FDA Proposes Shift to Annual Experimental COVID Shots

The U.S. Food and Drug Administration (FDA) announced on Monday it is proposing annual COVID-19 shots to "simplify" the nation's strategy. In addition, the FDA asked its Vaccine and Related Biological Products Advisory Committee (VRBPAC) to consider two COVID vaccine shots a year for some young children, older adults, and immunocompromised persons.

Clinical trials have not been conducted to determine if the bivalent booster is safe for children or immunocompromised people, and it's logical to assume yearly COVID vaccines will also enjoy the same benefits that come with bypassing rigorous regulatory standards.

Pfizer's plan from the outset was for there to be annual COVID shots like yearly flu shots. This was discussed during a Pfizer Feb. 2021 earnings call to investors where CEO Albert Bourla assured investors they would continue to make bank with yearly boosters after the pandemic ended.

During the 2021 Barclays' Global Health Conference, former

Pfizer CFO Frank D'Amelio said the company didn't "see this as a one-time event" but "as something that's going to continue for the foreseeable future."

Bourla, on Feb. 25, 2021 told NBC:

"Every year, you need to go to get your flu vaccine. It's going to be the same with COVID. In a year, you will have to go and get your annual shot for COVID to be protected."

In the same NBC article, Pfizer claimed its vaccine was 95% effective at preventing COVID – something now disproven – and the company likely already knew this as it began testing a third vaccine dose despite having an almost "perfectly effective" vaccine and was preparing the public for neverending boosters.

Meanwhile, the American people were told they would only need two primary doses of Pfizer and Moderna or one dose of the Johnson & Johnson shot to prevent COVID and protect their neighbor.

The FDA publicly outlined the strategy in briefing documents published before a VRBPAC meeting on Thursday, where the agency's vaccine advisors will vote on the proposal. Missing from the FDA's briefing documents is any mention of myocarditis or the study Pfizer was required to submit on Dec. 31, 2022, on subclinical myocarditis in men.

Instead, the agency gave a pitch to sell its vaccine advisors on yearly untested experimental boosters.

Per the FDA, vaccine makers would update the annual shot by predicting what might be the dominant strain in the coming winter each spring. This is the same process pharmaceutical companies use to formulate flu shots and primarily results in vaccines that are not, according to CDC data, effective. (For example, the CDC has acknowledged that in recent years, influenza vaccines have only been around 43% effective.)

Yet, if vaccine makers can "predict" the variant that will be dominant in the future and the success of a vaccine's protection is contingent upon its ability to target that variant, wouldn't they have known from the outset their vaccine would yield diminished efficacy as the virus mutates – and that it makes little sense to continue to vaccinate people with a vaccine targeting a COVID strain that no longer exists?

The FDA's proposed process also allows vaccine makers to forgo rigorous clinical trials for safety and efficacy and provides them with continued liability protection.

Currently, people who want to be fully vaccinated against COVID have to first get two shots of the original vaccine targeting the Wuhan variant that no longer exists, followed at least two months later by an untested booster tailored to the original variant and Omicron subvariants that are largely obsolete.

The most recent data shows vaccines yield negative efficacy with each successive dose – making the vaccinated more susceptible to disease. This was also not mentioned in FDA briefing documents.

Under the new approach, people would be advised to get whatever the latest version of the vaccine is, like the flu vaccine. According to Reuters, the Biden administration has also been planning for a fall vaccination booster campaign each year.

This is not the first time the Biden administration has intervened in what should be an independent process. The Biden administration said third booster doses would be offered in September 2021 to the general population prior to boosters undergoing review or receiving approval by the FDA, and against consensus among U.S. health experts data was lacking.

Still, the White House moved forward with its plan to make Americans eligible for a third dose of Pfizer or Moderna's

vaccines eight months after the date of their second dose. Two senior vaccine regulators resigned amid the action, saying they were pressured by the administration to sign off on the decision without sufficient data.

Even if VRBPAC votes not to approve the FDA’s new proposal on Thursday, FDA director Dr. Robert Califf can override it.