the police powers of the states—is, by definition and intention, coercive,<sup>45</sup> but is also generally regarded as morally praiseworthy.<sup>46</sup> Nonetheless, when an employee is faced with choosing between vaccination and loss of employment, consent to vaccination is coerced and cannot be considered voluntary. In addition, the consent form typically signed by the health care worker/patient as part of the vaccination process is arguably

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AND PUBLIC HEALTH LAW 149 (2005).

41. See THE NAZI DOCTORS AND THE NUREMBERG CODE 2 (George J. Annas & Michael A. Grodin eds., 1992) (citing THE NUREMBERG CODE para. 1 (1947) ("The voluntary consent of the human subject is absolutely essential.")).

42. RUTH R. FADEN & TOM L. BEAUCHAMP WITH NANCY M.P. KING, A HISTORY AND THEORY OF INFORMED CONSENT 339 (1986). In other words, "the coerced person's 'choice' is not his or her own but effectively that of the other." *Id.*

43. See generally Jennifer S. Hawkins & Ezekiel J. Emanuel, *Clarifying Confusions About Coercion*, HASTINGS CENTER REP., Sept.–Oct. 2005, at 16.

44. See FADEN ET AL., *supra* note 42, at 338–41, 344–46. Although imposing a new mandate on already employed workers as a condition of continued employment is clearly a threat, thus meeting the definition of coercion, the effect of an existing mandate on the decision whether to accept an offer of employment is arguably different. There is no settled agreement on the status of so-called coercive offers in health care or elsewhere. See *id.* at 163–64, 340–41.

45. See Stewart & Rosenbaum, *supra* note 11, at 615; see also *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905) ("[T]he liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members.").

46. FADEN ET AL., *supra* note 42, at 339.

defective.<sup>47</sup>

A consent form “is essentially a written documentation of the patient’s assumption of the disclosed risks, assumed in order to achieve a procedure’s potential benefits.”<sup>48</sup> When hospitals made the influenza vaccine first available and then mandatory for employees, they generally required workers to sign the same consent form used by those voluntarily seeking influenza vaccination (e.g., from an employee health clinic), even though the workers were being required to receive the influenza vaccine as a condition of employment. If health care employers choose to *mandate* vaccinations, however, they should not require the affected employees to sign a *consent* form.

Although employer liability for an adverse reaction may be limited under federal vaccination compensation programs<sup>49</sup> and/or state workers’ compensation laws, most health care employers who mandate vaccinations will want written documentation that the employees understand the relevant information—including the risks of the vaccine—along with a release of liability; thus, there are indeed similarities with the content of a consent form. Obtaining this documentation is good business practice and it should not present a difficult task. Health care employers can easily fashion an alternate form to satisfy their individual institutional concerns, such as sick leave or adverse events, as long as the form simply provides that the employee has read and understands the information and risks relevant to the vaccine and the employer’s vaccination policy. The form, however, should not be labeled as a consent form when the employee is complying with hospital policy.

Given the widely publicized assertions about the anticipated

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47. See Shepherd & Hall, *supra* note 4, at 1434. In the essay, Professors Shepherd and Hall state that “informed consent . . . is the most easily identified aspect of health law that is aimed at promoting patient interests.” *Id.*

48. HALL ET AL., *supra* note 40, at 172; accord Dana Ziker, *Reviving Informed Consent: Using Risk Perception in Clinical Trials*, 2003 DUKE L. & TECH. REV. 0015, ¶¶ 6–8, <http://www.law.duke.edu.go.libproxy.wfubmc.edu/journals/dltr/articles/2003dltr0015.html> (observing that there is a need to close the communication gap in the informed-consent process).

