

On December 11, 2020 and December 18, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer and Moderna vaccines. As of January 22, 2021, there are **no FDA approved Biologics License Application (BLA) vaccines** for the **treatment** of COVID-19.

CAN A VACCINE AUTHORIZED FOR USE UNDER AN EUA BE MANDATED*?

- Per the OSHA Defense Report published on November 19, 2020, any vaccine brought to market under an EUA lacks long-term safety data (1). Therefore, an employer can require employees to receive the COVID-19 vaccine but they must allow the employee to opt-out.
- Per the Food, Drug, and Cosmetics Act-21 U.S.C, (2). the HHS Secretary is to “establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
 - (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—
 - (iii) 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.
- Vaccine mandates under an EUA are considered ethically and legally problematic as the EUA requires less safety and efficacy data for vaccines than is required for full Biologics License Application (BLA) approval. (3)

IF THE COVID VACCINE IS MANDATED IN YOUR WORKPLACE AFTER BIOLOGICS LICENSE APPLICATION (BLA) APPROVAL, WHAT ARE YOUR OPTIONS?

- Per the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964**, employers are legally required to provide a reasonable alternative to employees with certain medical conditions or with sincerely held religious beliefs, practices, or observances that prevent them from taking the COVID-19 vaccination (4,5). Under the current circumstances, reasonable alternatives include masking, social distancing, remote work options, or working separated from others.
- Per the Equal Employment Opportunity Commission (EEOC)***, an employer cannot exclude an employee from a job based on a disability or religious objection if there is a way to provide a reasonable accommodation (6,7,8).
- The United States Court of Appeals for Third Circuit affirmed that a history of allergies and/or anxiety related to vaccination or its possible side effects qualified as an ADA-covered disability (9).
- Employees cannot object to a COVID-19 vaccination based on secular or conscientious grounds. A requirement to belong to an “organized religion or church” is not required, but an employee must prove that their beliefs are “held with a sincerity equating to that of traditional religious views”.

WHAT IF YOU ARE DENIED A RELIGIOUS EXEMPTION?

New Jersey Coalition For VACCINATION CHOICE

- If an employee is denied a religious exemption to a COVID-19 vaccination once it is approved as a BLA, the employee must file a charge with the EEOC. (If assistance is needed in filing such a claim, please contact NJCVC at NJCVCHhealthcare@gmail.com)

MORE ABOUT EUA AND BLA

- Emergency Use Authorization (EUA) means that Department of Health and Human Services Secretary Alex Azar concluded that COVID-19 is a serious or life-threatening disease; that it is reasonable to believe that the vaccine **may** be effective in preventing the disease; that the known and **potential** benefits of the vaccine outweigh the known and **unknown** risks; and that there is no adequate, approved, and available alternative. (10)
- An EUA allows vaccines to be used **before** full FDA approval, that is during the time that COVID-19 is considered an emergency. (11).
- Vaccines are biological agents that are typically approved and regulated by the FDA Center for Biologics Evaluation and Research under a Biologics License Application (BLA). For the vaccine to be approved, the FDA must decide that it is **both safe and effective** after a typically lengthy period where lab data and trial results are extensively reviewed. (12)

*An EUA approved vaccine is only weeks old and the body of law surrounding its use and application may continue to shift.

*Title VII of the 1964 Civil Rights Act applies to employers with 15 or more employees and prohibits many kinds of workplace discrimination, including discrimination based on religion. As a federal statute, Title VII supersedes conflicting state law. The Civil Rights Act requires that an employer must accommodate sincerely held religious practices “if the religious practice does not impose an undue hardship on the employer”.

**The EEOC is a federal agency that enforces civil rights laws against workplace discrimination. This commission has supported employees when their employer has refused a religious exemption.

References:

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