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Fifth COVID Shot Recommended Without Safety or Efficacy Data

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The emergency authorizations of Pfizer's and Moderna's bivalent COVID boosters are based on preliminary test results from a grand total of eight mice, and that data hasn't even been made public

Based on the antibody response in eight mice, the Biden administration has ordered 171 million doses of the two boosters

A reanalysis of data from the Pfizer and Moderna COVID vaccine trials found that, combined, the jabs were associated with a risk increase of serious adverse events of special interest at a rate of 12.5 per 10,000 vaccinated. Meanwhile, the risk reduction for COVID-19 hospitalization was only 2.3 per 10,000 participants for Pfizer and 6.4 per 10,000 for Moderna

According to a recent risk-benefit analysis of a third booster for university students, for each COVID hospitalization prevented, the booster will cause 18 to 98 serious adverse events

A number of top officials with the FDA, CDC and the NIH reportedly have serious concerns about the direction we're going in, yet are too afraid to speak out or push back

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August 31, 2022, the U.S. Food and Drug Administration authorized the reformulated COVID bivalent booster shots by Moderna and Pfizer1 — all without the required convening of its Vaccines and Related Biological Products Advisory Committee (VRBPAC), which would typically discuss or vote on the authorization or approval of a new vaccine.

Instead, the FDA pushed the matter before the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). ACIP met for eight hours September

1, 2022, and authorized the untested boosters 13-to-1.2 3 CDC director Dr. Rochelle Walensky endorsed the recommendation later that evening.

Pfizer's new booster, authorized for people age 12 and older, is a bivalent injection targeting Omicron subvariants BA.4 and BA.5, which are the two currently in circulation.

Moderna's shot, authorized for adults only, aged 18 and older, targets the already extinct Wuhan strain and Omicron subvariant BA.1.4 The two bivalent boosters is only be available to those who have already received the primary two-dose series and/or a monovalent booster at least two months ago.5

Safety and Efficacy Assumed Based on Mouse Data

As explained in "What They're Not Telling You About the New mRNA Boosters," the emergency authorization of these reformulated boosters is based on nothing more than preliminary test results from a grand total of eight mice,6 and that data hasn't even been released to the public.

In an August 30, 2022, article, Science explained the makeup of the reformulated boosters:7

> "Both the Pfizer-BioNTech collaboration and Moderna make their vaccines from messenger RNA (mRNA) coding for the spike protein of SARS-CoV-2. The new vaccines are bivalent.
>
> Half of the mRNA codes for the spike protein of the ancestral virus strain that emerged in Wuhan, China, in late 2019, which is also in the original shots; the other half codes for the spike protein in BA.1 or the one in BA.4 and BA.5, which have identical spikes …
>
> For the BA.4/BA.5 boosters, the companies have submitted animal data. They have not released those data publicly, although at the June FDA meeting, Pfizer presented preliminary findings in eight mice given BA.4/BA.5 vaccines as their third dose.
>
> Compared with the mice that received the original vaccine as a booster, the animals showed an increased response to all Omicron variants tested: BA.1, BA.2, BA.2.12.1, BA.4, and BA.5.
>
> The companies say clinical trials for the BA.4/BA.5 vaccines will begin next month [i.e. September 2022]; they need clinical data both for full approval of the vaccines — their recent submissions are only for emergency use authorization — and to help develop future updates.
>
> Presumably they will measure recipients' antibody levels, but not the vaccine's efficacy against infection or severe disease. Such trials are very expensive and were not done for the BA.1 shot either."

FDA and CDC Rely on Assumptions, Not Actual Data

A key take-home here is that efficacy against infection and severe disease has NEVER been ascertained. Those trials were not done for the original shot, and won't be done for the reformulated boosters. Yet the efficacy of these boosters is assumed and declared as having been "proven" based on the original trials.

Talk about a circular argument! It's just assumptions piled upon assumptions. Yet, based on the antibody response in eight mice alone, the Biden administration has now ordered 171 million doses of the two boosters.

Let's not forget that the mice actually did get infected with Omicron,8 although we don't know to what degree, since they haven't released the data. For all we know, the mice may have had a good antibody response, got sick and then dropped dead.

What's more, the monovalent Pfizer booster authorized for children aged 5 to 11, back in May 2022, was based on the antibody levels of just 67 children.9 So, when the FDA claims the original human trials were exhaustive and have conclusively proven the shots are both safe and effective, they're flat out lying.

In addition to apparent fraud being committed, and the fact that they eliminated the placebo groups midway, those human trials won't even be finalized for another two years or so, as all clinical trials require follow-up.

All we have are preliminary analyses, and FOIA released documents clearly show Pfizer has been less than transparent about adverse effects, as they mislabeled and dismissed almost all of them.

A reanalysis10 of data from the Pfizer and Moderna COVID vaccine trials found that, combined, Pfizer and Moderna mRNA COVID-19 jabs were actually associated with a risk increase of serious adverse events of special interest of 12.5 per 10,000 vaccinated. Meanwhile, the risk reduction for COVID-19 hospitalization was only 2.3 per 10,000 participants for Pfizer and 6.4 per 10,000 for Moderna. So, again, the risk-benefit is crazy lopsided AGAINST the shots.