49. Liability exposure may depend on the type of vaccine mandated, as well as the timing. See National Vaccination Injury Compensation Program, 42 U.S.C. § 300aa-10 to -27 (2006); 42 U.S.C. § 247d-6d(d)(1) (creating a limited exception to the rule proving immunity from suit under the act for claims against those who engage in willful misconduct); CDC, FREQUENTLY ASKED QUESTIONS ABOUT FEDERAL PUBLIC HEALTH EMERGENCY LAW 7 (Emily McCormick ed., 2009), available at <http://www2.cdc.gov/phlp/docs/FAQs%20Fed%20PHE%20laws%20101409.pdf>. See generally Craig A. Conway, *Federal PREP Act Provides Legal Immunity to H1N1 Vaccine Makers and Others*, U. HOUS. HEALTH L. PERSP. (Nov. 10, 2009), [http://www.law.uh.edu/healthlaw/perspectives/2009/\(CC\)%20PREP.pdf](http://www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20PREP.pdf) (providing an excellent overview of the complexity of liability limitation under the Public Readiness and Emergency Preparedness Act and explaining that Congress has not, at this time, appropriated funding for H1N1 vaccine-related adverse events).

morbidity and mortality associated with an influenza pandemic and the risk of infection among health care workers,<sup>50</sup> many health care employers may understandably wish to explore whether mandatory influenza vaccination policies are the most effective long-term strategy to reduce risks to workers and patients. In doing so, however, employers must remember that while there is nothing inherently improper about mandates, they do, by definition and design, limit or remove choice and compromise voluntariness. At the very least, reasonable exemptions should be provided.<sup>51</sup> Indeed, employers may find that appropriate education, responsiveness, comprehensive infection-control plans with appropriate sick-leave policies, incentives, and less-than-coercive sanctions may do more to change employees' minds and improve employee morale (and, in turn, overall vaccination rates).<sup>52</sup> After all, mandates have been and will continue to be the subject of legal challenges.<sup>53</sup> As one scholar has wisely noted, "These lawsuits can generate heated publicity that raises further doubts in people's minds about vaccine safety. Certainly, media reports about health care workers going to court to avoid vaccination are not apt to inspire the public's faith in vaccines."<sup>54</sup>

Employers should recognize that coercion in medicine is

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50. See *supra* notes 10–15 and accompanying text.

51. See *supra* notes 18–19 and accompanying text; see also Ziker, *supra* note 48, ¶ 19 ("Most people are less afraid of a risk they choose to take than of a risk imposed on them." (quoting DAVID ROPEIK & DAVID GRAY, RISK 16 (2002))).

52. There is no empirical evidence that mandatory vaccination policies protect patients or the public any better than less coercive measures, and there is widespread acceptance of the efficacy of less-than-coercive measures to control the spread of infection. For instance, extended home stays, combined with adequate social and medical support to enable adherence, were widely recommended for persons exhibiting influenza symptoms during the height of the H1N1 concern. See, e.g., *What To Do If You Get Sick: 2009 H1N1 and Seasonal Flu*, CDC (Jan. 10, 2010, 6:00 PM), <http://www.cdc.gov/h1n1flu/sick.htm>. These recommendations were described and reinforced with extensive information about symptoms to monitor and resource to consult. *Id.* Moreover, there is good evidence that open communication between health care professionals and patients, as is seen when there is transparency in the informed consent process, leads to better outcomes. For example, as Professors Larry Churchill and David Schenck explain in *Healing Skills for Medical Practice*, "Clinicians are concerned daily with convincing people to undergo physical examinations; accept probes into their private lives; endure diagnostic tests; or take medications that are inconvenient, sometimes painful, and occasionally incur risk. *Relational skills are fundamental to success in these persuasive endeavors . . .*" Churchill & Schenck, *supra* note 6, at 720 (emphasis added). Likewise, in the context of employee relations, relational trust, when built by education and transparency, arguably leads to improved outcomes in which employees choose to follow employer infection-control recommendations, rather than being forced into involuntary action by a mandate.

53. See Parmet, *supra* note 17, at 1952.

54. *Id.*

antithetical to the patient-centered movement, and that therefore, forcing employees into the patient role is inherently contradictory, requiring more careful attention to both the employer's prerogatives and the employee-patient's rights than is generally afforded by the imposition of mandates. If, however, an employer still chooses to implement a mandatory influenza vaccination policy, it is incumbent on the employer to acknowledge to the employee that it is a mandate. This significant fact should not be disguised by means of a consent form. An alternate form that signals clear attention to the provision of relevant information and evidence of the employee's understanding accomplishes the employer's goals while preserving the integrity of the informed consent doctrine; it does so by acknowledging that acquiescence to the vaccine is informed but not voluntary. Any other process is an unethical violation of the principle of informed consent.