

## **Opening Statement of Jason L. Schwartz, Ph.D., Yale School of Public Health**

“Guardrails to Ensure a Safe and Effective COVID-19 Vaccine”  
Subcommittee on Economic and Consumer Policy  
House Committee on Oversight and Reform

14 July 2020

Good morning, Chairman Krishnamoorthi and members of the Subcommittee. Thank you for the opportunity to participate in today’s briefing, as you examine the very important work that lies ahead in our nation’s response to COVID-19, particularly ensuring that the safety and effectiveness of any vaccine developed in the coming months is rigorously evaluated and continuously assessed by the scientists at the Food and Drug Administration (FDA) and their expert advisors. My name is Jason Schwartz; I am an Assistant Professor in the Department of Health Policy and Management at the Yale School of Public Health. A central focus of my research is U.S. vaccination policy and policy-making, particularly how evidence informs the development of vaccine regulation, financing, promotion, and delivery by government public health agencies.

The development of a safe and effective COVID-19 vaccine—multiple vaccines, ideally—is an essential component of any long-term strategy to address the pandemic and reduce its effects on public health, the economy, and our daily lives. Research and development of vaccine candidates is moving extremely rapidly, led by dozens of research groups in the United States and around the world and supported by billions of dollars of government investment. In scientific research, success is never guaranteed—vaccine development is no exception—and the pace of advances seldom follows prespecified timetables or forecasts. Nevertheless, the optimism we hear that one or more of the vaccine candidates currently in development may show promise in clinical testing in the months ahead is entirely reasonable, and so directing attention now to regulatory and policy issues related to the evaluation of COVID-19 vaccine candidates, their review and potential approval, and their potential use in large-scale vaccination programs is very much timely and appropriate.

There is remarkable, and entirely understandable, public interest in progress toward potential COVID-19 vaccines. Even very early research developments—often shared through press releases rather than peer-reviewed scientific publications—generate headlines and move financial markets. If, in the months ahead, large clinical trials of a vaccine suggest potential benefits, the public pressure on the FDA to expedite access to that vaccine through either an Emergency Use Authorization or traditional approval will likely be enormous. Moreover, some scientists and physicians have already raised concerns about potential political interference in the FDA’s decision-making activities in the months ahead, suggesting that the FDA may face outside pressure to accelerate the availability of a vaccine this fall as the November election approaches.

My primary message for today’s briefing is as follows—we are facing a public health crisis unlike any that anyone alive today has experienced, and the speed and urgency surrounding vaccine development is similarly unprecedented. However, the closer that our government health

agencies adhere to their well-established, time-tested processes for evaluating the safety and effectiveness of COVID-19 vaccines and developing evidence-based approaches for their deployment, the more confidence the public can have in the integrity and quality of those decisions and those vaccines, and the more likely it will be that COVID-19 vaccination programs approach the incredibly high expectations being placed upon them. This is no time for improvisation.

In the United States, we are fortunate to have an extremely robust and well-functioning system for rigorously and continuously evaluating the safety and effectiveness of vaccines before and after their initial approval and for producing widely respected, evidence-based guidelines for their use. This expertise resides principally within the FDA's Center for Biologics Evaluation and Research (CBER) and the Centers for Disease Control and Prevention's (CDC) National Center for Immunization and Respiratory Diseases (NCIRD). These career government scientists have unrivaled expertise required for the work regarding COVID-19 vaccines that lies ahead, and their activities can be further supported by the longstanding external expert advisory committees that have for decades supported the government's regulatory and policy-making work around vaccines. I am referring specifically to the Vaccines and Related Biological Products Advisory Committee (VRBPAC) at the FDA and the Advisory Committee on Immunization Practices (ACIP) at the CDC.

