

# FDA Full Approval of Pfizer's COVID-19 Vaccine: To Mandate or Not to Mandate, That is the Question

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Over the past year and a half, employers have become all too familiar with various public health agencies and their regulations, recommendations, and preventative measures. For the past several months, a big question for employers has been whether to mandate or not to mandate employee vaccinations as three vaccines were available but only under the Federal Drug Administration's (FDA) Emergency Use Authorization authority (EUA). Some employers have been hesitant to mandate that employees become fully vaccinated against COVID-19 without the full embrace of the vaccines by the FDA.

The FDA's August 23, 2021 full approval of the Pfizer-BioNTech COVID-19 vaccine for use by individuals over 16 years of age is news that many employers have been waiting for. The authorization of the Pfizer vaccine bolsters the legal support for private employers who wish to require employee vaccinations as a condition of employment. We thus expect more employers to consider mandatory policies for employees.

## Legal Support for Mandates

Even before Pfizer received FDA approval, courts have held that challenges to employer mandates were mostly without merit. In *Bridges, et al. v. Houston Methodist Hospital et al.*, C/A H-21-1774, 2021 WL 2399994 (S.D. Tex. Jun. 12, 2021), now on appeal to the Fifth Circuit, the district court dismissed the plaintiff employees' challenge to their healthcare employer's COVID-19 vaccine mandate. The court explained that the employer "is trying to do their business of saving lives without giving [employees] the COVID-19 virus. It is a choice made to keep staff, patients and their families safer" and "employees can freely choose to accept or refuse a COVID-19 vaccine; however, if [they] refuse, [they] will simply need to work somewhere else. Every employment includes

limits on the worker's behavior in exchange for his remuneration. This is all part of the bargain." The court's point remains the same even now—a few months later—and in fact has been reinforced by the FDA's approval of the Pfizer COVID-19 vaccine.

The U.S. Department of Justice (DOJ) has also appeared to support employer mandates, even of EUA only vaccines. On July 6, 2021, the DOJ formally issued a [Memorandum Opinion](#) for the Deputy Counsel to the President confirming that vaccinations that have been made available by the FDA through an EUA, such as the COVID-19 Moderna and Johnson & Johnson vaccines (and, at the time of DOJ issuance, Pfizer), may be legally mandated by employers. The DOJ concluded that a section of the Food, Drug, and Cosmetic Act (FDCA) "does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs."

## Key Takeaways and Practical Implications for Employers

With the FDA's stamp of full approval of the Pfizer COVID-19 vaccination, employers have an even clearer path to instituting mandatory policies for their workforce, so long as certain exemptions from the mandate are permitted and accommodated.

Below are answers to some of the questions employers are asking as they consider requiring vaccinations:

### → Can employers mandate COVID-19 vaccination as a condition of employment?

→ Yes, with some exceptions. Employers are legally permitted to require that employees become fully vaccinated against COVID-19 provided that employee requests for reasonable accommodations for medical or religious reasons are permitted and considered.

### → Can employers require testing and offer incentives?

- Some employers continue to offer incentives to employees who become vaccinated. Others are taking a hybrid approach, requiring either proof of full vaccination or submission of a weekly or biweekly negative test result.
- Some employers have decided against mandating vaccination for fear of losing employees in the current tight labor market.

### → What is the status of the Moderna and Johnson & Johnson COVID-19 vaccines?

→ For now, the Moderna and Johnson & Johnson vaccines remain under EUA. The FDA still maintains that these vaccines have met its "rigorous, scientific standards for safety, effectiveness, and manufacturing quality," and the "known and potential benefits clearly outweigh [the] known and potential risks." Best practice remains permitting employees to choose any of the three vaccines, rather than dictate that an employee take one in particular.

### → How will differences in state laws impact vaccine mandates?

→ Different states have different laws. We urge employers to evaluate the laws and rules for every jurisdiction in which they operate prior to implementing a mandatory vaccination policy.

→ **Do employers still need to be concerned about employees masking up?**

→ Despite full FDA approval of the Pfizer vaccine, employers should not lose sight of the importance of masking, social distancing, and other safety measures. The CDC and many state health agencies still recommend that even fully vaccinated individuals wear masks in public indoor settings when in an area with high or substantial community transmission—and that unvaccinated individuals should always wear a mask, regardless of community transmission level. OSHA recently issued [new guidance](#) reflecting the CDC's recommendations on mask wearing.

Nexsen Pruet's Employment and Labor Law team is closely monitoring all developments and new information related to COVID-19 and vaccinations. Our team of experienced lawyers regularly counsels employers on the complex issues surrounding the pandemic and vaccinations, and assists with crafting policies and procedures related to COVID-19. We stand ready to assist employers with these issues.