Employer Mandates for Vaccines Approved Under an EUA

This article is an opinion piece and should not be construed as legal advice for any specific situation. Please consult with an attorney for legal advice about your situation.

The single most commonly asked question I am receiving on a daily basis is regarding the COVID-19 "vaccine." People have a number of questions about the vaccine itself but, more pressingly, they want to know if it is or can be mandated. The answer to this is less clear than it may appear but I would generally say that the vaccine cannot be mandated or cannot be mandated without substantial legal risk for the mandator.

21 U.S. Code § 360bbb–3 is the relevant statute to part of this question. This part of the code is titled "Authorization for medical products for use in emergencies" and sets the rules for how such products can be authorized. Particularly relevant is part e which is below:

(e)Conditions of authorization

(1)Unapproved product

(A)Required conditions With respect to the <u>emergency use</u> of an <u>unapproved product</u>, the <u>Secretary</u>, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a <u>person</u> who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the <u>Secretary</u> finds necessary or appropriate to protect the public health, including the following:

(i)Appropriate conditions designed to ensure that health care professionals administering the <u>product</u> are informed—

(I) that the <u>Secretary</u> has authorized the <u>emergency use</u> of the <u>product;</u>

(II) of the significant known and potential benefits and risks of the <u>emergency use</u> of the <u>product</u>, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the <u>product</u> that are available, and of their benefits and risks.

(ii)Appropriate conditions designed to ensure that individuals to whom the <u>product</u> is administered are informed—

(I) that the <u>Secretary</u> has authorized the <u>emergency use</u> of the <u>product;</u>

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the <u>product</u>, of the consequences, if any, of refusing administration of the <u>product</u>, and of the alternatives to the <u>product</u> that are available and of their benefits and risks.

(iii)Appropriate conditions for the monitoring and reporting of adverse events associated with the <u>emergency use</u> of the <u>product</u>.

(iv)For manufacturers of the <u>product</u>, appropriate conditions concerning recordkeeping and reporting, including records access by the <u>Secretary</u>, with respect to the <u>emergency use</u> of the <u>product</u>.

Part e discusses the conditions of authorization for an unapproved product. All of the available vaccines are "unapproved products" meaning that they are not actually approved by the FDA; rather, they are available only under the emergency use authorization ("EUA").

Critical to this question is the language stating that "Appropriate conditions designed to ensure that individuals to whom the <u>product</u> is administered are informed... of the option to accept or refuse administration of the <u>product</u>, of the consequences, if any, of refusing administration of the <u>product</u>, and of the alternatives to the <u>product</u> that are available and of their benefits and risks." This language is sensible and follows with norms of not forcing the administration of experimental drugs on people that have been established globally since Nuremberg. Based on this it seems very clear that no state or federal agency can mandate the vaccine under the EUA.

The second part of the analysis is somewhat less clear and that is whether a private employer can mandate the vaccine. For a number of reasons that are beyond the scope of blog article my answer is probably not. That said, I think the answer is clearly no if you have a religious or medical exemption and, even if the answer is yes, I think employers are putting themselves at risk of serious liability if they choose to mandate an unapproved vaccine.

Under federal law it is illegal to discriminate against someone who is disabled or due to their religious beliefs. The standards differ between these two forms of discrimination and the religious exemption is [arguably] substantially stronger. As I think through the relevant law and precedent I believe it is likely that an employer that choose to discriminate against someone that refused the vaccine for religious or medical reasons would lose a case brought in defense of such a plaintiff.

I also think there is a substantial risk of liability for an employer that mandates these experimental vaccines for people without religious or medical exemptions. Ultimately these vaccines are truly experimental and so there is risk involved with taking them. The long term effects of the drugs have not been studied and neither has their safety in a number of cohorts such as pregnant women (I am unsure if any such studies have been completed recently for that cohort). As such, if an employer coerces an employee into taking these vaccines and they are injured it is possible the employer would be liable. Worse for the employer, since the manufacturers are immune to liability the entire claim would fall on the employer.

Ultimately, I believe it is plainly illegal for a government entity to mandate this vaccine, probably illegal for a private employer to mandate the vaccine, and definitely extremely risky for a private employer to attempt to mandate it.

Finally, people should know their rights. This article is not meant to provide legal advice about any specific situation and only reflects the opinion of the author. That said, you should not be intimidated or forced into taking an unapproved vaccine. If, after giving a fully informed consent, you choose to take the COVID vaccine that is fine, but you must be given the information about the risks and alternatives before you are able to offer informed consent. If anyone is pushing an alternative narrative, you should be talking to your attorney.