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Health Experts to F.D.A.: Make Your Vaccine Deliberations Public

A letter signed by nearly 400 health experts asked the agency to use its vaccine advisory panel when reviewing data on coronavirus trials.

By Sheila Kaplan

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A coalition of leading public health experts urged the Food and Drug Administration on Wednesday night to conduct full safety and efficacy reviews of potential coronavirus vaccines before making the products widely available to the public.

In a letter signed by nearly 400 experts in infectious diseases, vaccines and other medical specialties, the group called on Dr. Stephen Hahn, the F.D.A. commissioner, to be forthcoming about the agency's deliberations over whether to approve any new vaccine, in order to gain the public's trust.

"We must be able to explain to the public what we know and what we don't know about these vaccines," noted the letter, which was organized by the nonprofit Center for Science in the Public Interest. "For that to happen, we must be able to witness a transparent and rigorous F.D.A. approval process that is devoid of political considerations."

More than 30 experimental coronavirus vaccines are in clinical trials, with several companies racing to have the first product in the United States ready by the end of the year. The federal government has promised more than $9 billion to companies for these efforts to date. But many people are highly skeptical of these new vaccines, and might refuse to get them.

"Collaborations between scientists, the pharmaceutical industry and the federal government may bring us to a remarkable and historic achievement," the letter said. "But an effective vaccine will only be truly useful if a large proportion of the public is willing to take it."

The signers included academic researchers and former government officials from around the country, including the former surgeon general Dr. Joycelyn Elders; the former F.D.A. chief Dr. Jane E. Henney; and Dr. Luciana Borio, the former director for medical and biodefense preparedness at the National Security Council.

In an effort to reassure the public, Dr. Hahn said recently that he would seek the advice of the F.D.A.'s Vaccines and Related Biological Products Advisory Committee, although he has not said when the group would meet or which vaccine candidates it would consider.

The F.D.A. declined to comment on the letter Wednesday evening.

Dr. Paul Offit, a professor at the University of Pennsylvania and a member of the F.D.A.'s vaccine advisory panel, was also among the signers. In an interview, Dr. Offit called the agency's emergency authorization for hydroxychloroquine — a malaria drug that President Trump has promoted as a treatment for Covid-19, despite no evidence that it works — a "warning shot." The authorization was later revoked after a review found that 100 Covid-19 patients who took the drug had serious heart problems, including 25 who died.

"I think the administration bent or imposed its will on the F.D.A.," Dr. Offit said. "There's a concern that this would happen here, too."

The letter said that scientists carrying out vaccine trials should share the details of their Phase 3 trials, which test thousands of volunteers to see whether the products prevent coronavirus infections and whether they cause side effects. It's critical, the letter said, that the F.D.A. not approve any product until Phase 3 data are complete. The group also requested that volunteers be monitored for unexpected side effects that occur after the trials.

Dr. Offit said that the advisory board, which includes experts from academia, industry and government and makes much of its discussions public, could handle as many of the vaccine candidates as are ready to review.

"Typically they are two-day meetings," he said. "We could make them longer than that. We can go through all the data."

Dr. Rebekah Gee, chief executive of Louisiana State University health care services, who also signed the letter, said that research data on the vaccines must be made public.

"Everyone in our nation is anxiously awaiting a Covid-19 vaccine," she said. "It's important to public health to save lives, and for our economy, but we want to make sure that whatever is done is done in an open process that is devoid of political influence."