Dr. Fauci: Why FDA's coronavirus vaccine review will be politics-free

SEP 30, 2020

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Extensive checks and balances that include independent data analysis and a host of advisory groups staffed with career scientists will likely shield the Food and Drug Administration (FDA) coronavirus vaccine approval process from political pressure, according to Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases and a member of the White House coronavirus task force.

Dr. Fauci said that despite rising concern over political pressure to approve a COVID-19 vaccine prematurely, he is confident the FDA and its scientists will make their decisions in a professional manner and independent of election-year conflicts.

"These are professionals at the FDA that have been doing this their entire career. This is what they do every single day," he said.

Dr. Fauci discussed the FDA approval process on the latest episode of "Conversations with Dr. Bauchner," a JAMA Network™ podcast also broadcast on YouTube. He also provided an update on vaccine trials and plans to distribute vaccines after FDA approval.

FDA's independent process

"The big elephant in the room is: Will somebody try to make a political end-run to interfere with the process?" he said. "So, if you look at the standard process for how these things work ... it is really unlikely that this is gong to happen. Each of these vaccines has a data- and safety-monitoring board that is not beholden to the administration" or anyone else. "They are the ones that get the data."

These independent statisticians inform the pharmaceutical company sponsoring the vaccine whether the trial has reached a stage of documented efficacy that warrants the company applying to the FDA

for an emergency use authorization or the more permanent biological license application.

> “I trust the career scientists of the FDA and I certainly trust the commissioner of the FDA,” Dr. Fauci said. When the FDA and its commissioner, Stephen M. Hahn, MD, examine the data, it is also reviewed by their own advisory group and “when that happens, those data become public. The scientific community examines those data.”

Find out more about the vaccines that have entered phase 3 trials.

Vaccine approval by year’s end

Dr. Fauci said he is optimistic that one or more of the six vaccine trials now in the pipeline would be approved before the end of the year, depending on the amount of infection in the trial groups.

If the independent data analysts acknowledge sufficient evidence of safety and efficacy, they could advise the sponsoring companies that the vaccine is ready for early approval. Researchers are targeting at least 50% efficacy, but Dr. Fauci hopes some or all the vaccines could do better. “I would like to see at least a 70% to 75% efficacy,” he said.

The competition among vaccine trials may also yield some choices for treatment. “It may be different vaccines for different situations,” he said. For example, one of the vaccines, he noted, may be more effective in an older population or in a certain climate.

At approval, Dr. Fauci said about 20 million doses will be available for vaccination of medical personnel and first responders. By March or April 2021, about 700 million doses will be available for widescale vaccination, he said.

Learn how the AMA and 77 other prominent organizations recently urged federal health agencies to follow the evidence on coronavirus vaccine review.

More treatments on the way

Pending the approval of one or more vaccines, researchers continue to develop COVID-19 treatments that may improve outcomes for virus victims, Dr. Fauci said. Dexamethasone has become a standard of care and remdesivir continues to improve outcomes, but other treatments are in clinical trials, he said.

“What we are doing clinical trials on—but we don’t have yet solid proven clinical efficacy of—is in a

number of approaches," Dr. Fauci said.

The most promising among these is monoclonal antibodies, especially for patients at earlier disease stages, in the outpatient settings, in nursing homes as a prophylaxis. Also, he said, the hope is that this intervention would be helpful to prevent spread of COVID-19 within a household after one family members tests positive.

Convalescent plasma continues to be a treatment possibility, he added. "We know we have convalescent plasma, but we haven't nailed that down yet. We are pretty sure that will be safe. Also, hyperimmune globulin which is derived from convalescent plasma."

Also, Dr. Fauci noted ongoing clinical studies of anticoagulants and anti-inflammatories for advanced disease, and said the focus is "very heavily on treatment of early infection or prevention of early infection."

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The AMA is closely monitoring the COVID-19 pandemic. Learn more at the AMA COVID-19 resource center. Also check out pandemic resources available from the AMA *Code of Medical Ethics*, JAMA Network™ and *AMA Journal of Ethics*, and consult the AMA's physician guide to COVID-19.