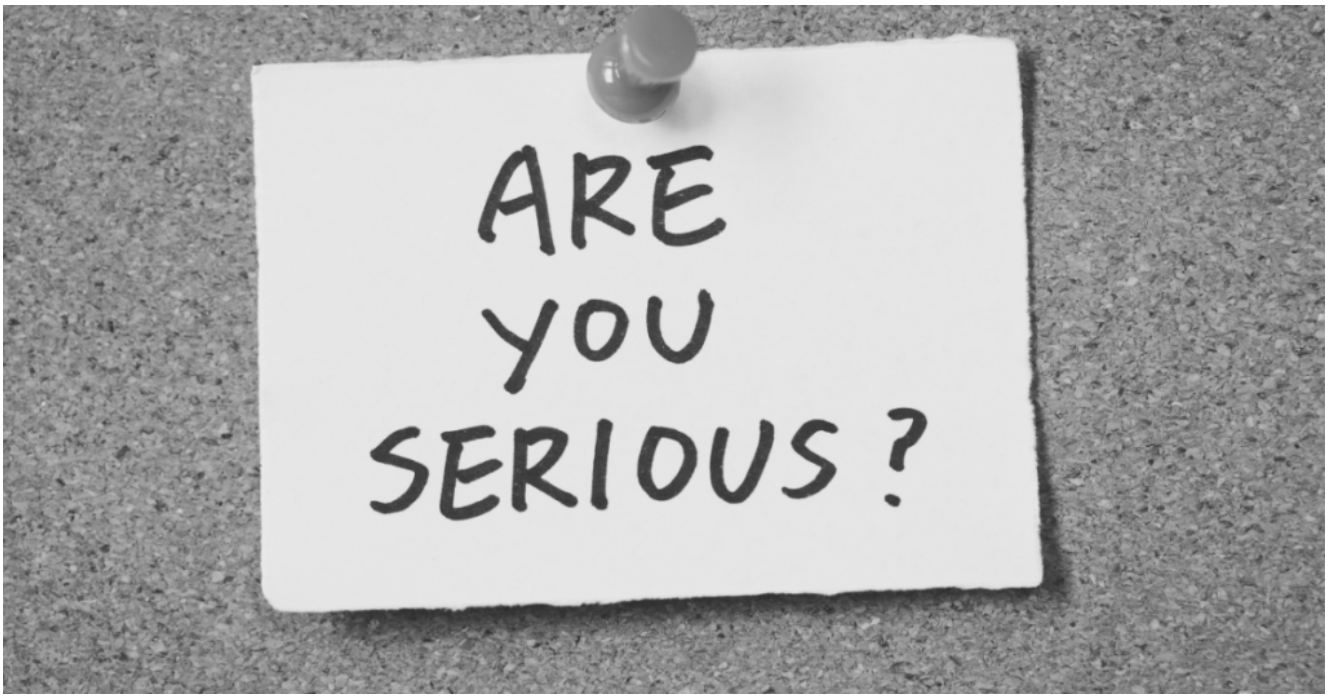
FDA Plans to Base Authorization of New COVID Boosters on Studies of Mice, Not Humans



The U.S. Food and Drug Administration (FDA) has officially lost its mind. The agency has adopted a controversial strategy to evaluate the new bivalent Omicron COVID-19 boosters scheduled to be rolled out in September.

The FDA has decided it will base its decision on whether to authorize the new boosters – developed just five minutes ago – on studies involving mice instead of humans.

It might be important to mention that mouse experiments are "notoriously unreliable."

"For the FDA to rely on mouse data is just bizarre, in my opinion," John Moore, an immunologist at Weill Cornell Medicine in New York told NPR. "Mouse data are not going to be predictive in any way of what you would see in humans."

Of course, the fine people at the FDA who clearly care nothing about public health justified cutting corners because "500 people a day [who probably have underlying conditions and just so happen to have COVID] are dying of coronavirus right now."

"Those numbers sadly might very well rise in the fall and the winter. The question is: 'Can we do something better?'" said Dr. Ofer Levy, a pediatrician at Harvard Medical School who advises the FDA. "And I think the answer is: 'We can, by implementing this approach.'"

Of course, you know Pfizer and Moderna have to be "all in" on this strategy. If studies were to be conducted properly . . . in actual humans . . . their teenage mutant ninja boosters would never be authorized.

They might as well have performed these studies in cats, goats or bears. What does it matter at this point? Science is dead and nobody cares about the fact that far more people are probably dying right now from the shots than the virus. Does anyone know how many "mice" got myocarditis from the modified jab, or will this not be disclosed to us until we file lawsuits or the FDA decides that in 75 years we can have that data?

According to the NPR, regulators will rely both on the results of mice studies and human neutralizing antibody data from the BA.1 bivalent booster studies to decide whether to authorize modified boosters. This should put our minds at ease, right?

Wrong. This was a significant point of contention during a recent meeting of the FDA's vaccine advisory panel (the Vaccines and Related Biological Products Advisory Committee) where it was specifically stated and acknowledged that using human neutralizing antibody data is in no way predictive of actual immunity.

In other words, they cannot claim this vaccine (gene therapy) "works" or "prevents severe disease or death" based on whether

it gives someone a temporary boost in antibody levels. This is the standard by which all other COVID vaccines have been deemed "effective" – and we wouldn't even be talking about modified boosters if they worked.

In addition, it should be noted that BA.1 is a different variant than what is in the new Omicron boosters – which will contain the original strain and BA.4 and BA.5 Omicron subvariants.

Literally, they are going to roll this out with no clinical trials, no human studies and based on human neutralizing antibody data from a COVID-19 vaccine that contains a different variant.

"We need to make sure that we have solid immunogenicity data in people to show that you have a dramatically greater neutralizing antibody response against BA.4, BA.5," said Dr. Paul Offit, pediatrician and advisor to the FDA. "I think anything short of that is not acceptable."

Pfizer and Moderna claim they will continue to gather more data from human studies, but the results of those studies won't be available until several months after the new booster is authorized and rolled out.

This is kind of a "roll this out now and apologize for the people it harms later" kind of scenario. Then, these pharmaceutical companies can claim immunity from liability due to an "emergency" that we all know does not exist.

Moderna reportedly submitted its application to the FDA for emergency use authorization (EUA) of its updated COVID booster for use in people age 18 and older on Tuesday. Pfizer and BioNTech submitted their application for EUA of their updated COVID booster for people aged 12 and older on Monday.

It's a good thing we still have an "emergency declaration" that allows these companies to cut corners and regulatory

agencies to sign off on experimental products that are killing and harming tens of thousands of people.

Meanwhile, the rest of us should do our best to separate ourselves from the cognitive dissonance of this sector of the "scientific community" and lawyer up. It's going to be a battle, especially for those in government jobs, the military and healthcare industry who will no doubt be forced to engage in this next level of experimentation.