When Doctors Become “Patients”: Advocating a Patient-Centered Approach for Health Care Workers in the Context of Mandatory Influenza Vaccinations and Informed Consent

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“You are no longer doctors, you are hospital patients.”1

In the 1991 movie The Doctor,2 William Hurt plays the protagonist, Dr. Jack Mackee, a renowned yet callous surgeon who discovers that he has a malignant tumor in his throat. He is suddenly transformed from “captain of the ship”3 into a patient in a world where the idea of patient-centered health care4 is unknown, and its amorphous principles are rejected and even ridiculed. Dr. Mackee’s experience as a patient teaches him that practicing medicine involves more than surgical skills.5

Today’s health care delivery has evolved from the physician-centered model showcased in The Doctor into a more patient-centered model.6 Although the definition and boundaries of

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2 Id.

3 See generally NANCY M.P. KING (ED.), THE PHYSICIAN AS CAPTAIN OF THE SHIP (Kluwer 1988)

4 On April 15-16, 2010, Wake Forest 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 different approaches it might engender, both in health law and in bioethics.” See Lois Shepard & Mark A. Hall, Patient Centered Law and Ethics, --- WAKE FOREST L. REV. _____, n.10 (2010).

5 Ultimately, Dr. Mackee 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 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 also Larry R. Churchill & David Schenck, Healing Skills for Medical Practice, 149 ANNALS OF INTERNAL MED. 720, 720 (2008); but see Chaney v. Plainfield Healthcare Center, No. 09-3661 (7th Cir. July 20, 2010)(holding that patient care preferences may be limited by federal civil rights laws).
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. Nonetheless, just as public health concerns and individual medical choices have come together in some health care decision-making contexts for centuries, 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 article 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 article proposes that the practice of requiring employees to sign a consent form when they receive the influenza vaccination as a condition of continued employment conflicts with the ethical and legal doctrine of informed consent, and 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 health care worker to sign a consent form. The article advocates that if, despite controversy over such policies, employers choose to mandate immunization, they 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.

7 Shepard & Hall, supra note 4, at 6.
9 This article 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
As demonstrated by the recent H1N1 outbreak, there is increasing public alarm and controversy over the risks of and response to global influenza pandemics. In the United States alone, there are between 15 million and 60 million seasonal influenza cases per year that “result in more than 200,000 hospitalizations and 36,000 deaths.” 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.” In fact, they contend, “[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 infectious.” While vaccination does not eliminate the chance of contracting influenza, one frequently cited statistic provides that vaccines “can reduce morbidity by 70%-90%” among health care workers.

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10 There are at least two flu seasons per year worldwide one in the Northern and one in the Southern hemispheres. In addition, in some tropical countries, the viruses are persistent throughout the year and peak once or twice in the rainy season. See World Health Organization, Seasonal Influenza, http://www.who.int/mediacenterfactsheet/fs211/en/index.html. [hereinafter referred to as “WHO fact sheet”].


12 Id.

13 Id. (citing Wilde JA, McMillian JA, Serwint J, Butta J, O’Riordan MA, Steinhoff MC, Effectiveness of influenza in health care professionals: a randomized trial. JAMA 281:908-13 (1999)).

14 Id. This statistic, however, has not been tested in a comparative effectiveness trial.
Over the past fifteen years, 40-50% of health care workers voluntarily elect to be vaccinated against seasonal influenza. 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 that workers be vaccinated annually as a condition of employment. While some institutions allow health care workers to decline vaccination based on religious beliefs or physical or philosophical concerns, many “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.”


16 Stewart & Rosenbaum, supra note 11, at 616.

17 The majority of private sector lawsuits concern union employees who argue that the new requirement are unlawful because they were unilaterally added by the employer and not part of the collective bargaining agreement. See infra note 25 and accompanying text. Moreover, there may be a difference between accepting employment that has a known influenza vaccination requirement and facing termination of employment when a new vaccination requirement in instituted. It likely is the difference between an offer and a threat. See infra text accompanying note 45.

