FDA Does a Bait and Switch with COVID Shots

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WASHINGTON, D.C. – The Food and Drug Administration (FDA) has done a bait and switch by announcing it approved its "first COVID-19 vaccine" in order to push the "vaccine" mandates and protect the Pfizer pharmaceutical company from legal liability. However, there is currently no fully licensed COVID shot on the United States market.

Albeit confusing, and probably intentionally so, this summarizes the current status of the Pfizer-BioNTech shots:

1. All existing Pfizer vials (in the hundreds of millions), remain under the federal Emergency Use Authorization (EUA) (meaning people have the "option to accept or refuse");
2. The third or "booster" Pfizer shot is identical to the above and remains under the EUA with limited use to certain categories of people;
3. BioNTech received FDA approval for people ages 16 and above under the name Comirnaty, but there are no Comirnaty doses available in the United States;
4. **In other words, there is currently NO FDA approved COVID-19 injection available anywhere in the United States**. Every COVID shot in America remains under the EUA law and thus people have the "option to accept or refuse" them; and
5. Even when an FDA approved COVID shot becomes available, individuals are protected by federal law and many states laws from being forced to get these shots based on their sincere religious beliefs or conscience rights.

On August 23, the FDA issued two separate letters for two separate injections. There are now two legally distinct (Pfizer vs. BioNTech), but otherwise identical products.

The first letter is regarding FDA's biologics license application approval for the Pfizer Inc/BioNTech COVID-19 injection which has been named Comirnaty. Yet Pfizer has not started manufacturing or labeling this drug for U.S. distribution, so it is not even available in the U.S. It is unclear whether or not it is protected by a liability shield, but web-based U.S. government communication indicates that the same program that provides compensation for COVID vaccine-related injuries will apply Countermeasures Injury Compensation Program (CICP) rather than the National Vaccine Injury Compensation Program). At this point, there apparently has been no compensation paid to people injured by one of the COVID shots via the CICP.

The Pfizer injection, on the other hand, is still considered experimental under U.S. law. There is a legal difference between products approved under authorization of emergency use (EAU) compared with those the FDA has fully licensed. The FDA issued another letter for the existing Pfizer shots which confirms they are still under EUA, are not fully approved, and has a liability shield.

EUA-approved COVID shots have a liability shield under the 2005 Public Readiness and Preparedness Act. Vaccine manufacturers, distributors, providers and government planners are immune from liability. People who have been injured can file a lawsuit if they can prove willful misconduct, and if the U.S. government has also brought an enforcement action against the party for willful misconduct. No such lawsuit has ever succeeded.

That means people must be told the risks and benefits, and they have the right to decline a medication that is not fully licensed. The federal Emergency Use Authorization law and the FDA, including the FDA Fact Sheet, state unequivocally that each person has the "option to accept or refuse" the shots. In addition to federal law, the FDA includes the Nuremberg Code and the Helsinki Declaration on its website, emphasizing the fact that people cannot be forced to take experimental drugs without their full consent.

The FDA's approval letter to Pfizer regarding the BioNTech injection, Comirnaty, states: "Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older."

This letter affirms the FDA has not approved the Pfizer/BioNTech injections for the 12- to 15-year age group, nor any booster doses for anyone.

Regarding the Comirnaty injection, the FDA admits, "We have determined that an analysis of spontaneous post marketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis."

Therefore, follow up studies will be required with children six months to 15 years as well as six studies for up to five years regarding the adverse effects of myocarditis and pericarditis.

In addition, the FDA bypassed and disregarded the normal advisory committee and public comment process for this license.

The letter states, "We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, ***did not raise concerns or controversial issues that would have benefited from an advisory committee discussion***" (emphasis added).

The FDA also acknowledges that while Pfizer-BioNTech has "insufficient supplies" (in other words, it is not currently available on the U.S. market) of the newly licensed Comirnaty vaccine actually available. However, **the letter also states there is "a significant amount" of the Pfizer-BioNTech shots which has been produced under the EUA and will continue to be offered under the same EUA status. In its approval letter, the FDA specifies the Pfizer shot under the EUA should remain unlicensed, is still available for use, and can be used "interchangeably" with the newly licensed Comirnaty product.** According to the FDA, the newly licensed Comirnaty injection and the existing Pfizer shot, while "legally distinct," are not any different in terms of their "safety or effectiveness."

Despite whether these COVID shots are licensed or not, they cannot be mandatory under Title VII. In general, employee vaccine religious exemption requests must be accommodated, where a reasonable accommodation exists without undue hardship to the employer, pursuant to Title VII of the Civil Rights Act of 1964. Many people hold sincere religious beliefs against taking the COVID shots or taking those derived from or which used at any stage of the development aborted fetal cell lines.

Title VII defines the protected category of religion to include "all aspects of religious observance and practice, as well as belief." 42 U.S.C. § 2000e(j). Moreover, as the EEOC has made clear, Title VII's protections also extend nonreligious beliefs if related to morality, ultimate ideas about life, purpose, and death. See EEOC, Questions and Answers: Religious Discrimination in the Workplace (June 7, 2008), ("Title VII's protections also extend to those who are discriminated against or need accommodation because they profess no religious beliefs…Religious beliefs include theistic beliefs, i.e. those that include a belief in God as well as non-theistic 'moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views.' Although courts generally resolve doubts about particular beliefs in favor of finding that they are religious, beliefs are not protected merely because they are strongly

held. Rather, religion typically concerns 'ultimate ideas' about 'life, purpose, and death'").

Liberty Counsel Founder and Chairman Mat Staver said, "The FDA has apparently tried to deceive people by issuing its two confusing letters without proper explanation. Despite the FDA's sleight of hand, there is currently no FDA approved COVID shot available in the United States. Even if there were an FDA approved COVID shot available, people still may request that employers, schools, and the military accommodate their sincerely held religious beliefs."

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