

Testimony of Paul A. Offit, MD

The Children's Hospital of Philadelphia before the:

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My name is Paul Offit. I am an attending physician in the division of Infectious Diseases at the Children's Hospital of Philadelphia and a Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania. I am also the co-inventor of the rotavirus vaccine, RotaTeq, which was recommended by the CDC for use in all infants in the United States in 2006 and by the World Health Organization for all infants in the world in 2013. I have been a member of the Advisory Committee on Immunization Practices at the CDC and am currently a member of the FDA's Vaccine Advisory Committee, VRBPAC, as well as the NIH's ACTIV group, assembled by Dr. Francis Collins to facilitate the development of COVID-19 vaccines.

The American public is skittish about the speed with which vaccines to prevent COVID-19 are being developed. And it's understandable. The language surrounding this effort is a little frightening. Phrases like "Warp Speed," "the race for a vaccine," and "vaccine finalists," have caused some to wonder whether critical phases of vaccine development are being skipped or, worse, that safety guidelines are being ignored. Further, the administration's politicization of science in areas like mask hygiene and social distancing, as well as the push to approve drugs such as hydroxychloroquine or biologicals such as convalescent plasma through an EUA without clear evidence of safety or efficacy, have caused some to wonder whether the same low

standards will be applied to COVID-19 vaccines. Indeed, recent polls have shown that more than half of all Americans would choose not to receive a COVID-19 vaccine if offered, which would make it difficult to achieve herd immunity by vaccination and eventually gain control of this pandemic.

Despite these understandable concerns, I am optimistic that what happened with hydroxychloroquine and convalescent plasma will not be repeated for vaccines, for several reasons:

First, the Data Safety Monitoring Boards that are supervising COVID-19 vaccines have been charged with holding them to the same standards of safety and efficacy that they would for any vaccine, which makes sense given that most of those who will initially receive these vaccines will be healthy, young people, unlikely to die from this infection.

Second, FDA Commissioner Hahn stated in a recent op-ed in the *Journal of the American Medical Association* that he would “rely on transparent discussions by the FDA’s VRBPAC Committee prior to vaccine authorization or licensure.” This committee is composed of academicians and researchers who are not associated with either industry or government and can be counted on to give an unvarnished appraisal of COVID-19 vaccines prior to approval.

Third, while the development of COVID-19 vaccines has been faster than any vaccine ever produced, one aspect of the development process is identical to the way vaccines have been developed for the past 70 years; specifically, the phase 3 trials. Phase 3 trials for COVID-19 vaccines are large, prospective, placebo-controlled trials of about 30,000 people. The size of these trials is typical. For example, the Human Papillomavirus Virus (HPV) vaccine phase 3 trial included about 30,000 participants and the conjugate pneumococcal vaccine trials about

35,000. As long as these phase 3 trials are allowed to proceed until there is clear, statistically robust evidence that the vaccines work and are safe in the groups that will soon receive them, then they will have been held to the same standards as previous vaccines.

Finally, during my service on the FDA's Vaccine Advisory Committee, I have come to know people at the FDA who are involved in vaccine licensure. They are exactly who you would want them to be—dedicated to protecting the public from products that are unsafe or ineffective. If COVID-19 vaccines are released before they are ready to be released, you will hear from these people. And you will also hear from people like Drs. Francis Collins and Tony Fauci, both of whom are trusted by the American public, as well as the many other academicians and researchers who wouldn't stand for this. The public is already nervous about these vaccines; if trusted health officials stand up and decry a premature release, the celebration by the administration will be short lived.

In summary, while people are understandably nervous about soon-to-be-released COVID-19 vaccines, I think they can take comfort in the fact that many people in supervisory positions, as well as a cadre of independent, academic scientists standing behind them, are monitoring this process and looking out for the public's best interests.