In a memo dated July 6, 2021, the DOJ’s Office of Legal Counsel concluded that the COVID-19 vaccines’ status as products authorized for emergency use does not prohibit public and private entities from requiring them as a condition of employment, education, or receipt of services. This memo comes on the heels of a recent decision by a federal court in Texas rejecting a challenge to a mandatory vaccination requirement in the employment context.

Below is a summary of what employers need to know about this development from the DOJ.
Background on the Food, Drug, and Cosmetic Act and the EUA

The Food, Drug, and Cosmetic Act (“FDCA”) generally prohibits any “new drug” or “biological product” from being introduced into commerce until it receives full FDA approval. In 2003, in response to concerns related to anthrax, Congress amended the FDCA to allow certain products to be made available in an emergency, even if the product has not yet received full FDA approval. When a product receives an Emergency Use Authorization (“EUA”), the Secretary is required to establish conditions that the Secretary finds necessary to protect the public health. Specifically, Section 564 of the statute requires that the secretary impose conditions:

"designed to ensure that individuals to whom the product is administered are 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."

Some have suggested that this language prohibits entities, such as employers and universities, from mandating that individuals receive a COVID-19 vaccine while only authorized pursuant to an EUA. And in the past few months, a number of lawsuits have been filed challenging various vaccination policies under the FDCA.

In accordance with the above requirement, the FDA included in each of the letters granting an EUA for the COVID-19 vaccines a requirement that an FDA Fact Sheet be made available to all recipients. The Fact Sheets in turn state that “[i]t is your choice to receive or not receive the ...Vaccine. Should you decide not to receive it, it will not change your standard of medical care.”

The DOL Memo

The DOL memo ultimately concludes that the FDCA “concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for vaccinates that are subject to EUAs.”

According to the DOJ memo, the language of the statute requires only that vaccine recipients be “informed” of certain information, including “the option to accept or refuse the administration of the product.” This requirement is satisfied when vaccine administrators provide the FDA Fact Sheet to recipients. The memo continues that, “if Congress has intended to restrict entities from imposing EUA vaccination requirements, it chose a strangely opaque way to do so, embedding the restriction in a provision that on its face requires only that individuals be provided with certain information.” Therefore, according to the DOJ memo, neither the FDCA nor the Fact Sheets purport to restrict private or public entities from requiring a vaccine in any context.

The memo also addresses the unique position of certain entities, such as universities, who may impose vaccination requirements on students and employees, and also administer vaccinations. According to the DOJ memo, “[t]here
is no indication ... that Congress intended to regulate such entities except with respect to the circumstances of their administration of the product itself.” Therefore, the DOJ memo acknowledges that employers that both administer COVID-19 vaccines and seek to mandate vaccines for their employees are no longer subject to Section 564 of the FDCA once they remove their administrator hat and put on their employer hat.

**Takeaways for Employers**

Although the DOJ memo is not binding authority on courts, this memo may provide some guidance to employers seeking to implement mandatory vaccination policies that such requirements do not run afoul the FDCA. Employers implementing (or considering implementing) mandatory vaccination policies can also take comfort in guidance previously issued by the EEOC stating that “[t]he federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID-19.” That said, the same EEOC guidance also states that employers implementing mandatory vaccination policies must consider reasonable accommodations for employees who, because of a disability or a sincerely held religious belief, do not get vaccinated for COVID-19.

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