18 Employers do have the authority to enact a vaccination policy as a condition of employment, unless a state law applies which permit the employees to opt out. See Mandatory Vaccinations: Precedent and Current Laws, citing Vaccination of Health Care Workers for H1N1 and Other Communicable Diseases, American Federation of Teachers, Frequently Asked Questions, available at http://www.aft.org/healthcare/downloads/FAQ%2020-%20HINI.pdf. This does not mean, however, that the mandate will not be subject to legal challenge. Wendy E. Parmet, Pandemic Vaccines – The Legal Landscape, 361(21) N.ENGL. J. MED. 1949, 1952 (May 10, 2010).

19 In discussing state law vaccination mandates, Professor Parmet sets forth some of valid concerns that individuals have in receiving vaccines. As a result of public distrust of vaccines, she notes that 48 states provide for religious exemptions and 21 allow for philosophical exemptions with respect to school children vaccination requirements and that the California and Massachusetts laws allow health care workers to choose between vaccination or a written declination. Reasonable exemptions, such as 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 arms.” See id. at 1952.

20 Stewart & Rosenbaum, supra note 11, at 616.
The legal landscape of vaccination laws is complex. Although vaccination is primarily governed by state law, there exists a web of related federal, military, and emergency legislation that can affect the 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. In these lawsuits, health

21 See supra note 8. Johnson v. Massachusetts, 197 U.S. 11 (1905) is the landmark case providing state’s authority to institute mandatory vaccination programs by way of the 10th Amendment; see also Kathleen S. Swendiman, Mandatory Vaccinations: Precedent and Current Laws, Congressional Research Service 5 (September 8, 2009) which provides an excellent overview of state law regarding mandatory vaccination and school vaccine requirements.


23 The Constitution provides Congress with war powers to raise and support the military. See U.S. CONST. ART. I, § 8, cl. 14, The Department of Defense (DoD), in 2008, implemented a policy directive requiring “all 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.” Department of Defense/Joint Forces, HA Policy: 08-005, Policy for Mandatory Seasonal Influenza Immunization for Civilian Health Care Personnel Who Provide Direct Patient Care in Department of Defense Military Treatment Facilities, April 4, 2008, available at http://www.mhs.osd.mil/Content/docs/pdfs/policies/2008/08-005.pdf; see also http://www.ethics.va.gov/docs/net/NET_Topic_20080130_Strategies_in_increasing_influenza_vaccination_rates_in_healthcare_workers-Ethical_Considerations.doc; Swendiman, supra note 21, at 5.

24 See Public Health Services Act, 42 U.S.C. § 247d-6d (West 2009); the Model State Emergency Powers Act (2001), available at www.publichealthlaw.net/Resources/Modellaws.htm; In August 2009, New York State issued an emergency regulation requiring all health care workers with direct patient contact be immunized. The regulation resulted in a spate of lawsuits being filed, see. Brynien v. Daines, N.Y. Sup. Ct. No. 8853-02 (2009); Patterson v. Daines, N.Y. Sup. Ct. No. 8830-09 (2009); Savoca v. New York State Dept. of Health, N.Y. Sup. Ct. No. 3355-09 (2009); Field v. Daines, N.Y. Sup. Ct. No. 114033-09 (2009). In October 2009, New York’s Governor suspended the regulation due to a diminished vaccine supply. In February 2010, the New York trial court dismissed the health care workers’ claims. See Parmet, supra note 18 at 1951; Stewart & Rosenbaum, supra note 11 at 616. In examining the effectiveness of such emergency mandates, however, Professor Parmet notes that “[i]n the peak of the outbreak, vaccine was either non-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 18, at 1961 (emphasis added).

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 and the Joint Commission on Accreditation of Health Care Organizations;\(^26\) (2) influenza vaccines are no more invasive than other required vaccinations (measles, mumps, rubella), tuberculosis tests, mask and respirator requirements and safety procedures already in place;\(^27\) (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;\(^28\) 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 or other theories of liability.\(^29\)

