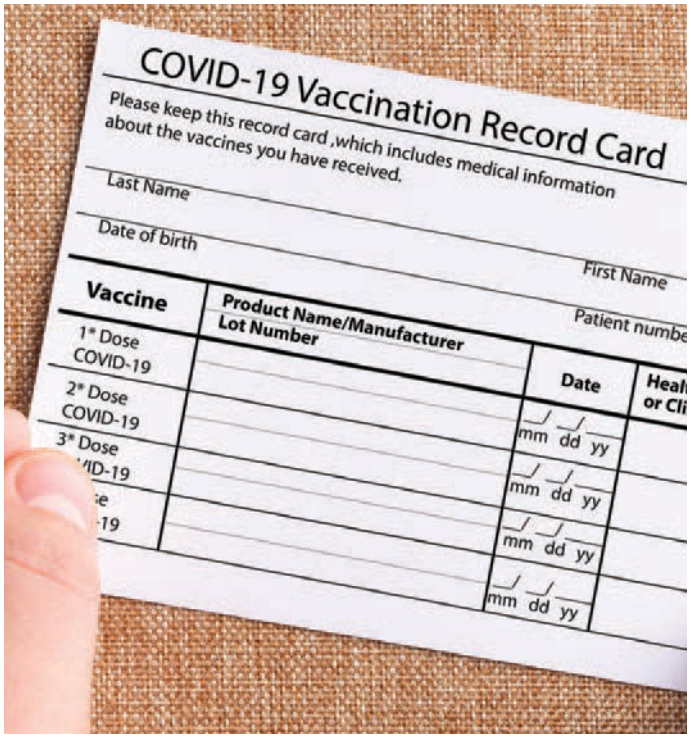
Employer-Mandated COVID-19 Vaccines:

A High-Stakes Gamble Now; A Better Bet In The Near Future

By Christine A. Samsel and Peter M. Goodloe

In the face of the COVID-19 pandemic, pharmaceutical companies scrambled to develop vaccines, quickly coming out with several options. Distribution of those vaccines initially surged, but public interest in receiving the vaccine has been waning, resulting in a failure to meet President Biden's vaccination goal—in other words, that by July 4, 70% of adults in the U.S. would have received at least one dose of a COVID-19 vaccine. The slowdown in vaccinations has fueled fear of a resurgence, particularly with the emergence of more virulent variants of COVID-19. Contending with the polarization of vaccine skepticism and the country's desire to return to "normal" in the wake of a global pandemic, many are wondering: Can employers require employees to get vaccinated against COVID-19? Should they do so in order to protect employees, patrons and the public?

Many news outlets recently reported that the federal government has indicated that employers can mandate COVID-19 vaccines, relying on guidance issued by the federal Equal Employment Opportunity Commission ("EEOC"). The guidance has been read to suggest that the answer is yes, but the current legal context for COVID-19 vaccines is different from ordinary, time-tested vaccines, and a closer look at the guidance itself reveals that it does not say that vaccines can be



mandated. Employers therefore should carefully consider their potential legal liability if they impose such a requirement prior to full approval of any such vaccines from the Food and Drug Administration ("FDA").

Ordinary Vaccine Considerations.

Employers generally can mandate "ordinary" vaccines, subject to business considerations, taking into account accommodations that may be required under the American with Disabilities Act ("ADA") or due to certain medical conditions (such as pregnancy or strong allergies to vaccine components), or for religious reasons. This analysis applies in the context of vaccines approved by the FDA through its formal process under which, after consideration of evidence from human studies, the agency determines that vaccines are safe and effective. For example, the FDA has formally approved many influenza vaccines, which in turn have been mandated by some employers (such as health care providers) in accordance with EEOC recommendations.

Emergency Use Authorization Status of COVID-19 Vaccines:

Unlike influenza and similar vaccines, COVID-19 vaccines are currently being made available not through the formal approval process of the FDA, but rather through a more streamlined "emergency use authorization" "EUA" process. The statutory provisions governing the FDA's emergency process include language that raises concerns about the potential legality of employers mandating vaccines authorized under an EUA. Specifically, the relevant provision requires that recipients of EUA products be informed, to the extent practicable, that they have ***"the option to accept or refuse administration of the [EUA] product ...,"*** a requirement applicable to the EUA-authorized vaccines. (See Federal Food, Drug, and Cosmetic Act ("FDCA"), Section 564(e)(1)(A)(ii)(III); "Vaccines" and approval letters and fact sheets, found https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.) Below we outline in more detail the FDA's formal approval process and the EUA process.

