

FDA Fully Approves Pfizer-BioNTech COVID-19 Vaccine: Implications for Employers

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Yesterday, the U.S. Food and Drug Administration (FDA) granted “full approval” to the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older. In other words, the Pfizer-BioNTech vaccine (which will now be marketed as “Comirnaty”) has received the top level of clearance a medical drug can possibly obtain from the U.S. government. Many employers and healthcare providers are now wondering how this latest news affects them, particularly with regards to vaccination mandates.

The FDA previously approved the Pfizer-BioNTech, Moderna, and Johnson & Johnson vaccines pursuant to the FDA's Emergency Use Authorization (EUA). Despite the vaccines' EUA approval, many employers remained wary of imposing vaccination mandates because the FDA had not fully approved the vaccines. However, several legal developments over the past months indicated that employers' legal risk was low, even without full FDA approval. For example, the U.S. Equal Employment Opportunity Commission has stated that employers may require their employees to get vaccinated without violating most federal anti-discrimination laws (subject to laws regarding reasonable accommodation). The U.S. Department of Justice also opined that the FDA's EUA regulations did not prevent employers from requiring mandatory COVID-19 vaccinations. Furthermore, several courts have upheld vaccination mandates notwithstanding the various lawsuits filed by displeased workers.

In short, even before the FDA's full approval, the legal risk to employers wishing to implement a vaccination mandate was arguably minimal, though it remains to be seen whether employees will continue to challenge vaccine mandates and whether favorable court decisions thus far might be overturned on appeal. Now that the Pfizer-BioNTech COVID-19 vaccine has received the FDA's full approval, the legal risk to employers desiring to implement a mandate should be even lower, but keep in mind that a few states still prohibit vaccine mandates. More importantly, some employees who were hesitant to get the vaccine might be more willing to do so now.

If an employer concludes that the time is right to impose a vaccine mandate, there are several recommendations to bear in mind:

1. Determine the best method of communicating the mandate to employees, including (a) how much notice to give before enacting the mandate, and (b) how the company will obtain and maintain proof of vaccination.
2. Ensure that there is a clear accommodation policy for handling any

disability, medical condition, or religious concern.

3. Depending on the jurisdiction, consider any compensation-related laws that might be triggered by the mandate, including (a) reimbursement for time spent traveling to and receiving the vaccine, and (b) paid sick leave for time required to receive the vaccine or to recuperate from its aftereffects.
4. Contemplate how some employees and clients might respond to the mandate, and develop a plan beforehand for responding to any apprehension or opposition to the mandate.

The laws relating to the COVID-19 pandemic are rapidly evolving with almost daily updates and changes in federal and state policies, regulations, etc. Holland & Hart will continue to track any developments related to the COVID-19 vaccines and correlating workplace issues.

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