

COVID-19 Vaccine and Employer Mandates

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Development of a safe and effective vaccine to limit transmission of COVID-19 has remained a vital priority since the onset of the global COVID-19 pandemic. In the United States, vaccines must be approved by the Food and Drug Administration (FDA) before they can be marketed and distributed, which is normally a lengthy process.¹ In exigencies, a vaccine that has not yet been formally approved by FDA can be granted emergency use authorization (EUA), allowing an otherwise unapproved product to be used and distributed during a public health or other emergency.²

On December 11, 2020, FDA issued an EUA for a COVID-19 vaccine developed by Pfizer and German partner BioNTech,³ which has demonstrated upwards of 90% efficacy in trials.⁴ On December 17, 2020, FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended issuance of an EUA for Moderna's COVID-19 vaccine.⁵ Additional EUA applications for other vaccine candidates are also anticipated. While vaccines authorized via EUA begin distribution, public and private employers across the U.S. are considering the potential for issuing vaccine mandates applied to their workforces, especially among health care workers (HCWs). This memorandum addresses employer-mandated vaccination during the COVID-19 pandemic, providing key legal and factual updates for public health officials and employers.

Question: Can public and private sector employers mandate employees obtain a COVID-19 vaccine authorized by FDA via an EUA?


Response: *Most likely yes.* Public and private-sector vaccine mandates (i.e., conditioning specific benefits, rights to access, or attaching fines to vaccination) have generally been accepted in the United States for decades, especially in public health emergencies.

In 1905, the U.S. Supreme Court upheld a mandatory smallpox vaccination requirement in *Jacobson v. Massachusetts*.⁶ The requirement, issued by the City of Cambridge, imposed a \$5 fine on those who refused vaccination.⁷ The Court acknowledged that state and local governments are authorized to enact reasonable laws or regulations to protect public health and safety,⁸ including tailored vaccine requirements for persons who would not likely be harmed directly by the vaccination itself.

Since the Court's seminal decision in *Jacobson*, states and localities have lawfully required vaccinations precedent to school or day care attendance as well as pursuant to employment in specific health care settings.⁹ Several state statutes also allow for compulsory (or forcible) vaccination during public health emergencies (although these are subject to considerable constitutional challenges).¹⁰ Many states also recognize a variety of medical, religious, or philosophical exemptions to these requirements.¹¹

Unbound from constitutional requirements, private sector employers have considerable leeway in requiring employee immunization.¹² The Occupational Safety and Health Administration (OSHA)¹³ and the Equal Employment Opportunity Commission (EEOC)¹⁴ have previously approved employer-mandated influenza vaccination schemes that comply with anti-discrimination laws.

The federal Occupational Safety and Health Act requires employers to provide places of employment that are "free from recognized hazards that are causing or are likely to cause death or serious physical



harm.”¹⁵ This requirement could potentially be interpreted as imposing a duty on employers to require COVID-19 vaccination where vaccines have proven safe and efficacious. While OSHA has not yet opined on specific COVID-19 mandates, it previously has emphasized that employees should be properly informed of vaccine benefits.¹⁶

The federal Americans with Disabilities Act (ADA) allows employers to mandate vaccination so long as reasonable accommodations are provided to employees with disabilities.¹⁷ Accommodations are not required in cases of undue hardship or where others may be directly threatened and there is no way to provide a reasonable accommodation that would eliminate or reduce the direct threat.¹⁸ Additionally, Title VII of the Civil Rights Act requires reasonable accommodation for employees with religious objections to vaccination, except in cases of undue hardship.¹⁹

On December 16, 2020, EEOC updated its COVID-19 guidance to provide specific information related to the COVID-19 vaccine.²⁰ EEOC clarified that if an employer mandates vaccination and an employee cannot get vaccinated because of a disability or a sincerely held religious practice or belief, and no reasonable accommodation is possible, then the employer may lawfully exclude the employee from the workplace. It further noted that this exclusion does not automatically permit termination, as some employees may be able to telework, and additional federal, state, and local equal employment opportunity protections must be followed. Additionally, employers mandating and administering the COVID-19 vaccine should be aware that pre-screening questions may implicate ADA provisions on disability-related inquiries; any such inquiries must be “job-related and consistent with business necessity.” Pre-screening questions may also implicate Title II of the Genetic Information Nondiscrimination Act (GINA), which prevents employers from acquiring or disclosing genetic information (subject to certain exceptions) and using genetic information to make decisions related to terms, conditions, and privileges of employment.

