

The Wall Street Journal

New omicron-specific COVID booster expected to be approved before trial data is in

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'The vaccines are safe,' FDA commissioner says; clearance is similar to approach FDA takes with flu shots



The new show it expected to be approved by the FDA this week. AFP VIA GETTY IMAGES



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The Food and Drug Administration is expected to authorize new COVID-19 booster shots this week without a staple of its normal decision-making process: data from a study showing whether the shots

were safe and worked in humans.

The shots, modified to target the [latest versions of the omicron variant](#), won't have finished testing in humans when the FDA makes its decisions.

Instead, the [agency plans to assess the shots](#) using data from other sources such as research in mice, the profiles of the original vaccines and the performance of earlier iterations of boosters targeting older forms of omicron.

“Real world evidence from the current mRNA COVID-19 vaccines, which have been administered to millions of individuals, show us that the vaccines are safe,” FDA Commissioner Robert Califf said in a recent tweet. The FDA pointed to Califf’s tweets when asked for comment.

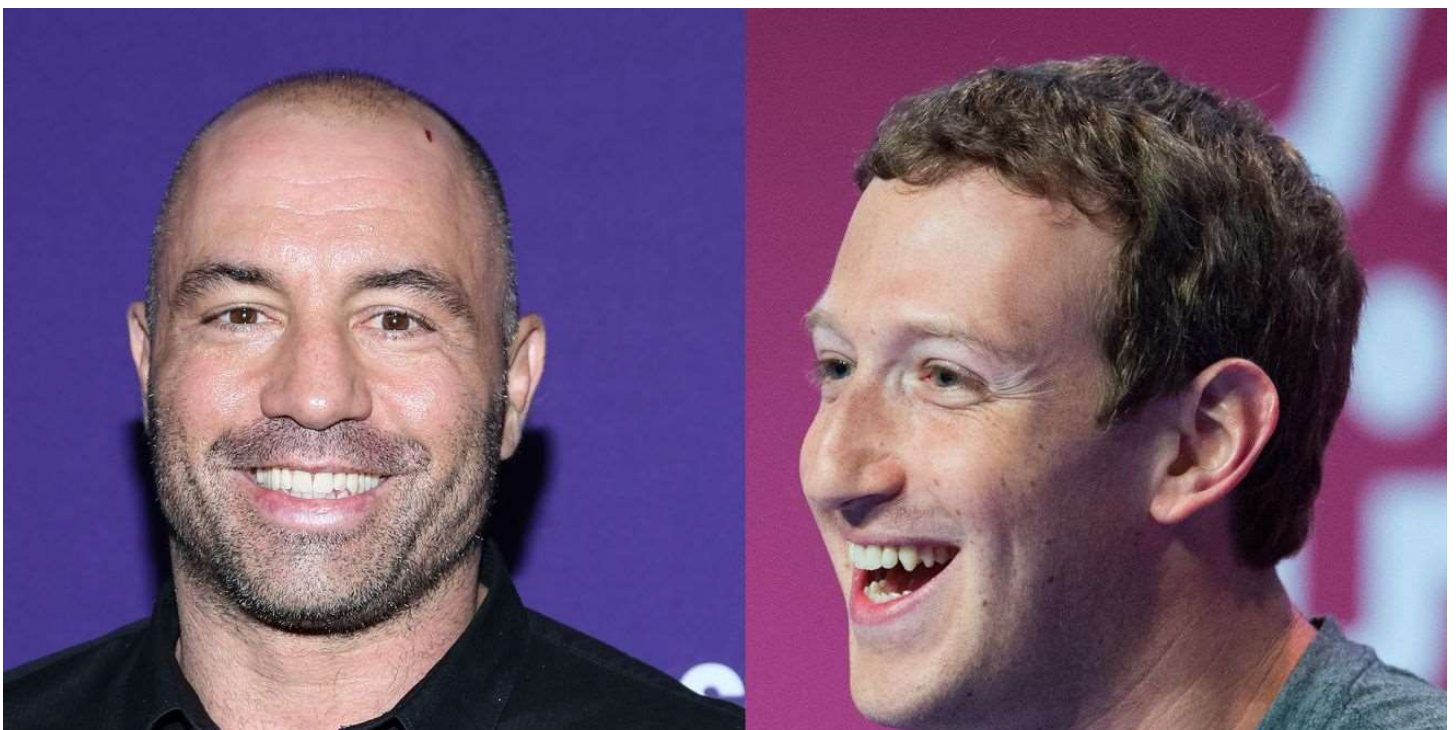
Clearance of the doses, without data from human testing known as clinical trials, is similar to the approach the FDA takes with flu shots, which are updated annually to keep up with mutating flu viruses.

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