For over 50 years, advisory committees have been regular and influential contributors to the FDA in supporting its core regulatory responsibilities related to the review of vaccines, pharmaceuticals, and other products, as my research has explored.<sup>1</sup> These committees provide the FDA with access to preeminent scientists and physicians from outside of the federal government who assemble to review evidence from clinical trials and other sources and offer recommendations regarding how the FDA should act on pending applications for approval (or, in some cases, regulatory changes to already-approved products). Advisory committees expand the expertise available to support FDA's decision-making and are thought to increase the perceived legitimacy of its subsequent decisions. While the FDA is not required to follow the recommendations of its advisory committees, it most often does.<sup>2</sup>

FDA advisory committees also help to enhance the transparency of its decision-making. In accordance with the provisions of the Federal Advisory Committee Act, advisory committees meetings largely occur in public, giving members of the public and other interested stakeholders opportunities to see relevant evidence regarding the safety and effectiveness of products, to observe committee deliberations, and to comment directly to the committee and FDA staff who participate actively in these meetings. This kind of transparency can be extremely helpful in allaying concerns about the grounds for FDA's decisions or potential allegations regarding interference in its scientific assessments and subsequent decision-making.

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<sup>1</sup> Schwartz JL. [Fifty Years of Expert Advice—Pharmaceutical Regulation and the Legacy of the Drug Efficacy Study](#). *New England Journal of Medicine*. 2016;375(21):2015-2017.

<sup>2</sup> Zhang AD, Schwartz JL, Ross JS. [Association Between Food and Drug Administration Advisory Committee Recommendations and Agency Actions, 2008-2015](#). *The Milbank Quarterly*. 2019;97(3):796-819.

With respect to vaccines, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) has been an active contributor to FDA’s work related to vaccines since its creation in 1981, meeting regularly to discuss scientific considerations related to vaccine candidates in development, to evaluate clinical trial data for vaccine candidates approaching possible approval, to review the composition of the annual influenza vaccine, and other topics, as my colleagues on today’s panel can speak to first-hand.<sup>3</sup> At the CDC, the Advisory Committee on Immunization Practices has been similarly valuable, serving for over 60 years as the gold-standard for evidence-based recommendations regarding how FDA-approved vaccines should best be used in different populations.<sup>4</sup>

As COVID-19 vaccines move ahead in their development, those efforts should continue to balance the obvious urgency of the work with an insistence that there can be no compromises with respect to the safety and effectiveness evidence expected of any vaccine in order for it to be authorized or approved for use. It is encouraging that statements from FDA leadership have thus far appeared sensitive to this challenge and this responsibility.

There are extremely difficult scientific and policy questions ahead regarding the evaluation and use of COVID-19 vaccines, questions that will benefit from *more eyes, more perspectives, more expertise, more institutional knowledge, more transparency*, not less. Adhering to longstanding practices and norms for assessing the safety and effectiveness of vaccines in general and in specific populations—including the participation of the FDA’s and CDC’s expert advisory committees meeting and deliberating openly, as they have done for decades—would enhance health agencies’ decision-making and public confidence in the vaccines so eagerly anticipated.

Public confidence in vaccination is fragile and has been under growing threat in recent years. While no pre-approval evidence review process, no matter how rigorous, can eliminate the possibility of unfavorable evidence emerging after a vaccine is approved and much more widely administered, the actions taken by the FDA and its counterparts in the months ahead can greatly reduce that possibility. The emergence of a serious safety concern related to a COVID-19 vaccine—or even the *perception* by the public that corners were cut or political pressure was applied in a rush to approve it—would be greatly damaging not only to COVID-19 vaccination efforts but also to public confidence in *all* recommended vaccines. And our already overwhelmed public health and health care systems cannot bear the burden of simultaneously battling COVID-19 alongside outbreaks of measles, influenza, and other vaccine-preventable diseases in the months and years to come.

There is very important, very difficult work ahead with respect to COVID-19 vaccines, but the momentum behind research and development and the expertise of our government public health scientists and their expert scientific advisors at the FDA, CDC, and elsewhere give me reason for optimism. Thank you to the members of the Subcommittee for your interest in these issues and for the invitation to participate in today’s briefing.

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<sup>3</sup> Schwartz JL. [The First Rotavirus Vaccine and the Politics of Acceptable Risk](#). *The Milbank Quarterly*. 2012;90(2):278-310.

<sup>4</sup> Schwartz JL, Mahmoud A. [A Half-Century of Prevention—The Advisory Committee on Immunization Practices](#). *New England Journal of Medicine*. 2014;371(21):1953-1956.