New American

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FDA Clears New Covid Boosters

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The new Covid boosters for Americans aged 6 months and older are now cleared for use by the Food and Drug Administration (FDA) in a bid to counter the poor effectiveness provided by all previous doses against the new Covid variants that are currently in circulation.

The FDA issued full approval for updated shots from Moderna and Pfizer/BioNTech for individuals 12 and older, and issued emergency use authorization (EUA) for those aged 6 months to 11 years. The authorization is more than puzzling, since the Covid public health emergency ended on May 11, 2023.

According to the announcement, the regulators are "confident in the safety and effectiveness of these updated vaccines" and believe that "the benefits of these vaccines for individuals 6 months of age and older outweigh their risks." The assessment was made solely based on the "manufacturing data" provided by Pfizer and Moderna.

The FDA also claims that the side effects that one might experience after receiving the new boosters are "similar" to those reported for previous formulations. It is not clear how that was estimated, since no human trials have been conducted.

As for the safety of the previous formulations, they have been nothing short of disastrous. The mRNA-based shots of Pfizer and Moderna result in serious adverse events at a rate of one in 800, according to a study published last year in the journal *Vaccine*. Furthermore, research published in 2022 in *JAMA Cardiology* disclosed that these vaccines have been associated with myocarditis in young individuals at a significantly high rate, ranging from six to 28 times more frequent than after natural infection.

What about efficacy? The new shots are supposed to target XBB.1.5 (aka Kraken), a subvariant of the omicron variant that emerged last spring. The decision to target Kraken was made by the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) in June. That subvariant, however, has already been largely displaced by newer strains, including EG.5 (aka Eris) and FL.1.51, according to the U.S. Centers for Disease Control and Prevention (CDC).

Still, the FDA expects the boosters to provide "good" protection against circulating variants. Pfizer and Moderna, whose word is taken at face value by federal regulators, claim that their new boosters work on EG.5 and FL.1.51. Yet it appears that both Eris and FL.1.51 have evolved from a separate branch of the XXB variant than Kraken, which casts serious doubt on the perceived effectiveness of the new formulations. Besides, given the rapid mutation of the Covid virus, it is hard to predict which variants will be dominant this winter.

Those interested in a deep dive into the available manufacturing data, as well as the FDA violating its own procedures, might want to read a Substack essay, "FDA has Gone Rogue," written by renowned

scientist and vaccine expert Dr. Robert Malone. In it, Malone shows how "the data clearly demonstrate that there is no longer a COVID public health emergency, and there are no human data demonstrating safety and effectiveness of these mismatched 'vaccine booster' products."

Reaffirming its previous statements, the FDA noted in its announcement that it anticipates that the composition of boosters may need to be updated annually, akin to the seasonal flu vaccine.

Despite the lack of any meaningful data, the Biden administration will be urging all eligible Americans to get these new shots, as reported in late August.

This approach is not recommended by Dr. Paul Offit, vaccine advisor to the FDA, who opined that most healthy Americans under the age of 75 would not require this extra dose.

"Specifically, those over 75 years of age, those who have health problems that put them at highest risk of severe disease (such as obesity, chronic lung disease, chronic heart disease, and diabetes, among others), those who are immune-compromised, and those who are pregnant" are the people who need the booster, Offit told the *Daily Mail*.

Last Thursday, Dr. Joseph Ladapo, Florida's surgeon general, advised people to steer clear of the updated boosters, saying that not only were there no clinical trials proving the shots' safety, but they might actually make people more susceptible to the diseases with each additional dose.

The next step is for the CDC's Advisory Committee on Immunization Practices to make recommendations on who should get the new booster shots, which are expected today. Dr. Mandy Cohen, the new director of the CDC, will sign off soon after, allowing inoculations to begin.

It's worth noting that, for the first time, the federal government will not be covering the cost of the jabs. According to media reports, the price per dose will range between $110 and $130, with most insurance plans covering it. To "assist" some 28 million uninsured Americans, the administration has introduced the Bridge Access assistance program, for which it has allocated $1.1 billion. This initiative is slated to remain in effect throughout 2024.

Manufacturers have reassured they're prepared to deliver shots in the coming weeks.

The public's appetite for the previous formulation was low, with only just over 20 percent of American adults having taken it. Last year, American taxpayers shelled out $4.9 billion for 171 million doses, the majority of which went to waste. The new boosters will likely be as desirable.