



What Employers Need to Know About the Emergency Use Status of the COVID-19 Vaccines

Insights

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Although the COVID-19 vaccines are expected to receive full FDA approval – perhaps as soon as later this month – an increasing number of businesses are not waiting for full authorization and are pressing forward to require their workers or patrons to get inoculated to battle the recent surge and get employees back to work. But many employers remain hesitant to mandate the vaccine because they haven't yet received full clearance and are currently approved under the FDA's Emergency Use Authorization (EUA). In these critical and tense weeks (or months) before full approval is granted, what should employers know about the EUA status...and should it prevent you from considering vaccine mandates?

What is Emergency Use Authorization?

The Pfizer, Moderna, and Johnson & Johnson vaccines are currently subject to the FDA's EUA, which permits the agency to approve drugs, vaccines, medical devices and other products for use on an expedited basis. Although the development process for the vaccines was expedited, they were still subject to trials on tens of thousands of people to determine safety and efficacy – the same stringent testing process that other vaccines go through.

The FDA's 2017 [guidance](#) on EUA products nevertheless notes that recipients must be informed about the right of refusal and any accompanying consequences. For example, the EUA on the Pfizer vaccine includes [paperwork](#) instructing healthcare providers administering the vaccine to tell recipients that they can refuse the shot. The [paperwork](#) for vaccine recipients notifies them they can refuse without changing their standard medical care. These notifications have caused confusion among those who are hesitant about receiving the vaccine and those who believe they should not be subject to an employer mandate. But this directive seems to be targeted at whether an individual can be forced to take the vaccine by a government entity, not whether an employer can condition an individual's continued employment on taking the vaccine. After all, in at-will employment settings, an employee can always pursue alternative employment if they do not want to get vaccinated as a condition of their current job.

Are There Legal Concerns with Mandating Under the EUA Status?

Prior to the COVID-19 pandemic, there had only been one prior instance of an EUA vaccine – the

anthrax vaccine in 2005 – but that vaccine was not widely distributed and therefore the general public was not readily familiar with the EUA status before this past year. And although the Equal Employment Opportunity Commission (EEOC) indicated late last year that employers can require their workers to get the current COVID-19 vaccines without violating most federal anti-discrimination laws (subject to reasonable accommodation principles, of course), the guidance did not explicitly address the EUA.

The combination of these two factors led many employees (and employers) to raise questions regarding how the emergency authorization affects an employer's decision to mandate COVID-19 vaccines. And once the vaccines became widely available and some employers began mandating the vaccine, some employees filed legal challenges to mandatory vaccine policies in Texas, New Mexico, North Carolina, and California (among other places).

- In the most high-profile case, 117 hospital workers in Texas sued to block the hospital's mandatory vaccination policy, relying on – among other arguments – the FDA's EUA. The plaintiffs claimed the emergency provisions under which the vaccines were authorized do not even apply to private employers. Federal Judge Lynn Hughes was not persuaded and dismissed that lawsuit. The plaintiffs have appealed this decision.
- In North Carolina, a federal lawsuit challenging the Durham County Sherriff's Department's decision to require vaccinations refers to the COVID-19 vaccine as “experimental.” The plaintiff's argument is also grounded in public policy, relying on a portion the EUA statute. This case is currently pending in the U.S. District Court for the Middle District of North Carolina.
- These pieces of litigation are similar in many respects to the first two lawsuits challenging mandatory vaccine policies that were filed in New Mexico and Los Angeles.

On the heels of the general success that employers have had defending their vaccine mandates in the courts, the U.S. Department of Justice just expressed the opinion that EUA status does not prevent employers, schools, and other entities from mandating COVID-19 vaccinations.

Despite the fact that all court decisions rendered to date and the DOJ opinion all provide support for employers requiring their workers to receive the COVID-19 vaccine, some employers remain concerned about the risk of legal challenges where the vaccinations are approved only under the FDA's EUA. Which leads to the million-dollar question: when will the EUA be removed in place of full authorization?

When Will Full FDA Approval Occur – and Will That Remove Legal Concerns About Mandatory Vaccinations?

Pfizer officials indicated that it expects the FDA to grant full approval of its vaccine by January 2022 at the latest. But Acting FDA Commissioner Janet Woodcock has said a decision should come well before then. In last week's town hall, in fact, President Biden said that full FDA approval could come as early as August or September.

Even without full approval, however, many businesses – along with more than [600 universities and schools](#) – are already mandating COVID-19 vaccinations for students or employees. In response to legal challenges over the mandates, employers and schools have come out on top thus far. When the vaccines receive full FDA approval in the coming weeks or months, the basis for many of these lawsuits will be removed entirely and employers will be on even firmer ground to mandate vaccines among their workforces.

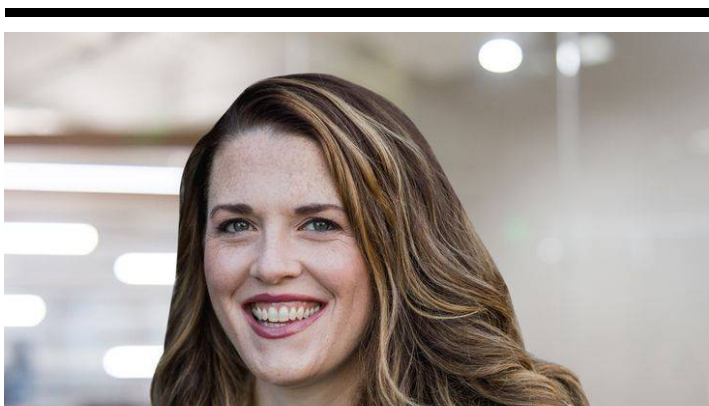
What Should Employers Do?

There are [several options you can consider in an effort to improve the vaccination rate at your workplace](#) before you implement a mandate, starting with communicating with and educating your workforce. In a recent [survey](#) by the Kaiser Family Foundation, about 30% of unvaccinated people say they were waiting for vaccines to receive full approval. Removing this specific concern will certainly make life easier for employers, but it remains vital to continue to communicate data and information to your workforce about the safety and efficacy of the COVID-19 vaccines. This includes information, where available, from locally trusted experts who are able to address worries or misconceptions that employees may have about the vaccines and their effects.

Beyond launching an information campaign, you can also consider incentives, enhanced testing policies for the non-vaccinated, ramped-up safety protocols for those who haven't received the vaccine, and mandates. [You can read detailed information about these options here](#). If your business decides to proceed with a mandatory vaccine policy, you should consult [our list of top seven considerations to take into account before doing so](#) and coordinate with your Fisher Phillips attorney.

As usual with COVID-19, the winding path toward the end of the pandemic still contains significant challenges and probably more surprises. We will continue to monitor developments and provide updates as appropriate. Make sure you are subscribed to [Fisher Phillips' Insight system](#) to get the most up-to-date information. If you have questions about how to ensure that your vaccine policies comply with workplace and other applicable laws, contact your Fisher Phillips attorney, the authors of this Insight, or visit our [Vaccine Resource Center for Employers](#).

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