On the other hand, opponents of private sector mandatory influenza vaccination policies typically argue that: (1) the Centers for Disease Control and Joint Commission on Accreditation of Health Care Organizations reports stating that vaccines are the most effective transmission deterrent are out of date or have not been based on adequately scheduled for arbitration August 2010); *see also* Susan R. Hobbs, *With Flu Seasons Under Way, Mandatory Vaccination Policies Meet with Resistance*, *The Bureau of Nat’l Affairs, Human Res. Report* 4 (2009).\(^{26}\) Defendants Opposition to Plaintiff’s Motion for Injunction Pending Arbitration at 3-4, *Serv. Employees Int’l Union, Local 121RN v. HCA Health Servs. of Cal., Inc.*, 2009 WL 3872138 (N.D. Cal. 2009) (No. C 09-5065) [hereinafter Defendant’s Opposition]. \(^{27}\) *Id.* at 6, 15. \(^{28}\) *Virginia Mason*, 511 F.3d at 911, 914; Defendant’s Opposition at 3-4, 19-20; Stewart & Rosenbaum, *supra* note 11, at 615.\(^{29}\) Hobbs, *supra* note 25, at 3 (quoting interview by BNA with David LaGrande, Communications Workers’ of America Director of Occupational Safety and Health (Oct. 9, 2009)). However, even if health care workers are forced to become vaccinated against the seasonal or H1N1 virus, some critics argue that this mandate is insufficient unless other measures, such as sick or other leave and workers’ compensation benefits for health care workers who become ill or suffer side effects from the vaccine, are guaranteed. *Id.* at 2.
sized comparative effectiveness trials; otherwise, mandatory vaccinations subject employees to hazardous work conditions and may be detrimental to employees’ physical health; 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; mandatory vaccinations arguably violate employees’ rights to the free exercise of religion under the First Amendment; mandatory vaccination policies restrict employees’ personal freedom and autonomy by not allowing employees to refuse vaccination for religious, cultural, or philosophical reasons; and hospitals and other employers should instead implement evidence-based effective infection control policies that address the spread of the virus in the treatment and waiting areas, provide for personal protective equipment to health care


31 Plaintiffs’ First Amended Complaint at 5-6; Plaintiffs’ Reply Brief in Support of Motion for Injunctive Relief Pending Arbitration at 9-10, Serv. Employees Int’l Union, Local 121RN v. HCA Health Servs. of Cal., Inc., 2009 WL 3872138 (N.D. Cal. 2009) (No. C 09-5065) [hereinafter Plaintiff’s Reply Brief]; Plaintiffs’ Complaint at 8.

32 Common side effects of the seasonal flu vaccine include soreness, cough, runny nose, flu-like symptoms and rare possible allergic reaction, http://www.vaccineinformation.org/flu/qandavax.asp. There have been some reports of a link between the influenza vaccination and Guillain-Barre Syndrome. Id. However, 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 16, at 1960-61. 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 mandatory immunization, http://www.cbsnews.com/stories/2009/09/15/health/main5313104.html ; Following the two peaks in H1N1 flu in 2009, there were 60 reported deaths attributed to the H1N1 vaccination and 11,180 adverse events following monovalent H1N1 vaccination. See http://vaers.hhs.gov/resources/2010H1N1Summary_June03.pdf , last accessed August 3, 2010.

33 Plaintiffs’ First Amended Complaint at 6, 8; Plaintiffs’ Reply Brief at 1, 11; Plaintiffs’ Complaint at 7-8.

34 Hobbs, supra note 25, at 2.
workers, and abolish harsh absentee and sick leave policies that “encourage employees to work when sick.”

While scientists, scholars and courts continue to debate and weigh the merits of all these arguments, this article 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. The rationale underlying informed consent was articulated by Justice 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.” Moreover, the doctrine of informed consent provides that “it is wrong to force another to act against his or her will.”

Informed consent serves, *inter alia*, to increase patient trust, protect patient autonomy, and foster rational decision making. In fact, the doctrine has been called “[t]he most prominent legal tool used by those seeking to reform the physician-patient relationship.”

In order to be valid, however, consent must be not only informed, but also voluntarily given. Voluntariness is a complex and challenging concept, as there are many influences on individuals’ health care decisions, only some of which can be

35 *Id.* at 2.
38 Schloendorff v. Society of NY Hospital, 105 N.E. 92 (NY 1914).
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 unavoidable harm so severe that the person is unable to resist acting to avoid it.” When patients face health problems and undergo medical treatment, so-called “situational coercion” is often a problem, as many patients feel powerless and vulnerable. Situational coercion is not true coercion, however; true coercion requires that one party have the capacity to threaten another.