In prior vaccine-related guidance EEOC has recommended that ADA-covered employers simply “encourage employees to get the influenza vaccine” rather than requiring it.²¹ Encouraging vaccination (and the means to access vaccines) may help avoid complex ethical debates and legal concerns over certain exemptions or required actions prior to implementing a mandate. For example, unionized employees may raise legal issues if vaccines are mandated outside the collective bargaining process.²² Since vaccines are never fool-proof, encouraging, rather than requiring, vaccination can help mitigate any potential legal challenges arising in the event of a vaccine-related injury.

HCW vaccine mandates are often justified legally by balancing competing interests between assuring public and workplace safety versus respecting HCWs’ vaccination concerns.²³ Some scholars intimate that the sheer scale of the COVID-19 pandemic could lend courts to uphold mandates against challenges.²⁴

Potential mandates are already under consideration among public officials and organizations nationally. In a July 1 report, the New York State Bar Association called for a statewide COVID-19 vaccine mandate as soon as a safe and viable vaccine is available and public health officials recommend it.²⁵ Virginia State Health Commissioner Dr. Norman Oliver also indicated a plan to mandate a safe vaccine in an August 21 interview, though Governor Ralph Northam’s administration may not implement such plans.²⁶ Conversely, a November 19 Banner Health news release (applicable to its Colorado hospitals) indicates that a mandate will not be required, at least initially.²⁷ Given that certain vaccines are currently under consideration for EUA authorization and starting distribution, different approaches may emerge rapidly.

Because COVID-19 vaccines are available without full biologics license applications (BLAs), concerns may arise whether FDA’s mere authorization may circumvent vaccine mandates. The Food, Drug, and

Cosmetic Act (FDCA) states that individuals receiving EUA interventions must be informed “of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives”²⁸ Consistent with the Act, Pfizer-BioNTech guidance documents for its recently-authorized vaccine explain that recipients may opt to accept or refuse it,²⁹ consistent with the legal premise that the vaccine cannot be compelled or forcibly administered among autonomous persons.

Whether individuals may refuse an EUA vaccine, however, is legally distinct from whether an EUA vaccine may be mandated as a condition of continued employment. Nothing in FDA’s letter of authorization expressly limits or prohibits employer mandates.³⁰ In sum, there is currently no express limitation preventing employers from mandating a vaccine distributed pursuant to EUA, rather than one issued through a full BLA, provided (1) anti-discrimination protections are assured and (2) any applicable state laws or exemptions are honored. However, per legal recognition of a personal option to take or refuse the vaccine, many employers may choose to highly encourage, rather than mandate, the vaccine.

In addition to FDA’s EUA, CDC’s Advisory Committee on Immunization Practices (ACIP) makes its own determinations as to which vaccines it may recommend. ACIP completes its own safety review of vaccines to provide official federal vaccine recommendations that stakeholders, including state public health agencies, follow closely.³¹ On December 12, 2020, ACIP recommended the Pfizer-BioNTech vaccine for public use in persons above 16 years of age.³² ACIP plans to address the Moderna vaccine during a December 19 meeting.³³ If FDA and ACIP disagree on utility and safety of this or other COVID-19 vaccines forthcoming, employees may have a stronger legal basis to counter a mandate related to a specific vaccine.

In sum, key determinants whether a COVID-19 vaccine is mandated among HCWs include (1) proof of the vaccine’s efficacy and safety; (2) specific authorization via FDA; (3) review and recommendations from ACIP; (4) additional elaborations from EEOC or OSHA; (5) state- or local-based emergency orders to issue mandates; and (6) emerging guidance from public and private sector employees as to the perceived or actual need of widespread vaccination among employees to assure their safety as well as patients and staff.

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¹ 42 U.S.C.A. § 262(a)(2)(C)

² 21 U.S.C.A. § 360bbb-3(a), (b)(1)(C).

³ Katie Thomas et al., *F.D.A. Clears Pfizer Vaccine, and Millions of Doses Will Be Shipped Right Away*, NEW YORK TIMES (Dec. 11, 2020), <https://www.nytimes.com/2020/12/11/health/pfizer-vaccine-authorized.html>.

⁴ Katie Thomas, *New Pfizer Results: Coronavirus Vaccine Is Safe and 95% Effective*, NEW YORK TIMES (Nov. 18, 2020), [https://www.nytimes.com/2020/11/18/health/pfizer-covid-vaccine.html?action=click &module=RelatedLinks &pgtype=Article](https://www.nytimes.com/2020/11/18/health/pfizer-covid-vaccine.html?action=click&module=RelatedLinks&pgtype=Article).

