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 November 20, 2020, Pfizer and German partner BioNTech submitted an EUA application to FDA for a COVID-19 vaccine,³ which has demonstrated upwards of 90% efficacy in trials.⁴ Additional EUA applications for other vaccine candidates are also anticipated. While FDA conducts its review, 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.*⁵ The requirement, issued by the City of Cambridge, imposed a $5 fine on those who refused vaccination.⁶ The Court acknowledged that state and local governments are authorized to enact reasonable laws or regulations to protect public health and safety,⁷ 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.⁸ Several state statutes also allow for compulsory (or forcible) vaccination during public health emergencies (although these are subject to considerable constitutional challenges).⁹ Many states also recognize a variety of medical, religious, or philosophical exemptions to these requirements.¹⁰

Unbound from constitutional requirements, private sector employers have considerable leeway in requiring employee immunization.¹¹ The Occupational Safety and Health Administration (OSHA)¹² and the Equal Employment Opportunity Commission (EEOC)¹³ have previously approved employer-mandated influenza vaccination schemes that comply with anti-discrimination laws.

The federal Americans with Disabilities Act (ADA) allows employers to mandate vaccination so long as reasonable accommodations are provided to employees with disabilities.¹⁴ Accommodations are not required in cases of undue hardship or where others may be directly threatened.¹⁵ Additionally, Title VII of the Civil Rights Act requires reasonable accommodation for employees with religious objections to
vaccination, except in cases of undue hardship. EEOC has not expressly opined whether COVID-19 could allow employers to bypass accommodations pursuant to the direct threat or undue burden exceptions.

Finally, 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.” This requirement could potentially be interpreted as imposing a duty on employers to require COVID-19 vaccination if the vaccine proves safe and efficacious.

Neither EEOC nor OSHA have provided specific guidance regarding COVID-19 vaccine mandate in the workplace. Both agencies, however, have provided guidance relating to vaccine mandates generally. OSHA emphasizes that employees should be properly informed of vaccine benefits. EEOC recommends that ADA-covered employers simply “encourage employees to get the influenza vaccine” rather than requiring it.

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. 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. Some scholars intimate that the sheer scale of the COVID-19 pandemic could lend courts to uphold mandates against challenges.

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. 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. Conversely, a November 19 Banner Health news release (applicable to its Colorado hospitals) indicates that a mandate will not be required, at least initially. Once a COVID-19 vaccine is authorized for use, different approaches may emerge rapidly.

Since COVID-19 vaccines may become available soon without a full biologics license application (BLA), concerns may arise whether FDA’s mere authorization may circumvent vaccine mandates. The Food, Drug, and Cosmetic Act 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 . . .”

Whether individuals may refuse an EUA vaccine, however, is distinct from whether an EUA vaccine may be mandated as a condition of continued employment. 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.
As well, FDA authorization of a COVID-19 vaccine does not automatically assure approval of its use via CDC’s Advisory Committee on Immunization Practices (ACIP). ACIP completes its own safety review of vaccines, providing official federal vaccine recommendations that stakeholders, including state public health agencies, follow closely.\(^2\) If FDA and ACIP disagree on the utility and safety of a specific vaccine, employees may have a stronger legal basis to counter a vaccine mandate.

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.

__This document was researched and developed by Jen Piatt, JD, Senior Attorney, and Hanna Reinke, Senior Legal Researcher, J.D. Candidate 2022, and reviewed by James G. Hodge, Jr., J.D., LL.M., Director, Network for Public Health Law – Western Region Office, Sandra Day O’Connor College of Law, Arizona State University (ASU).__

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Supporter:

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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).
6. Id. at 12.
7. Id. at 25.
9. Id. at 6.
10. Id. at 3, 4.
15 Id.
18 Supra note 12.
19 Supra note 13.
20 Va. Mason Hosp. v. Wash. State Nurses Ass’n, 511 F.3d 908 (9th Cir. 2007).
22 Brian Dean Abramson, Preparing Health Care Providers for a COVID-19 Vaccine, 13 J. HEALTH & LIFE SCI. L. 2, 3 (2020).