Repeat Boosting Can Destroy Your Immune Function

Aside from the risk of immediate adverse effects of these experimental gene transfer injections, there's also the issue of immune destruction through repeat exposure. A number of scientists have warned that repeated injections appear to be breaking down people's immune systems. As noted by independent journalist Rav Avora:11

> "The European Medicines Agency has warned12 against the potential adverse immunological effects of repeated boosting every four months.
>
> As Dr. Marty Makary from Johns Hopkins has noted,13 recent research shows a 'reduced immune response against the Omicron strain among people previously infected who then received three COVID vaccine doses compared to a control group that previously had COVID and did not have multiple shots.'
>
> It is just impossible to overstate the unconditional absurdity of the FDA and CDC decision. Not only is the booster merely available to the public … but it is recommended by the state for everyone, including children and teenagers — those with least to gain and most to lose."

Indeed, the population most likely to be mandated to take a bivalent booster are students, and according to a recent risk-benefit analysis,14 which assessed the impact of booster mandates for university students, between 22,000 and 30,000 previously uninfected students (aged 18 to 29) must be boosted to prevent a single COVID-19 hospitalization.

And, for each COVID-related hospitalization prevented, the booster will cause 18 to 98 serious adverse events, including 1.7 to 3 "booster-associated myocarditis cases in males," plus another 1,373 to 3,234 cases of "grade ≥3 reactogenicity which interferes with daily activities."

In short, mandating a third COVID shot for university students will result in a net expected harm of massive proportions, which is completely unethical. Anyone who cannot compute that 18 to 98 serious injuries plus another 3,000+ injuries that are bad enough to interfere with daily living is WORSE than one COVID hospitalization really should not be in a public health position. They belong in a remedial first-grade math class.

Public Health Officials Go Along to Get Along

Sadly, a number of top officials within the FDA, CDC and the National Institutes of Health reportedly have serious concerns about the direction we're going in, yet are too afraid to speak out or push back, so the death toll keeps mounting. In a July 15, 2022, Substack article, Makary and Dr. Tracy Beth Hoeg shared the following:15

> "The calls and text messages are relentless. On the other end are doctors and scientists at the top levels of the NIH, FDA and CDC. They are variously frustrated, exasperated and alarmed about the direction of the agencies to which they have devoted their careers.
>
> 'It's like a horror movie I'm being forced to watch and I can't close my eyes,' one senior FDA official lamented. 'People are getting bad advice and we can't say anything.'
>
> That particular FDA doctor was referring to two recent developments inside the agency. First, how, with no solid clinical data, the agency authorized COVID vaccines for infants and toddlers, including those who already had COVID. And second, the fact that just months before, the FDA bypassed their external experts to authorize booster shots for young children …
>
> At the NIH, doctors and scientists complain to us about low morale and lower staffing: The NIH's Vaccine Research Center has had many of its senior scientists leave over the last year, including the director, deputy director and chief medical officer. 'They have no leadership right now …' one NIH scientist told us …
>
> Another CDC scientist told us: 'I used to be proud to tell people I work at the CDC. Now I'm embarrassed.' Why are they embarrassed? In short, bad science. The longer answer: that the heads of their agencies are using weak or flawed data to make critically important public health decisions … And that they have a myopic focus on one virus instead of overall health …
>
> An official at the FDA put it this way: 'I can't tell you how many people at the FDA have told me, 'I don't like any of this, but I just need to make it to my retirement.'"

Even Dr. Paul Offit, one of the most prominent pro-vaccine propagandists in U.S. history and a member of the FDA's VRBPAC, has the common sense to question the sanity of rolling out untested shots to millions of people. In late August 2022, just two days before the FDA authorized the two bivalent boosters, he told the Wall Street Journal:16

> "I'm uncomfortable that we would move forward — that we would give millions or tens

of millions of doses to people — based on mouse data."

Why Is FDA Making Unsubstantiated Claims in Ads?

The FDA is also advertising the COVID shots — and making bizarre unscientific claims in those ads. Here are two recent COVID booster campaign messages tweeted out by the FDA:

> "It's time to install that update! #UpdateYourAntibodies with a new #COVID19 booster."17"Don't be shocked! You can now #RechargeYourImmunity with an updated #COVID19 booster."18

By law, the FDA should not engage in the advertising of drugs — historically, they've never even worked with drug companies to create ads19 — and the agency certainly should not put out false and misleading claims about drugs, as this is illegal. So, why are they doing both? As reported by Tablet magazine:20

> "The continuation of unchecked conflicts of interest, and several recent authorizations for uses of new medical products that are in many ways unproven, demonstrate that the FDA is essentially unresponsive to public outrage, culminating in the bizarre spectacle of … promoting bivalent boosters on social media through unsubstantiated claims …
>
> [A]cting not as a neutral regulator but actively advertising on behalf of pharmaceutical companies with government purchase contracts. The FDA's disregard for its congressional mandate is not unique to this moment — it is a symptom of its decadeslong transformation into an agency captured by the corporations it is tasked with regulating."

Why Is FDA Ignoring Red Flags?