The FDA's Formal Approval Process.

The FDA's normal process for authorizing the development and marketing of a vaccine has two general stages. In the first stage, the agency approves an "investigational new drug" application (IND), which authorizes the company involved to conduct studies in humans of the effects of the vaccine (clinical studies). Phase 1 clinical studies focus on determining the safety of the vaccine; Phase 2 clinical studies provide further evidence of safety, as well as initial evidence of effectiveness; and Phase 3 clinical studies are typically large-scale studies of safety and effectiveness. In the second stage of development and marketing, the company submits an application to the FDA for formal approval to market the vaccine (a biologics license application, or "BLA". The FDA considers all of the clinical evidence from the IND studies and makes a risk-benefit analysis of whether to approve the BLA, requiring "substantial evidence" of effectiveness in order to approve the BLA. Existing guidance and case law regarding employer-mandated vaccines all appear to have involved vaccines with approved BLAs.

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The FDA's Streamlined EUA Process.

In the aftermath of the Sept. 11, 2001, terrorist attacks, Congress decided that, in emergency situations, the FDA should be permitted to authorize the market entry of drugs (including vaccines) that have not been approved through the FDA's full formal process. Specifically, Congress created Section 564 of the FDCA, which gives the FDA authority to allow the marketing of unapproved drugs if the Department of Health and Human Services ("HHS"), through the secretary of HHS, has issued a declaration that there is a public health emergency. (See 21 U.S.C. § 360bbb-3.) The premise presumably is that, in an emergency situation, the FDA will allow a greater degree of risk, in part by not requiring the full range of clinical studies that would be necessary for formal approval. In the case of an emergency vaccine, a company is not required by the FDCA to submit an IND, nor is it required by the FDCA to submit a BLA; instead, under Section 564, it submits an application for an EUA. The applicable standards under Section 564 for issuing an EUA for a vaccine include that "it is reasonable to believe that the product may be effective in . . . preventing such disease."

An EUA, therefore, is very different from a formal approval by the FDA. Due to the 9-11 attacks, Congress had a strong sense of what it means to be in an emergency situation. The first response of Congress to those attacks was the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (enacted in June 2002 as PL 107-188), but its FDA-related provisions provided only a modest variation on the agency's formal drug-approval process. Then Section 564 was added to the FDCA by the National Defense Authorization Act for Fiscal Year 2004 (enacted in November 2003 as PL 108-136). Subsequently, Section 564 was reenacted with technical changes as part of the Project Bioshield Act of 2004 (enacted in July 2004 as PL 108-276). The section thereafter was amended several times.

Recognizing the potential for adverse reactions to medical countermeasures, Congress also passed the Public Readiness and Emergency Preparedness Act (enacted in December 2005 as PL 109-148), known as the "PREP Act," to establish liability protection for the administration or use of medical countermeasures, including products marketed under EUAs, and to create a fund to compensate those injured by such countermeasures. (The PREP Act does not provide protection in cases of willful misconduct.)

There was strong bipartisan consensus on these laws as responses to the 9-11 attacks. As part of this process, Congress anticipated that a pandemic would likely occur at some point and made an effort to think through the issues that could arise in that regard.

EUA Requirements.

From its inception, Section 564 has imposed conditions upon the emergency use of FDA-regulated products, including vaccines. Importantly, these have always included the requirements that recipients be informed, to the extent practicable, that they have "the option to accept or refuse administration of the [EUA] product [and] of the consequences, if any, of refusing administration of the product." (Section 564(e)(1)(A)(ii)(III).) This is a logical requirement, given the increased level of potential risk involved in taking an EUA drug as compared to a drug approved through the formal FDA process.

