FDA and CDC Sign Off on Fourth COVID Vaccine Dose, Bypass Vaccine Advisors

U.S. health agencies on Thursday authorized a fourth round of experimental Moderna and Pfizer/BioNTech COVID shots for 34 million Americans aged 50 and older in what was arguably one of the stupidest and deadliest decisions ever made.

The immunocompromised ages 12 and older will be able to get a fifth COVID vaccine dose as their "second booster."

Both the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) bypassed their "independent vaccine advisors," who were not allowed to make a peep (let alone, vote) about the lack of science or potential safety issues of an additional vaccine dose.

We are just supposed to trust the agency that tried to keep the data it relied upon in approving Pfizer's COVID vaccine a secret for 75 years, who receives a substantial part of its funding from the companies whose products it regulates and who

signed off on a fourth dose based on data bought and paid for by the billion-dollar COVID vaccine manufacturers?

"The evidence considered for authorization of a second booster dose following primary vaccination and first booster dose included safety and immune response information provided to the agency as well as additional information on effectiveness submitted by the companies," the FDA said in a statement.

"No new safety concerns were reported during up to three weeks of follow-up after the second booster dose," the agency added. (They only followed these people for "up to three weeks?" It can take longer than three weeks for blood clots, myocarditis, prion diseases, paralysis, cancers and numerous other conditions to manifest.)

Instead, FDA and CDC vaccine experts are scheduled to meet next week to discuss whether it's safe and effective to authorize the fourth dose the agencies' already authorized. This is the equivalent of a judge rendering a verdict before the lawyers make their arguments.

As if it couldn't get worse, the CDC took the stupidity a step further clearing a second booster dose for all adults "who received a primary vaccine and booster dose of Johnson & Johnson's Janssen COVID-19 vaccine at least 4 months ago."

Yes, those who subjected themselves to an increased risk of blood clots to get the "one and done" shot are now looking at a third dose because the first two didn't work. In addition, these individuals can get an mRNA vaccine as a booster regardless of age.

There's no safety or efficacy data to support these recommendations. They're based purely on the same pseudoscientific woo permeating what has become the world's biggest mass experiment.

"We're hoping that by taking this action, we will help allow

people to take steps to protect themselves should we have another wave that comes through this country," the FDA's top vaccine official, Dr. Peter Marks, told reporters Tuesday.

But what the agency really did, was showcase for all to see that it cares more about politics and profits than it does public health and science.

The FDA's decision wasn't based on U.S. data, but on inadequate non-peer-reviewed data from Israel. The only difference is that U.S. health agencies went a step further and expanded eligibility to age 50 for a fourth dose, which was not assessed in any study.

Both Moderna and Pfizer are developing new versions of their vaccines that may be rolled out later this year. But for now, the new round of boosters will be of the same formulation of previous versions that didn't work.

Marks said getting a second booster now would "not preclude people" from getting another round of shots in the fall if a new version of the vaccine is rolled out, which is nothing short of insanity.

"There may be a need for people to get an additional booster in the fall along with a more general booster campaign if that takes place because we may need to shift over to a different variant coverage," said Marks.

Experts respond to booster news

"There are very few, if any, people who, in my opinion, require a fourth dose," Dr. Anna Durbin, professor of international health and director of the center for immunization research at Johns Hopkins Bloomberg School of Public Health told The Washington Post.

"In general, it's too early to recommend a fourth dose, except for those who are immune-compromised," said Dr. Paul Goepfert,

professor of medicine at the University of Alabama at Birmingham and an expert in vaccine design.

“Unless there’s clear evidence something is of value, don’t give it,” Dr. Paul Offit, director of the Vaccine Education Center at Children’s Hospital of Philadelphia, told ABC News.

“We’re going to have to learn to live with mild disease at some point,” said Offit. Frequent boosting “is not a reasonable thing to do, and it’s not something most people will do anyway.”

Perhaps nobody summed up Tuesday’s events better than Dr. Marty Makary, surgeon and public policy researcher at Johns Hopkins University.

> *Well folks, the answer is a clear "NO". FDA just authorized 4th doses for everyone >50 despite a lack of data that 4th doses reduce hospitalization risk and strong opposition from their own FDA experts—experts who did not get to vote as they normally do before authorizations. https://t.co/CIm9kNcS2G*
>
> *— Marty Makary MD, MPH (@MartyMakary) March 29, 2022*

Makary said in a tweet there is “zero clinical data that a 4th dose reduces hospitalization risk,” let alone, evidence that a third dose reduces the risk in young people.

> *There is zero clinical data that a 4th dose reduces hospitalization risk. There isn't even any evidence that a 3rd dose reduces hospitalization risk in young people.*
>
> *— Marty Makary MD, MPH (@MartyMakary) March 29, 2022*

Even the editor of the New England Journal of Medicine – with notorious conflicts of interests with Pfizer – who serves on the board of the FDA’s vaccine advisory panel said he hadn’t

“seen enough data on fourth doses to make a determination about whether they are needed for anyone beyond those who are already recommended to get them.”

> *The editor of the New Engl Journal, who sits on VRBPAC, has said he "hadn't yet seen enough data on fourth doses to make a determination about whether they are needed for anyone beyond those who are already recommended to get them – adults who are severely immune deficient"*
>
> *— Marty Makary MD, MPH (@MartyMakary) March 29, 2022*

And let’s not forget what happened last fall when the FDA pulled the same shenanigans with the first booster doses. Two high-level FDA officials quit the agency.

> *Political interference over boosters was the issue behind 2 high-level FDA departures in the fall. There is no greater slap in the face of science than bypassing the customary FDA external expert voting process over an authorization with insufficient supporting clinical data.*
>
> *— Marty Makary MD, MPH (@MartyMakary) March 29, 2022*

Makary called on the new FDA commissioner, Dr. Robert Califf, insisting he reserve the decision until his vaccine safety panel could convene.

> *Biden & his new FDA commiss @DrCaliff_FDA (under pressure from Pharma) should insist on a vote by FDA's external experts before authorizing 4th doses. Public health confidence has been signif eroded. Bypassing the expert vote to push 4th doses will make it worse. Science>politics*
>
> *— Marty Makary MD, MPH (@MartyMakary) March 29, 2022*

Both Pfizer and Moderna have argued for a second booster/fourth dose of their COVID vaccines. Pfizer and BioNTech said data collected when the Omicron variant was dominant showed potency of the initial booster wanes within three to six months against both symptomatic infection and severe disease.

The BA.2 variant is expected to become the dominant variant in the U.S. in upcoming weeks. Studies have not been done to assess the efficacy of a fourth dose/second booster with this variant.

Both Pfizer and Moderna have an obvious financial incentive to promote more shots: They are projected to earn tens of billions of dollars in COVID vaccine sales this year.