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, but is also generally regarded as morally praiseworthy. Nonetheless, when an employee is faced with choosing between vaccination and loss of employment, consent to vaccination is coerced

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43 RUTH R. FADEN & TOM L. BEAUCHAMP WITH NANCY M.P. KING, A HISTORY AND THEORY OF INFORMED CONSENT, 339 340 (1986) (explaining that “the coerced person’s choice is not his or her own but effectively that of the other”).


45 See FADEN ET AL., supra note 43, at 338-9, 344-6. Although imposing a new mandate upon 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 upon 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 340-1 and 163-4.

46 See supra note 24 and accompanying text. See Jacobson v. Massachusetts, 197 U.S. 26-27 (“[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 free 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.”)

47 FADEN ET AL, supra note 43, at 339.
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 defective.\textsuperscript{48}

A consent form “is essentially a written documentation of the patient’s assumption of disclosed risks, assumed in order to achieve a procedure’s potential benefit.”\textsuperscript{49} 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 are now being required to receive the influenza vaccine as a condition of employment. If health care employers choose to \textit{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\textsuperscript{50} 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

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\textsuperscript{48} Shepard & Hall, \textit{supra} note 4, at 5. In the article, Shepard and Hall state: “Informed Consent . . . is the most easily identified aspect of health law that is aimed at promoting patient interests.”
\textsuperscript{49} \textit{Hall, Bobinski & Orentlicher, supra} note 41, at 172; see also Dana Ziker, \textit{Reviving Informed Consent: Using Risk Perception in Clinical Trials}, 2003 \textit{Duke Law & Tech Rev.} 0015, available at http://www.law.duke.edu/journals/dltr/articles/2003dltr0015.html (discussing that there is a need to close the communication gap in the informed consent process.)
\textsuperscript{50} 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-10-300 aa -27; Public Readiness and Emergency Preparedness Act, 42 U.S.C. 247d-6d at § 319F-3 (exempting from compensation those who engage in willful misconduct. Immunity may not be available unless within the effective date and for the geographic area where immunity provided); Craig Conway, \textit{Federal PREP Act Provides Legal Immunity to H1N1 Vaccine Makers and Others}, available at http://www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20PREP.pdf (providing an excellent overview of the complexity of liability limitation under PREP and explaining that Congress has not, at this time, appropriated funding for H1N1 vaccine adverse events); See also Emily McCormick, editor, \textit{Frequently Asked Questions about Federal Public Health Emergency Law}, (Sept. 2009)( based on the Apr. 28, 2009, teleconference \textit{FEDERAL PUBLIC HEALTH EMERGENCY LAW: IMPLICATIONS FOR STATE & LOCAL PREPAREDNESS AND RESPONSE}, at 9-10)).
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employers can easily fashion an alternate form to satisfy their individual institutional concerns, such as sick leave, adverse events, etc., 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 a consent form when the employee is complying with hospital policy.

Given the widely publicized assertions about the anticipated morbidity and mortality associated with an influenza pandemic, and the risk of infection among health care workers, 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. 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). After all, mandates have been and will continue to be the subject of

51 See supra notes 10-15 and accompanying text.
52 See supra notes 19-20 and accompanying text; see also Ziker, supra note 42 (citing DAVID ROEIK & DAVID GRAY, RISK: A PRACTICAL GUIDE FOR DECIDING WHAT’S SAFE AND WHAT’S DANGEROUS IN THE WORLD AROUND YOU 15 (2002) (“Most people are less afraid of a risk they feel that they have some control over.”)
53 There is no empirical evidence that mandatory vaccination policies protect patients or the public any better than less coercive measures, and there is wide-spread acceptance in the efficacy of less than coercive measures to control the spread of infection. For instance, home stays of many days’ duration, 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. These recommendations were described and reinforced with extensive information about symptoms to monitor and resources to contact. Moreover, there is good evidence that open communication
legal challenges. As one scholar has wisely noted, “[t]hese 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.”

Employers should recognize that coercion in medicine is 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 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.

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 Larry Churchill and David Schenck explain in Healing Skills for Medical Practice, “[c]linicians 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.” See Churchill & Schenck, supra note 6, at 720 (emphasis added) (internal citations omitted) Likewise, in the context of employee relations, relational trust when built by education and transparency, arguably leads to improved outcomes where employees choose to follow employer infection control recommendations, rather than being forced into a non-voluntary action by a mandate.

Parmet, supra note 18, at 1952.

Id.