As evidence of the regulatory scope of Section 564, consider that Congress has created only one exception to the notification and right of refusal requirements, which concerns the armed forces. Specifically, these requirements may be waived for the armed forces if the U.S. president determines, in writing, that complying with such requirements is not in the interests of national security. (See 10 U.S.C. § 1107a.) The clear implication is that, in the absence of such a written waiver by the president, each member of the armed forces has the right of refusal and must be informed of such right. No such presidential determination for EUA COVID-19 vaccines has been made, and approximately one-third of the armed forces had declined to accept the vaccine as of the first quarter of 2021, according to Pentagon officials. Given that Congress has not enacted any other exceptions, it stands to reason that the general rule is that each individual in the United States has these same rights.

COVID-19 Vaccines under EUAs.

On Feb. 4, 2020, HHS declared a public health emergency for purposes of Section 564. On March 27, 2020, an HHS declaration became effective for the FDA to issue EUAs for drugs, including vaccines. With respect to COVID-19 vaccines, the FDA has used its discretionary authority under Section 564 to establish EUA vaccine standards not expressly required by that Section, including requiring an IND application and Phase 1, Phase 2 and Phase 3 clinical studies.

As of this writing, three COVID-19 vaccines have received EUAs from the FDA, the Pfizer-BioNTech vaccine, authorized on Dec. 11, 2020, the Moderna vaccine, authorized on Dec. 18, 2020, and the Janssen (Johnson & Johnson) vaccine, authorized on Feb. 27, 2021. (See "Drugs and Biological Products" and approval letters and fact sheets https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.).) Each of the letters granting the EUA states that the vaccine is "an investigational vaccine not licensed for any indication."

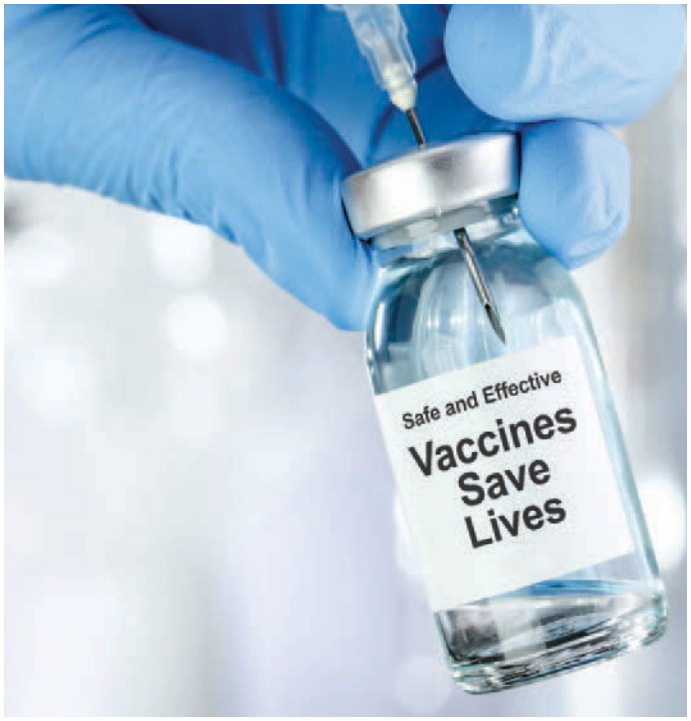
Each of the EUA letters states, among other things, that the FDA has concluded that "it is reasonable to believe that [the vaccine] may be effective." The letters also state that the manufacturers are required to give a "fact sheet" to health care providers who administer the vaccines that instruct them to inform vaccine recipients of the right to refuse the vaccine. Notably, upon termination of the current HHS declaration of a public health emergency under Section 564, the further marketing and administration of an EUA vaccine will generally become illegal, unless and until the vaccine is formally approved by the FDA. (In the case of a patient who received an unapproved product during an emergency period, Section 564 provides that, notwithstanding termination of the emergency declaration, the patient's attending physician is authorized to find that it is necessary for the patient to continue using the product. It is not clear at this point how that authority will apply to the current EUA vaccines, but it is clear that the authority does not apply to employers.)

Preemption and State Laws regarding EUA Vaccines.

