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Nation's Leading Vaccine Authorities Urge Thorough Review of Safety and Efficacy of COVID-19 Vaccines

Completed Phase 3 Trials and Transparent Process Necessary for Public Confidence, Experts Say

WASHINGTON—COVID-19 vaccines should be made widely available only after the Food and Drug Administration has been able to evaluate safety and efficacy data from completed Phase 3 clinical trials, according to the nation's leading vaccine authorities. Nearly 400 experts in virology, epidemiology, vaccinology, clinical care, and public health are calling on FDA Commissioner Stephen Hahn to ensure a thorough, transparent process that will give experts and the general public alike reassurance that the candidate vaccines are safe and effective.

The federal effort to accelerate progress on COVID-19 vaccines, branded as "Operation Warp Speed," has as its stated goal the delivery of 300 million doses of a safe and effective COVID-19 vaccine by January 21. The need for such a vaccine for COVID-19, which has killed more than 157,000 and infected more than 4.7 million Americans, is urgent, the experts say. But the process should be as thorough as the FDA's review for previous vaccine candidates and involve open meetings of the FDA's Vaccines and Related Biologics Product Approval Committee.

Vaccine investigators should share Phase 3 trial design details, including by making available the Data Safety Monitoring Boards' "stopping rules" to decide whether a study should be terminated early, the experts write. They also urge continuous monitoring for unexpected severe side effects that might only become apparent after large numbers of people are vaccinated.

Signatories to the letter include Dr. Luciana Borio, former Director for Medical and Biodefense Preparedness at the National Security Council; former Surgeon General Dr. Jocelyn Elders; former FDA Commissioner Dr. Jane Henney; Dr. Peter Hotez, Professor of Pediatrics and Molecular Virology and Microbiology at Baylor College of Medicine; Pulitzer Prize-winning author Laurie Garrett; Dr. Rebekah Gee, CEO of Health Care Services at LSU Health; Dr. Bruce Gellin, President of Global Immunization at the Sabin Vaccine Institute and former Director of the National Vaccine Program Office; John Moore, PhD, Professor of Microbiology and Immunology at Cornell University; Mark Lipsitch, DPhil, of the T.H. Chan School of Public Health at Harvard University; Dr. Paul Offit, Professor of Vaccinology at the

University of Pennsylvania; Dr. Walter Orenstein, former Director of the United States Immunization Program at the Centers for Disease Control and Prevention; Amy Pisani, Executive Director of Vaccinate Your Family; and Dr. William Schaffner, Professor of Preventive Medicine at Vanderbilt University School of Medicine.

"To maximize the use of a COVID-19 vaccine(s) by the American people, it is therefore essential that the science and public health communities work with the federal government to increase public confidence in any approved or authorized product," the experts wrote to Hahn. "However, we can only perform as advocates if we ourselves are persuaded that the vaccine(s) truly is safe and effective. We must be able to explain to the public what we know and what we don't know about these vaccines. For that to happen, we must be able to witness a transparent and rigorous FDA approval process that is devoid of political considerations."

The letter to Hahn was organized by the nonprofit Center for Science in the Public Interest, whose president, Dr. Peter G. Lurie, previously served as Associate Commissioner at the FDA.

"Because they will be given to many healthy, young people—who are at relatively low risk of dying from COVID-19—these vaccines need to be held to the highest standards of safety and efficacy," said Offit.

“We have seen what happens when certain drugs, like hydroxychloroquine, preventive measures, such as masks, or public policies, such as whether to open or close schools, become politicized,” said Lurie. “There is no place for politicization if uptake of a safe and effective vaccine is to be maximized and the pandemic is to be controlled.”

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