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# Pfizer's Own Informed Consent Documents Undermine FDA and CDC's Cries of "Safe and Effective"

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Mar 22, 2022, 20:05ET



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UPDATE





Pfizer's own informed consent documents, recently obtained by ICAN, show it discloses potential concerns, including myocarditis, original antigenic sin, and birth defects, while the FDA & CDC whitewash these concerns to declare these products are safe and effective.

ICAN has now obtained the materials used by the Cincinnati's Children's Hospital in conducting its studies of the Pfizer booster vaccine, including in children. The documents prepared in consultation with Pfizer tell us a lot about how Pfizer understands the risks of its products.

Pfizer is clearly worried about the risks of **myocarditis (heart inflammation)** in kids. Pfizer's own informed **consent documents** reveal that the risk of myocarditis may be as high as 1 in 1,000 (see page 4).

But the FDA and CDC blithely ignored this risk in approving the Pfizer mRNA shot in kids. Only *after* rushing this product through the approval process did the CDC begrudgingly admit that "Myocarditis and pericarditis have rarely been reported, especially in adolescents and young adult males within several days after COVID-19 vaccination."

Pfizer is also aware of the possibility of **original antigenic sin and pathogenic priming** (unwanted immune responses that leave one worse off in response to a virus than if one had done nothing). Pfizer warns parents of clinical trial participants that "it cannot yet be ruled out that the study vaccine could make a later COVID-19 illness **more severe**"

(emphasis added). The FDA and CDC go to great lengths to hide that information while proclaiming "safe and effective" over and over again like a mantra.

Pfizer appears very worried about the potential of the **teratogenesis** (harm to a developing fetus) and even possibly **mutagenesis** (harm to DNA). So even though this is a trial in *children*, Pfizer disclosed to the parents of these children that "the effects of the COVID-19 vaccine on sperm, a pregnancy, a fetus, or a nursing child are not known."

But then Pfizer goes even further to **state** that:

- "If your daughter is pregnant, planning to become pregnant or is breast feeding a baby, she cannot be in the study as there may be risks to the unborn baby or nursing baby. Nobody knows what these risks are right now."
- "If your daughter becomes pregnant, she will have to leave the study."
- "If your child is a boy, and he thinks he may have gotten a girl pregnant, he or you must tell your child's study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study."
- "If your son is taking part in this study, he is not allowed to donate sperm for at least 28 days after his last vaccination."

Let's just pause to acknowledge just how deeply unsettling this language is. But it just goes to show that Pfizer wanted to make sure that they had no data at all on pregnancy outcomes.

Given that, the CDC's **recommendation** to pregnant women to get vaccinated is scientifically unsound to say the least.



Compare these two statements:

"Accumulating data provide evidence of both the safety and effectiveness of COVID-19 vaccination in pregnancy." – CDC

"Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy." – BioNTech/Pfizer

The FDA and CDC have a job to do – evaluate the evidence without bias to keep the public safe. Instead, the FDA and CDC have turned themselves into a marketing department on behalf of the pharmaceutical industry. The American people deserve better than this.

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