The FDCA is a federal regulatory statute that preempts conflicting state laws. This preemptive force may very well include the individual's right of refusal under Section 564. Many states have been considering and enacting legislation concerning vaccinations, with some seeking to prohibit mandatory vaccines, and others contemplating imposing vaccine mandates under certain circumstances. It remains to be seen whether laws mandating vaccines will pass, and if so, whether they would survive a legal challenge asserting that the right to refuse the vaccine in the FDCA preempts conflicting state law.

Anticipated Full Approval of COVID-19 Vaccines.

On May 7, 2021, Pfizer and BioNTech announced the initiation of a Biologics License Application—in other words, the companies are seeking "full" FDA approval of their vaccine. Data to support the BLA will be submitted to the FDA on a rolling basis over the coming weeks, with "Priority Review" requested. Moderna followed soon after, on June 1, 2021. Johnson & Johnson/Janssen's BLA is expected to be forthcoming later this year. Priority Review is a designation reserved for drugs that offer major advances in treatments, and in such a review, the FDA aims to get a drug through the entire process in six



months (standard review typically takes 10–12 months). The Priority Review timeline thus could result in full approval of these vaccines by year-end, which may help improve vaccination rates, and would clear the way for employer vaccine mandates.

EEOC Guidance regarding COVID-19 Vaccines.

In its original guidance issued in December 2020 (the "Guidance"), the EEOC implied that employers can mandate COVID-19 vaccines. However, at that time, the EEOC carefully sidestepped the issue of whether employers may mandate vaccines authorized under an EUA, versus those approved pursuant to the FDA's formal approval process, incorporating into the Guidance a link to the FDA website regarding EUAs.

The EEOC updated the Guidance on May 28, 2021 (the updated Guidance can be found https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws). The EEOC did ***not***, contrary to many news reports, authorize mandatory vaccines. Rather, keeping in line with its prior position, the EEOC continued to sidestep this issue. Specifically, the prefatory language to Section K of the updated Guidance states (emphasis added):

> The EEOC has received many inquiries from employers and employees about the type of authorization granted by the U.S. Department of Health and Human Services (HHS) Food and Drug Administration (FDA) for the administration of three COVID-19 vaccines. These three vaccines were

> granted Emergency Use Authorizations (EUA) by the FDA. ***It is beyond the EEOC's jurisdiction to discuss the legal implications of EUA or the FDA approach. Individuals seeking more information about the legal implications of EUA or the FDA approach to vaccines can visit the FDA's EUA page. The EEOC's jurisdiction is limited to the federal EEO laws as noted above ....*** The technical assistance on vaccinations below was written to help employees and employers better understand how federal workplace discrimination laws apply during the COVID-19 pandemic caused by the SARS-CoV-2 virus and its variants. The technical assistance here is based on and consistent with the federal civil rights laws enforced by the EEOC and with EEOC regulations, guidance, and technical assistance. Analysis of how it applies in any specific instance should be conducted on an individualized basis.

The EEOC's Guidance is ***expressly limited*** to the interplay between vaccinations and federal civil rights/equal employment opportunity laws, such as the Americans with Disabilities Act (ADA), the Rehabilitation Act, the Genetic Information Nondiscrimination Act and Title VII of the Civil Rights Act, as amended by, among other things, the Pregnancy Discrimination Act. Thus, employers should derive no comfort from this Guidance as it pertains to the legality of mandating COVID-19 vaccines that remain under EUA status. Because the current legal context for COVID-19 vaccines is different from ordinary, time-tested vaccines (such as those for influenza), employers should carefully consider their potential legal liability when considering imposing vaccine mandates prior to full approval of such vaccines by the FDA.

Employer Vaccine Mandates and EUAs.

Given these facts, can an employer mandate employees to get vaccinated under threat of termination or other employment action? In other words, is an employer that mandates EUA vaccinations subject to—and in violation of—Section 564(e)(1)(A)(ii)(III) by becoming a "person who carries out any activity for which the [EUA] is issued?" The law regarding EUAs is unclear and as yet untested.

