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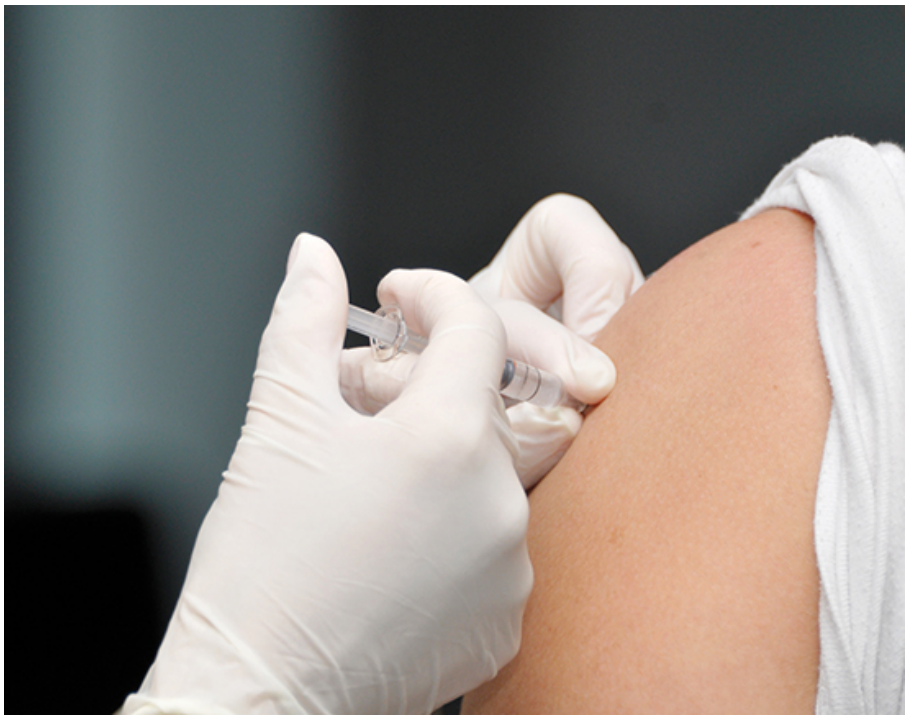
Vaccine advisory group: Don't rush COVID-19 vaccine approval

by Melissa Jenco, News Content Editor



Editor's note: For the latest news on COVID-19, visit https://www.aappublications.org/news/2020/01/28/coronavirus.

The National Vaccine Advisory Committee (NVAC) is urging federal authorities to use a traditional approval process for a COVID-19 vaccine despite the possibility it could take months.

The Food and Drug Administration's (FDA's) Biologics License Application process "is both time-tested for rigor and is well trusted by the public and to put it in a nutshell we think it should be considered the default for approval of this vaccine as it is for all others," said John B. Dunn, M.D., M.P.H., FAAP, who co-chairs the NVAC Vaccine Confidence Subcommittee with H. Cody Meissner, M.D., FAAP.

NVAC member Leonard Friedland, M.D., vice president and director of scientific affairs and public health at GSK Vaccines, said that process is very formal and detailed. It can take a year, although sometimes it is shorter. By contrast, the FDA's emergency use authorization (EUA) can take a matter of days and isn't as transparent, he said.

Dr. Dunn said NVAC recognizes hundreds of people are dying daily and an EUA may be warranted for some high-risk groups.

"What the recommendation emphasizes is that the use of such an expedited processes should only be done circumspectly and with a real abundance of caution," said Dr. Dunn, medical director of preventive care, clinical lead for immunization population management at Kaiser Permanente Washington.

This NVAC recommendation is one of five the group approved Wednesday to advise Assistant Secretary for Health Admiral Brett P. Giroir, M.D., on how to improve public confidence in a possible COVID-19 vaccine. A recent Gallup poll found 35% of people said they would not be willing to take the vaccine even if the FDA had

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approved it.

"In order to ensure we have high confidence in COVID-19 vaccines, which is going to be critical to achieving high uptake of these vaccines, we really feel that there's a need for immediate action to take proactive steps to build public confidence specifically in development, safety processes, approval and recommendation criteria," Dr. Dunn said.

NVAC also recommended creating a federal immunization safety task force and an independent group of vaccine and public health experts to review safety data and monitor any safety concerns that arise. In addition, the group urged regular communication with the public and community engagement efforts to help inform policies and ensure they address the needs of groups that are disproportionately affected by the pandemic.

Prior to receiving the recommendations, Dr. Giroir, a four-star general trained in pediatric critical care, said "there will be no shortcuts when it comes to the safety of COVID-19 vaccines."

"Like all vaccines undergoing clinical trials, COVID-19 vaccine candidates are undergoing rigorous scientific testing and must meet FDA standards for safety and effectiveness," he said. "There is no political influence in this process."

Resources

- Information from the CDC about COVID-19 for health care professionals
- Information about COVID-19 from the AAP Red Book
- Information about COVID-19 from the AAP
- Information for parents from HealthyChildren.org on coronavirus