Written by <u>Veronika Kyrylenko</u> on June 30, 2022

## FDA Panel Supports Omicron-specific Boosters Despite Lack of Safety, Efficacy Data; Biden Places \$3.2B Order With Pfizer

According to a common saying, "Insanity is doing the same thing over and over again and expecting different results." When it comes to the coronavirus vaccines, it has become clear that they have not put a dent in the pandemic numbers. On the contrary, as of October 2021, the number of people who died with or because of Covid after the vaccines were rolled out for the general population in late March 2021 had <u>surpassed</u> the 2020 number of Covid-related fatalities sans shots.

Dr. Rochelle Walensky, the director of the Centers for Disease Control and Prevention (CDC), the agency ultimately responsible for public health advice, has admitted without much attention from the mainstream media — that Covid infection was "worsening over time" among the vaccinated. Instead of ditching the unstudied gene therapeutics that were already making people more susceptible to the disease, the government introduced additional doses of that therapy, "boosters," which were gradually recommended to all Americans, including those as young as five. Some adults older than 50 and those who have weakened immunity may get two.

The health authorities, Dr. Walensky among them, argued that they try to stay "ahead of the virus," but, so far, the virus seems to outpace both the government and the pharmaceutical companies.

And so the race continues.

On Tuesday, the FDA's "independent" vaccine panel, formally known as the Vaccines and Related Biological Products Advisory Committee (VRBPAC), <u>voted to support</u> new booster shots targeting the omicron variant this fall, and those will likely become available in October.

The panel has not yet decided if the modified boosters should target the omicron variant and its most current sublineages, BA.4 and BA.5, or both omicron and the older ancestral strains of the virus (which account for 0 percent of the circulating variants, per CDC data presented during the hearing).

Remarkably, two distinguished members of the VRBPAC voted against the authorization: Dr. Paul Offit,







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director of the Vaccine Education Center and professor of pediatrics in the Division of Infectious Diseases at Children's Hospital of Philadelphia, and Dr. Hank Bernstein, professor of pediatrics at the Zucker School of Medicine.

Offit began by saying that there are currently no Covid strains in circulation that would escape vaccine protection against the "serious illness." There's no surprise here, yet it is not clear if the vaccines are to thank. The omicron strain has been far milder than delta, which, in turn, was milder than previous strains, which still posed virtually no threat to people younger than 80 and with no multiple comorbidities.

Questioning the efficacy of the extra dose, Offit noted that the increase in the neutralizing antibodies provided by the omicron-specific booster shot was estimated to be 1.7 percent. While that may seem "statistically significant," it is not clear if it is "clinically significant," he said. Quoting a study from the U.S. National Institutes of Health, Offit noted that the protection offered by the extra dose in people vaccinated with two or three doses of the "prototypical," i.e., original, vaccine, and then boosted with a "prototypical" booster, was "meaningless."

"I think as a new product it should be handled as a new product," Offit said. "I think we need a higher standard than what we've been given. I'm not comfortable enough to support the risk of a new product."

In an op-ed published in <u>STAT News</u> on Wednesday, Offit explained in greater detail why the omicron and earlier variant boosters "are little or no better than a standard booster":

The immune system responds to the first sight of the viral spike protein by making neutralizing antibodies and by starting to lay down memory cells that are an archive <u>of what</u> <u>it is seeing</u>. Those memory cells improve over a multi-month period and are then triggered into action when the immune system reencounters the spike protein, <u>either as an infection</u> <u>or in a booster vaccination</u>. The resulting neutralizing antibody response doesn't appear to depend very much on whether the boost was with the original sequence, the Beta sequence, the Delta sequence, or the Omicron sequence — all are about equally as good at reawakening immune memory cells.

Meaning, it doesn't matter which strain a person encounters either naturally or via vaccine — Offit believes that the immune response will be "about equally as good."

That certainly sounds a bit confusing, since if the vaccines granted reliable protection against the virus, people would not experience breakthrough infections. Yet they do, and they get sick with Covid multiple times, with Covid <u>becoming chronic</u> in some cases. <u>Pfizer knew</u> that would be the case, and so did the FDA. Dr. Offit certainly must have known that as well.

Dr. Bernstein echoed Dr. Offit's concerns over the lack of efficacy data.

"I think including an Omicron strain in the vaccine seems to have some potential, but data, especially for BA.4 and BA.5, are limited at this time, and that's why I'm struggling to even make a strain change at this time," he cautiously noted.

Bernstein also repeated the claim that current vaccines are already protective enough against severe Covid outcomes.

Neither of the high-profile experts mentioned safety concerns over the additional doses of the shots that

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are already associated with the stunning number of adverse reactions. In his op-ed, Offit said that "everyone who needs a vaccine dose [needs to get] one, particularly never-vaccinated people who have been fooled by <u>distortions about vaccine safety</u>," linking to an article in *The Atlantic*, "The Anti-vaccine Right Brought Human Sacrifice to America."

Those pressing issues, however, were addressed during the public comment section of the hearing. The speakers — non-establishment doctors and scientists — pointed to the avalanche of evidence suggesting the shots pose a grave danger to public health.

Dr. Eric Feintuch of the <u>Inalienable Rights Alliance</u>, who was one of the speakers, told *The New American* that the decision was "unethical" and "defying science."

"Each and every one of the VRBPAC members voting 'yes' needs to read over 1200 peer reviewed articles that cover all aspects of safety [of the vaccines]," said Dr. Feintuch. He pointed to the over <u>1.3</u> <u>million adverse events</u> in the drastically underreported VAERS, which the CDC <u>is not even analyzing</u>.

Such behavior on the part of the government is viewed as criminal by the doctor:

A special session of Congress needs to be organized to investigate the FDA and its role in not only ignoring the safety signals, but not analyzing the data for accuracy and safety and taking the word of these pharmaceutical companies without double checking their analysis.

Based on the analysis of the official FDA documents, the Inalienable Rights Alliance found a whopping 23 instances of the FDA failing to do its duty to verify the safety and efficacy data related to Covid shots.

If the FDA follows the panel's recommendation, which it usually does, vaccine makers will need to roll out modified boosters of their shots, which they have been working on since November 2021.

Following the vote, the Biden administration promptly <u>struck a \$3.2 billion deal</u> with Pfizer to acquire 105 million doses of an updated shot pending FDA signoff on the new formula — "with options for up to 300 million doses."

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