Under FDCA section 510(a) (and *Pom Wonderful, LLC v. Coca-Cola Company*, 573 US 102, 109 (2014)), there is no general private right of action under the FDCA, but the question of whether Congress intended to create such a right under Section 564(e)(1)(A)(ii)(III) apparently has not been addressed. However, such a scenario could give rise to a claim for wrongful termination in violation of public policy under state law, given the clear right of refusal under Section 564. The FDCA does not address this issue, but it would be difficult to argue that the required disclosure of the "consequences" of refusing administration of the vaccine contemplates things like termination of employment (as opposed to health-related consequences). Moreover, as noted above, once the current HHS declaration of a public emergency under Section 564 is terminated, an employer mandating that employees receive an EUA vaccine will do so knowing (or presumed to know) that such a mandate is unlawful.

Current Legal Landscape.

At least four federal lawsuits have been filed against employers mandating COVID-19 vaccines. Most recently, and in the first case to result in a ruling on the issue, on May 28, 2021, over 100 employees of Methodist Hospital asserted claims against their employer for imposing a vaccine mandate. (*Jennifer Bridges, et al. v. The Methodist Hospital d/b/a the Methodist Hospital System, et al.*, filed in Texas state court in Montgomery County as Cause No. 21-06-07552, subsequently removed to U.S. District Court for the Southern District of Texas, Houston Division, as Case No. 4:21-cv-01774.) The issue came to a head when the employer suspended without pay and threatened to terminate nearly 200 employees. On June 12, 2021, Judge Lynn N. Hughes, in a very brief opinion (available https://int.nyt.com/data/documenttools/houston-methodist-court-ruling/3468984fc566cea5/full.pdf), dismissed all of the plaintiffs' claims on the employer's motion. On the wrongful termination claim, the court noted that "Texas law only protects employees from being terminated for refusing to commit an act carrying criminal penalties to the worker," which receiving the vaccine would obviously not do. (Order on Dismissal, p.1.) Further, the court noted that Texas

does not recognize a public policy exception to at-will employment, and went on to say that even if it did, "the injection requirement is consistent with public policy." (*Id.*, p.2.) The court gave short shrift to the detailed arguments regarding Section 564, devoting only two short paragraphs to the issues. (*Id.*, p.3.) The court opined that the plaintiffs were not being "coerced" into getting the vaccine; they could simply work somewhere else, likening the EUA vaccine mandate of the employer to a "changed office" or "earlier start time" directive. (*Id.*, p.4.) The dismissal was promptly appealed to the Fifth Circuit. (Case No. 21-20311, June 14, 2021.) In the meantime, over 150 employees of the hospital have been terminated or resigned.

Other filed cases include one in New Mexico in which the plaintiff, an employee of the Dona Ana Detention Center, asserted that he was threatened with termination of employment due to his exercise of his federal right to refuse the EUA vaccine in the face of his employer's vaccine mandate (*Legaretta v. Fernando Macias, et al.*, Case No. 2:21-cv-00179, filed in federal district court in New Mexico on Feb. 28, 2021); a similar case in California, in which the plaintiffs assert that the defendants' policy of mandating that all of its employees be vaccinated against COVID-19 constitutes prohibited "human experimentation without consent" in violation of the Nuremburg Code, among other things (*California Educators for Medical Freedom, et al. v. The Los Angeles Unified School District, et al.*, Case No. 21-cv-02388, filed in federal court in the Central District of California on March 17, 2021); and another in North Carolina, in which a former deputy claims he was wrongfully terminated for refusing to receive a COVID-19 vaccine (*Neve v. Birkhead*, Case No. 1:21-cv-00308, filed in federal court in the Middle District of North Carolina on April 16, 2021).

Plaintiffs' lawyers have wasted no time jumping on this issue, filing lawsuits and issuing demand letters around the country. The dearth of case law on these issues, coupled with the legal requirements of the EUA process, will doubtless lead to more such suits in the face of employer mandates. The *Houston Methodist* decision offers little comfort to employers, given the Texas law idiosyncrasies involved in the case, and the likelihood that courts in other jurisdictions will not view the scant legal analysis and reasoning as persuasive on the complicated legal issues involved. For example, the *Houston Methodist* decision did not address the issue that Congress believed the legal force of Section 564 made it necessary to create, in the case of the armed forces, a statutory exception to the notification and right of refusal requirements.