⁵ Denise Grady et al., *FDA Panel Endorses Moderna's Covid-19 Vaccine*, NEW YORK TIMES (Dec. 17, 2020), <https://www.nytimes.com/2020/12/17/health/covid-vaccine-fda-moderna.html>.

⁶ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

⁷ *Id.* at 12.

⁸ *Id.* at 25.

⁹ KATHLEEN S. SWENDIMAN, CONG. RESEARCH SERV., RS21414, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS 2, 4 (2011).

¹⁰ *Id.* at 6.

¹¹ *Id.* at 3, 4.

¹² *Id.* at 5; see also Rene F. Najera & Dorit R. Reiss, *First Do No Harm: Protecting Patients Through Immunizing Health Care Workers*, 26 HEALTH MATRIX: J. L. MED. 363, 380 (2016).

¹³ Letter from OSHA Acting Assistant Secretary Jordan Barab to Congresswoman Marcy Kaptur (Nov. 9, 2009), <https://www.osha.gov/laws-regs/standardinterpretations/2009-11-09>.

¹⁴ EEOC, PANDEMIC PREPAREDNESS IN THE WORKPLACE AND THE AMERICANS WITH DISABILITIES ACT (Mar. 21, 2020), <https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act>.

¹⁵ 29 U.S.C.A. § 654(a)(1).

¹⁶ *Supra* note 13.

¹⁷ 42 U.S.C.A. §§ 12112, 12113.

¹⁸ *Id.*; see also EEOC, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term= (last updated Dec. 16, 2020).

¹⁹ 42 U.S.C.A. §§ 2000e(j), 2000e-2(a)(1).

²⁰ EEOC, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term= (last updated Dec. 16, 2020).

²¹ *Supra* note 14.

²² *Va. Mason Hosp. v. Wash. State Nurses Ass'n*, 511 F.3d 908 (9th Cir. 2007).

²³ Christine Nero Coughlin et al., *When Doctors Become "Patients": Advocating a Patient-Centered Approach for Health Care Workers in the Context of Mandatory Influenza Vaccinations and Informed Consent*, 45 WAKE FOREST L. REV. 1551, 1556 (2010).

²⁴ Brian Dean Abramson, *Preparing Health Care Providers for a COVID-19 Vaccine*, 13 J. HEALTH & LIFE SCI. L. 2, 3 (2020).

²⁵ NEW YORK STATE BAR ASS'N, HEALTH LAW SECTION, *COVID-19 Report 64-65* (July 1, 2020), https://nysba.org/app/uploads/2020/07/7-1-20_REV-2-Final-NYSBA-HEALTH-LAW-SECTION-TASK-FORCE-REPORT-w-Vacc-update.pdf.

²⁶ Jackie DeFusco, *Northam Not Planning on COVID-19 Vaccine Mandate Despite Support from Top Official*, ABC8NEWS (Aug. 24, 2020), <https://www.wric.com/news/northam-not-planning-on-vaccine-mandate-despite-support-from-top-health-official/>.

²⁷ *Banner Health Offers COVID-19 Update for its Colorado Hospitals*, FORT MORGAN TIMES (Nov. 19, 2020), <https://www.fortmorgantimes.com/2020/11/19/banner-health-offers-covid-19-update-for-companys-colorado-hospitals/>.

²⁸ 21 U.S.C.A. § 360bbb-3(e)(1)(A)(ii)(III).

²⁹ Pfizer-BioNTech, *Fact Sheet for Healthcare Providers Administering Vaccine 7* (Vaccination Providers), U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/144413/download> (last visited Dec. 14, 2020); Pfizer-BioNTech,



Fact Sheet for Recipients and Caregivers 4, U.S. FOOD & DRUG ADMIN.,
<https://www.fda.gov/media/144414/download> (last visited Dec. 14, 2020).

³⁰ U.S. Food & Drug Admin., Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization (Dec. 11, 2020),
<https://www.fda.gov/media/144412/download>.

³¹ Mary S. Holland, *Liability for Vaccine Injury: The United States, The European Union, and the Developing World* 67 EMORY L.J. 415, 418-19 (2018).

³² Jan Hoffman, *C.D.C. Panel Recommends Pfizer Vaccine for Patients as Young as 16*, NEW YORK TIMES (Dec. 12, 2020), <https://www.nytimes.com/2020/12/12/health/covid-vaccine-teens-cdc.html>.

³³ CDC, *Meeting of the Advisory Committee on Immunization Practices* (Dec. 18, 2020),
<https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2020-12-19-20.pdf>.