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If It's Okay for Mice, It's Good Enough for People, Right?

The U.S. Food and Drug Administration appears set to circumvent its own regulatory process in order to authorize Pfizer's new bivalent COVID-19 vaccine that targets the Omicron BA.4 and BA.5 subvariants — without requiring clinical trials on humans.

By Madhava Setty, M.D.

Its audacity on full display, Pfizer — arguably the most criminal corporation in history — has asked the U.S. Food and Drug Administration (FDA) to greenlight its new bivalent COVID-19 vaccine that targets the Omicron BA.4 and BA.5 subvariants for people 12 and older "to help the country prepare for potential fall and winter surges of the coronavirus," Pfizer CEO Albert Bourla said in a statement.

Bourla's good intentions are sadly thwarted by FDA regulations that require an Investigational New Drug (IND) application be submitted and approved before a drug can be tested in humans.

Luckily, the FDA can circumvent the inconvenience of its own regulatory processes by allowing itself the ability "to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR, Sec. 312.23 or Sec. 312.20."

Section 312.20 of the Code of Federal Regulations specifies that a clinical investigation cannot commence until an IND application has been submitted and approved. Nevertheless, Pfizer on Monday submitted an IND for its new formulation.

Now that the FDA and Pfizer have crossed their Ts and dotted their Is to make sure all the rules are followed, how do we know these products are safe and will work?

This is where the rodents come in — the products seem to work on mice.

As NPR reported, "For the first time, the FDA is planning to base its decision about whether to authorize new boosters on studies involving mice instead of humans."

Yes, it's an unprecedented move by the FDA, but Dr. Ofer Levy, professor of pediatrics at Harvard and advisor to the FDA argues that the country has had enough experience with the vaccines at this point to be confident the shots are safe and that there's not enough time to wait for data from human studies.

He has a point. There were still only 30,479 uninvestigated deaths reported in VAERS after administration of the shots as of Aug. 19.

In any case, why should the FDA be concerned with such things as human studies in the first place?

This maneuver by the FDA may finally unshackle the agency from its overly restrictive responsibility to fulfill its own mission and become more agile in bringing products to market.

Not to be left behind, Moderna also requested the FDA authorize its bivalent vaccine for human beings over the age of 17.

Similar to the Pfizer vaccine, Moderna's vaccine also, for good measure, will encode for the spike protein for the original ancestral SARS-CoV-2 strain, which for all intents and purposes, does not exist on our planet any longer.

Meryl Nass, M.D., summarized it this way:

> "No clinical trials. (You need to obtain an IND before you can start testing the vaccine in humans. Pfizer applied 4 days ago.)"

Taking no chances, the FDA will not convene the Vaccines and Related Biological Products Advisory Committee (just like the first time the FDA authorized boosters) and has announced this today to see how much opposition the agency gets.

Can we dispense with the pretense any of this is about health?

No sane person vaccinates the entire country with an experimental vaccine without trials — particularly since the whole country already has some immunity, the virulence is low and the evidence supports higher all-cause mortality with an increasing number of vaccine doses.

What is in the vaccine that they are desperate to inject us with?

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.

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