Tablet magazine also highlights the FDA's now-consistent disregard for safety issues, even when data clearly point to problems. This includes data showing frequent boosters can weaken immune function, and the fact that Pfizer, in its pediatric trial, actually observed a higher rate of severe COVID in the vaccine group than the placebo group.

The FDA also allowed Pfizer to discount 365 symptomatic cases in the pediatric trial and only count 10 cases that occurred after the third dose. This is how they got to 80% efficacy. In reality, however, the efficacy was negative after doses 1 and 2. As noted by Tablet magazine:21

> "In a vaccine meant to prevent illness for an age group that is already at extremely low risk, this data should have been a red flag for the FDA. Why, then, has the body charged with protecting Americans from inadequately tested products been so eager not just to authorize these products for emergency use, but to enthusiastically recommend them?"

Clearly, the fact that 75% of the FDA's funding comes from the drug industry is one factor that contributes to this corruption. Another is the revolving door between the agency and industry, with officials passing back and forth between the two.

A third factor is the financial conflicts of interest of individual officials. Tablet magazine reviews several examples of VRBPAC members receiving hundreds of thousands and even millions of dollars from drug companies, be it in the form of research grants, speakers' fees

or consulting fees.

Recent Studies Demonstrate Insanity of Continuing Boosters

In closing, at least three new studies demonstrate the insanity of continuing down the path of boosters:

1. Japanese researchers have found in vitro evidence of antibody dependent enhancement (ADE) following Moderna's mRNA injection.22 23

2. A preprint study24 posted on bioRxiv in mid-September 2022 found Omicron sublineage BA.2.75.2 is exceptionally good at escaping neutralizing antibodies.

> On average, this sublineage was neutralized fivefold less potently than BA.5, making it the most resistant variant to date. According to the authors, "These data raise concerns that BA.2.75.2 may effectively evade humoral immunity in the population."

3. Another September preprint25 26 27 by Chinese researchers detail how and why SARS-CoV-2 variants are outracing vaccination efforts, and the role played by original antigenic sin.

4. In addition to BA.2.75.2, other variants with impressive immune evading capabilities include BR.1, BJ.1, and BQ.1.1. According to the authors,28 many of the variants now emerging have mutations converging in particular "hotspots" on the receptor binding domain (RBD).

They suspect this convergent evolution is linked to humoral immune imprinting, in other words, the phenomenon of original antigenic sin,29 the end result of which is reduced immunity and an increased risk of symptomatic infection.

If you're up for some, at times, complex scientific jargon, check out coauthor Yunlong Richard Cao's Twitter thread in which he does his best to lay out the findings. Cao explains the convergent RBD evolution as follows:

> "Due to immune imprinting, BA.5 breakthrough infection caused significant reductions of nAb [neutralizing antibody] epitope diversity and increased proportion of non-neutralizing mAbs [monoclonal antibodies], which in turn concentrated immune pressure and promoted the convergent RBD evolution."

The take-home message here is that this convergent RBD evolution — which is making new variants increasingly capable of evading neutralizing antibodies — is the result of a narrow antibody response.

It's a byproduct of "vaccinating" the world during an active outbreak. The end result is that both natural immunity and the COVID jabs are rendered more or less null and void. If that's not reason enough to quit this booster madness, I don't know what is.

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Notes

1 New York Times August 31, 2022 (Archived)

2 Rumble, Friday Roundtable September 2, 2022

3 Pharmacy Practice News September 1, 2022

4 Sky News August 15, 2022

5 FDA August 31, 2022

6 Tablet September 18, 2022

7 Science August 30, 2022

8 Rav Arora Substack September 12, 2022

9 Forbes May 17, 2022

10 SSRN June 23, 2022, Revised September 9, 2022

11 Rav Arora Substack September 12, 2022

12 Bloomberg January 11, 2022

13 Sensible Medicine August 23, 2022

14 SSRN September 12, 2022

15 CommonSense July 15, 2022

16 WSJ August 28, 2022

17 Twitter FDA September 7, 2022

18 Twitter FDA September 9, 2022

19 FDA.gov Drug Advertising Q&A

20 Tablet September 18, 2022

21 Tablet September 18, 2022

22 Scientific Reports 2022; 12 Article number 15612

23 Eugyppius September 19, 2022

24 BioRxiv September 16, 2022 DOI: 10.1101/2022.09.16.508299

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26 Twitter Ulrich Elling September 17, 2022

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29 Journal of Immunology January 15, 2019; 202(2): 335-340

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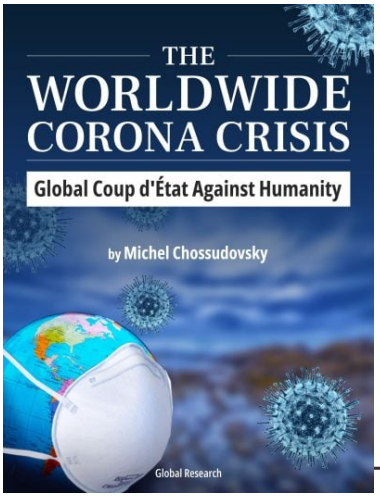

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