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July 28, 2021

DOJ Takes Stance on Mandatory COVID-19 Vaccine Policies: They Do Not Violate Federal Food and Drug Laws

According to a [legal opinion](#) posted online on July 26, 2021, the U.S. Department of Justice officially took the position that the Food, Drug, and Cosmetic Act (FDCA)—which authorizes an "emergency use authorization" (EUA) for a vaccine—does not prohibit entities, including employers, from requiring a vaccine even if authorized for emergency use only.

Background on Emergency-Use-Based Challenges to Mandatory Vaccine Policies

All currently available COVID-19 vaccines (Pfizer, Moderna, and Johnson & Johnson) were approved in the United States on an expedited basis under a provision in the FDCA that permits an EUA for a medical product, such as a vaccine, under certain emergency circumstances. One of the most common legal challenges employer-mandated vaccine policies have faced to date is that, because COVID-19 vaccines currently only have emergency-use status, employers cannot lawfully mandate those vaccines.

Challengers have relied upon an FDA regulation providing that, with respect to vaccines subject to EUA status, individuals 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 to the product that are available and of their benefits and risks."

The DOJ's Position Is Consistent With Recent Court Rulings Striking Down Mandatory Vaccine Challenges

In June 2021, in *Bridges et al. v. Houston Methodist* (June 2021), a federal district judge in the U.S. District Court for the Southern District of Texas dismissed a class action brought by 117 employees related to their hospital-employer's mandatory vaccine policy. With respect to the employees' EAU challenge, the court found that the FDCA did not provide the employees with a cause of action to sue employers and that the act imposed requirements only on the Secretary of Health and Human Services (who oversees the FDA). This case is currently pending before the U.S. Court of Appeals for the Fifth Circuit.

More recently, on July 21, 2021, in *Klaassen et al. v. The Trustees of Indiana University*, a federal district judge in the U.S. District Court for the Northern District of Indiana denied a motion for preliminary injunction in a case brought by eight students against Indiana University over the university's mandatory vaccination policy for students. The court stated that the informed consent requirement under the EUA statute only applies to medical providers, which the students conceded: "The University is not directly administering the vaccine to its students instead it is requiring students to obtain the vaccine from a medical provider and to attest that they have been vaccinated, save for certain exemptions." The court went on to discuss that the students have options, including applying for an exemption, deferring entry, or taking a semester off, and that the requirement to get vaccinated did not amount to coercion. The case is currently pending before the U.S. Court of Appeals for the Seventh Circuit.

The DOJ's Position Also Is Consistent With EEOC Guidance

The federal agency responsible for enforcing federal anti-discrimination laws, the Equal Employment Opportunity Commission (EEOC), has also taken a position supportive of mandatory vaccine policies. On May 28, 2021, the EEOC issued revised guidance stating that "federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID-19, subject to the reasonable accommodation provisions of Title VII and the ADA and other EEO considerations." However, the EEOC also stated in its updated guidance that "[i]t's beyond the EEOC's jurisdiction to discuss the legal implications of EUA or the FDA approach."

Practical Impact for Employers

With the blessing of both the DOJ and the EEOC, mandatory vaccine policies now have more support from federal agencies than before. While mandatory vaccine policies are not immune from legal challenges, the federal support provides increased clarity (and legal defenses) to employers seeking to introduce vaccine mandates.

From a legal perspective, employers considering implementing mandatory vaccine policies should continue to be mindful that such policies must have exemptions for those with religious objections or disabilities. The mandates also need to comply with applicable state and local laws. For example, Montana passed a law prohibiting employers from discriminating based on vaccination status, and a few states have prohibited public employers from doing so. From an employee relations perspective, employers considering vaccine mandates also should consider the impact such policies will have on employee morale as well as on labor shortages that certain industries are facing.

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