FDA's Pfizer Documents Expose Major Discrepancies With COVID Narrative, Possible Fraud

How do we get information about the vaccines we take?

We get it from our doctors, our friends and the media. We hear experts like Dr. Anthony Fauci and Dr. Rochelle Walensky talk about them.

We see advertisements for the COVID-19 vaccines. And we see COVID vaccines in the news, day in and day out.

On the other hand, there exist official, legal documents that lay out precisely what the evidence showed when decisions were made to issue an Emergency Use Authorization (EUA) for the Pfizer-BioNTech vaccine, and a license for Pfizer's Comirnaty vaccine.

These documents tell us what information Pfizer and the U.S. Food and Drug Administration (FDA) are willing to stand by.

The documents also establish the legal requirements for issuing the EUA and license for Pfizer's vaccines.

It may come as a shock, but what the FDA said when it issued both the EUA and the license for Pfizer's vaccines was very different from what you heard from the Centers for Disease Control and Prevention (CDC), the media and other sources.

Messaging around vaccine safety in pregnancy conflicts with what is known

For example, the CDC strongly encourages vaccination during pregnancy, although as late as December 2021, the FDA and Pfizer claimed the information available was inadequate to determine risk in pregnancy.

Here is the precise language on the Comirnaty label:

"Available data on Comirnaty administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."

That is a pretty clear "We don't know."

Yet here is CDC Director Walensky assuring us the vaccine poses no health risks with regard to pregnancy or fertility:

Five months later, in October 2021, her message is the same:

In August 2021, when the Comirnaty license was issued, Fauci, director of the National Institute of Allergy and Infectious

Diseases, confirmed vaccination in pregnancy is safe:

Here are the talking points provided by the American College of Obstetricians and Gynecologists (ACOG) to obstetricians and gynecologists on how to convince women to be vaccinated, even during the earliest stages of pregnancy, when risks from most drugs and vaccines are highest.

One of ACOG's "key recommendations is:

"Vaccination may occur in any trimester, and emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health."

Yet the CDC, in its own Jan. 7 Morbidity and Mortality Weekly Report, stated there was insufficient data to make any determination of COVID vaccine safety in the first trimester.

So, while the federal agencies had no reason to believe the vaccine was safe in pregnancy, and made sure their legal documents said so, they nonetheless advertised the vaccine as safe for pregnant women.

Then ACOG, a nonprofit professional organization of obstetricians, not only provided their members with false information on vaccine safety, but furthermore instructed them on the use of propaganda to convince expectant mothers to take the shot.

CDC guidance contradicts Comirnaty label

The CDC guidance in some instances is inconsistent with statements on the label, or package insert, for Pfizer's Comirnaty vaccine.

The label, a legal document, was last updated on Dec. 20, 2021.

Here are three examples of inconsistency:

1. The CDC made the false claim on its website that anaphylactic reactions occur at approximately the same rates after COVID vaccines as after other vaccines. (I just looked for the citation and see the claim was removed).
   Now, CDC informs us that "safeguards are in place" in case you do develop anaphylaxis after a COVID shot.

   The Comirnaty label and CDC website make plain that administration of the vaccine is limited to only those facilities able to medically manage anaphylactic reactions.

   A March 2021 study, led by Dr. Kimberly G. Blumenthal of Massachusetts General Hospital (where Walensky was chief of Infectious Diseases until January 2021) showed the rate of anaphylaxis among employees of Mass General Brigham after COVID vaccination, using standard criteria, was about 50-100 times higher than the rate claimed by CDC, which was equivalent to the rate calculated by the Vaccine Adverse Event Reporting System (in which underreporting by a factor of 10 to 100 is believed to occur).

   I wrote about this in The Defender in January 2021, revealing how the CDC used inappropriate and inadequate data to derive such a low rate.

2. While the CDC website suggests episodes of myocarditis are mild and resolve quickly, the Comirnaty label plainly states:
   "Information is not yet available about potential long-term sequelae [an aftereffect of a disease, condition or injury, or secondary result]."

3. Vaccine makers, health authorities and others claim COMIRNATY and other COVID vaccines could not possibly cause or stimulate cancer or cause fertility problems. What does the label say?
   "COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility."

Early messaging did not reflect FDA's EUA review

Around the time the FDA granted EUA for the Pfizer vaccine — at warp speed — on Dec. 11, 2020, the FDA issued an EUA review memorandum.

Although people who had already had COVID were encouraged and sometimes forced to be vaccinated, the memorandum states "very few cases of confirmed COVID-19 occurred" among the 3% of clinical trial participants who had evidence of prior infection.

"However, available data are insufficient to determine whether such individuals could benefit from vaccination," the FDA memorandum stated.

Although the FDA on Dec. 10, 2020, gave Pfizer authorization (an EUA) to vaccinate everyone age 16 and up, the FDA document points out, "only one confirmed COVID-19 case was reported" in the 16- to 17-year-old age group.

In other words, there were no data to support efficacy in this age group. No wonder four members of the FDA advisory committee voted no, and one abstained from supporting authorization.

My suspicion is that authorization of the vaccine for 16- and 17-year-olds was needed in order to put COVID vaccines on

CDC's recommended childhood schedule despite lack of supporting data, so the FDA pushed it through.

And sure enough, the CDC advisory committee on Aug. 30, 2021, voted 13-1 in favor of putting the vaccine on the childhood schedule. This will provide it a different form of liability protection, and open the door to mandating the vaccines for school attendance.

However, I just searched and did not find evidence that the vaccine was subsequently added to the childhood schedule. Very interesting.

Pfizer not required to test vaccine for asymptomatic infection

Even though the specter of asymptomatic infections drove masks, social distancing, school closures, working from home, etc., the FDA did not require Pfizer to test its vaccine to see if it prevented asymptomatic infection.

The FDA memorandum states:

"Data are limited to assess the effect of the vaccine against asymptomatic infection …."

Yet the entire point of vaccinating to achieve herd immunity, allegedly, was to prevent spread from person to person.

How is it possible neither the FDA nor Pfizer sought out evidence that the vaccine prevented transmission?

The FDA states:

"Data are limited to assess the effects of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination."

Risk of vaccine-enhanced disease remains ‘unknown’

The biggest concern of scientists everywhere, including Fauci, was the potential for the vaccine to cause antibody-dependant enhancement, a problem that had occurred occasionally with new vaccines and had occurred with a coronavirus vaccine prototype.

However, Pfizer did not test its vaccine for the risk of vaccine-enhanced disease.

The FDA memorandum stated:

“Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and or licensure.”

Pay close attention to this language. First, the FDA notes that the risk of the vaccine causing worse disease “needs to be evaluated further.” “Needs” means it is necessary.

But just one line farther down, FDA states studies to do so “could” be conducted later, letting Pfizer and itself off the hook for conducting any of these “needed” trials and studies.

The bottom line is that the CDC, FDA and National Institutes of Health have not been working to protect the public during the COVID pandemic, but instead to protect themselves (in the case of the FDA) and to broadcast false information to the public regarding vaccine safety (in the case of the NIH and CDC).

Do these lies rise to the level of fraud?

Watch my interview today with James Lyons-Weiler to learn more:

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