

Statement of Jay Bhattacharya, MD, PhD

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Good morning Chairman Krishnamoorthi, Ranking Member Cloud, and other committee members, thank you for the opportunity to speak with you today. My name is Jay Bhattacharya and I am a health economist and Professor of Medicine at Stanford University, where I direct the Center for Demography and Economics of Health and Aging. I hold an MD and a PhD in Economics and I have 20 years of experience working on the economics of infectious disease. My published work over the past decades includes studies on H1N1 flu, H5N1 flu, and on SARS-CoV-2. In addition to my academic work, I have worked closely with federal regulatory agencies on health policy issues. Over the past decade, I have worked with the Center for Medicare and Medicaid Services (CMS) on issues related to physician payment, measurement of costs and quality of care, geographic variation in health care practices, risk adjustment modeling, and access to care. Additionally, I have worked with the FDA over the past several years, and in particular with the Center for Biologics Evaluation and Research (CBER), on post-market surveillance of biologics products, including studies involving the safety of flu vaccines.

In my opening remarks today, I will address two topics related to vaccine development in the context of COVID-19 – (1) the regulation of the safety of SARS-CoV-2 vaccines currently under development, and (2) policy mechanisms to prioritize access to the vaccines by vulnerable populations, should they prove safe and effective.

The development of vaccine candidates for SARS-CoV-2 has proceeded at a remarkable pace. In a report released [yesterday](#), the World Health Organization identified 23 candidate vaccines currently in clinical evaluation, which means being tested on human populations, and 137 vaccine candidates in preclinical evaluation. The vaccine candidates employ a variety of technologies, both traditional and novel, all with the same goal of producing a sustained antibody response that can neutralize SARS-CoV-2 virus and prevent COVID-19 infection. This is an extraordinary scientific effort in a short period of time in response to the extraordinary challenge posed by the COVID-19 epidemic.

The rapid development of vaccine candidates naturally brings with it worries about the safety of the ultimately approved vaccine. These are not idle worries, as vaccines are biologically potent agents and need to be tested thoroughly in a very wide population before they are deployed widely. At the same time, even discredited challenges to the safety of a vaccine, like in the case of the MMR vaccine, can lead many people to avoid vaccination with unfortunate consequences for the spread of deadly disease.

I want to make two points to assure you and the American public about the process that the FDA will follow to ensure the safety of the SARS-CoV-2 vaccines. First, in my experience working with them over the past years, I have found the FDA scientists and epidemiologists who work on drug and biologics safety to be among the most careful and conscientious researchers I have ever worked with. They are immune from political influence and follow the data diligently in their decision making.

The FDA is a conservative organization in the sense that it would much rather ask for more study to make sure that a product it is evaluating is actually safe and effective (even at the cost of delaying access to a good drug or vaccine) than take the risk of approving something that ex post proves unsafe. A [study](#) published last year in Biostatistics found that the FDA approved only a third of all vaccine

candidates that entered clinical evaluation. The FDA is not afraid to say no to a vaccine candidate if the evidence warrants it. In the case of the SARS-CoV-2 vaccine candidates, my understanding is that the Phase 3 studies currently underway will enroll tens of thousands of patients, so that even relatively rare adverse events can be detected.

Even after a vaccine is approved, the FDA will continue to play a key role in monitoring for safety issues. Even for a well-tested vaccine with clinical studies involving tens of thousands of patients, safety issues may arise when the vaccine is provided to hundreds of millions of people that were not found in the studies. To this end, the FDA conducts post-market surveillance studies of drug and vaccine long past the approval of the vaccine for widespread use.

Second, I wanted to address Operation Warp Speed, which as you know is the Administration's plan to accelerate research and development efforts for a SARS-CoV-2 vaccine. To my knowledge, the operation has two main parts: (1) to provide financial support for studies of the safety and efficacy of the most promising vaccine candidates, and (2) to make financial commitments for the large scale production of vaccine doses even before the regulatory process for drug approval is complete. The main thing I want to emphasize about the first part is that the studies that will be conducted will be evaluated by the FDA regulatory process I just mentioned. Cutting corners on safety evaluation will be impossible under the FDA's watchful eye. The second part is a gamble – what if we invest a large amount of money to manufacture a vaccine that, after the studies are complete, turn out to not work very well? That's the downside. The upside is that if the vaccine is safe and it works, tens of millions of doses will be available and we will not need to fight so hard over who gets the first doses among the limited supply. This is a big gamble, but one that makes sense given the huge economic costs and health harms of the COVID-19 epidemic.

I will finish by briefly giving my thoughts on who should be prioritized to receive a safe and effective vaccine. To my mind, the answer is simple and is driven by who is most vulnerable. An overwhelming body of clinical evidence shows that the elderly – and especially the oldest old -- are at highest risk of hospitalization and death from COVID-19 infection. This problem is compounded by the fact that patients with multiple chronic diseases are also at high risk, and of course elderly patients are at highest risk to have chronic diseases. In my view, if there are limited doses of the vaccine available initially, the priority should go to Medicare patients. An additional advantage of this approach is that this can readily be accomplished through existing Medicare programs, to provide the vaccine to the Medicare beneficiaries – at no cost to them.

While there has been a lot of political clash over a wide range of issues regarding COVID-19, I believe that all Americans (and indeed the whole world) can celebrate together if and when a safe and effective is developed. Soon I hope.