U.S. Regulatory Agencies Plan to Create New Rules to Fast-Track 'Revamped' COVID Vaccines, Ignoring Thousands of Reported Adverse Events

The Biden administration is preparing to fast-track emergency use authorization of revamped COVID vaccines to combat the Omicron variant, even though a study from South Africa showed the new variant is fast-spreading but causes less severe illness than previous variants.

The U.S. Food and Drug Administration (FDA) has been in conversations about rapidly authorizing the new vaccines, and has met with vaccine makers to set guidelines for the type of data needed to swiftly evaluate the changes to currently authorized vaccines. So far, federal regulators have identified cases in 16 states.

"The FDA will move swiftly and CDC will move swiftly after,"

Centers for Disease Control and Prevention Director Rochelle Walensky said on ABC's "This Week with George Stephanopoulos," adding, "We're every day hearing about more and more cases."

According to the latest data from the CDC's Vaccine Adverse Event Reporting System (VAERS), there have been 927,740 reports of adverse events, including 19,532 reports of deaths, following COVID vaccines since Dec. 14, 2020. Historically, VAERS has been shown to report only 1% of actual vaccine adverse events.

Under the rules that the FDA is putting into place to fast-track new COVID vaccines, drugmakers working on the new vaccines would be expected to meet standards similar to those required for authorization of boosters, a source familiar with the matter said.

This means pharmaceutical companies wouldn't have to conduct large studies with thousands of subjects to show their vaccines are safe and effective but could study the immune response in only a few hundred subjects.

Drugmakers would only need about three months to develop and test the new vaccines, a source familiar with the matter said. Then the companies would seek authorization through an expedited review process that would take the FDA only one to two weeks to make a decision, according to the source.

With a study period of about three months, it is impossible to detect any long-term adverse events that could occur from receiving the 'revamped' vaccines.

Biden administration officials last week announced a number of expanded COVID restrictions using the Omicron variant as a justification. The restrictions include a 24-hour COVID testing requirement for international travelers regardless of vaccination status, expanded mask requirements for travelers through mid-March on planes, buses and trains, and at domestic transportation hubs such as airports and indoor bus terminals

and doubled fines for noncompliance and repeated offenses.

U.S. health officials say COVID vaccines and boosters are the best defense against COVID while continuing to ignore the benefits of natural immunity, safe and effective COVID treatments and the increasing reports of severe adverse reactions to VAERS.