These types of claims will be short-lived, however, given the likely imminence of full FDA approval of the vaccines. Full approval by the FDA would put the brakes on future lawsuits related to EUA status of mandatory vaccines, but we'll likely see a proliferation of cases alleging failure to accommodate medical conditions, disabilities and religious objections in their stead.

Considerations for Mandatory Vaccines Moving Forward.

Once the vaccine is fully approved, it is likely that more employers will consider mandating—and will actually mandate—vaccines as a condition of employment. The EEOC Guidance confirms that federal civil rights laws do not prohibit such mandates, provided certain requirements are met. Summarized below are some of the key issues addressed in the updated Guidance.

Required Accommodations: Employers must consider accommodations that may be required under the ADA, or due to certain medical conditions (such as pregnancy or strong allergies to vaccine components), or for religious reasons. Requests for religious accommodation may be based on objections to the concept of vaccines generally, or specific to a particular vaccine (e.g., gene-based vaccines). This requires a similar analysis to that required of employers with respect to, for instance, flu shots.

Documentation and Confidentiality: Employers may request proof of vaccination of employees on a non-discriminatory basis, and requiring proof of vaccination does not, in and of itself, violate the ADA or other civil rights laws. However, although requesting proof of vaccination is not a medical inquiry, the information received by the employer (e.g., a copy of a CDC vaccination card) is considered medical information that must be treated in a confidential manner and maintained in a file separate from the employee's personnel file.

Collection of such information also may be required under applicable state or local law. For example, both the recently updated Emergency Temporary Standards ("ETS") promulgated by the California Occupational Safety and Health Standards Board define "fully vaccinated" employees, who are required to follow less stringent COVID-19 mitigation protocols, to mean that the employer ***has documentation showing*** that the

employee received, at least 14 days prior, either the second dose in a two-dose COVID-19 vaccine series or a single-dose COVID-19 vaccine.

Incentives: The EEOC Guidance outlines, among other things, the parameters of incentives that may be provided by employers to employees for obtaining the vaccine. As expected, and in keeping in line with the proposed regulations issued by the EEOC last year, incentives may be offered to employees obtaining the vaccine through the employer, but the incentives cannot be so substantial as to be considered coercive. What's the reasoning for this? Administering the vaccine requires prescreening questions that would be prohibited under the ADA unless they are voluntary; excessive incentives undermine the voluntary aspect of responding to the screening questions. Notably, this concern is not present to the same extent when employees are rewarded for obtaining vaccines through their own health care providers rather than directly through the employer. (Employers should keep in mind, though, that incentives, regardless of size, generally are taxable to the employee.)

Takeaways:

At present, it is very risky for employers to mandate COVID-19 vaccines. In addition to the prospect of litigation as outlined above, it is questionable whether workers' compensation would cover employee side effects or death from mandatory vaccines if employers cannot legally require such vaccines in the first instance. The legal issues surrounding mandatory COVID-19 vaccines are currently unsettled, but will doubtless be fleshed out in the near future through the pending litigation and the anticipated full FDA approval of the existing vaccines.

At this juncture, given the uncertainty surrounding the legality of mandating EUA-status vaccines, the safer course of action is to ***encourage*** employees to get the vaccine rather than mandating it, providing facts about the vaccine and legally permissible incentives to do so, and accommodating those who are unable to get the vaccine for religious, medical or disability-related reasons. The EEOC recommends this course of action, and the CDC and other public health agencies have created toolkits to assist employers in encouraging vaccinations. Alternatively, if employers elect to mandate vaccines, they would be well-advised to await full FDA approval and follow EEOC and other applicable guidance at that time.

Employers should continue to monitor this evolving situation, consider these issues as well as the additional considerations that doubtless will arise, and work with legal counsel in developing and regularly updating their vaccine strategy and policies.

The COVID-19 Numbers as of July 27, 2021…..

	World	U.S.	Nevada
Cases Reported	195 million+	35.4 million+	353,000+
Deaths	4.18 million+	627,000+	5,854
Vaccines Administered	3.815 billion+	343.9 million+	2.699 million+
Fully Vaccinated	1.09 billion+	163.6 million+	1.266 million+

*Information compiled by Jeff Rodefer from the World Health Organization dashboard, the Centers for Disease Control and Prevention, the Nevada Department of Health and Human Services, and the New York Times.

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