

Comments of Peter Lurie, MD, MPH
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Before the Food and Drug Administration's Vaccines and
Related Biological Products Advisory Committee Meeting
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I am Peter Lurie, President of the non-profit Center for Science in the Public Interest and an Associate Commissioner at FDA from 2014 to 2017. I have no conflicts of interest to disclose. In addition to the scientists who have toiled to produce, in record time, the data we have before us today, I would especially like to thank the Food and Drug Administration for committing to the Advisory Committee process and for conducting its review in a transparent manner, particularly under concerted political pressure.

I would like to address just two issues today.

The first relates to the interpretation of the data on the Pfizer vaccine. I think we can all agree that, based on the data accrued to date, the products demonstrate a striking degree of efficacy in preventing confirmed COVID-19, one that is shared across a variety of demographic, clinical and other subgroups. And I agree with the FDA reviewers that there is no evidence of a major safety signal. However, the extent of more minor adverse events is notable. These include injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), all substantially elevated compared to rates in the placebo group. I do not believe that these events should stand between this product and authorization, but I do think the rates of these events are sufficiently elevated to merit open and even-handed discussion with patients. We are already facing significant levels of vaccine hesitancy and if patients are not forewarned about these adverse effects, the word will surely spread rapidly, potentially exacerbating the hesitancy problem.

I also welcome FDA's identification of the disproportionate numbers of Bell's Palsy cases (4 in the vaccine groups vs. 0 in the placebo group) as a matter that should continue to be monitored, including in the postmarketing phase. The allergic reactions that have apparently emerged in the British vaccination campaign are also important, given that hypersensitivity-related adverse events occurred in 0.63% of vaccinated patients compared to 0.51% in the placebo group.

The second issue relates to trial design now that at least one safe and effective vaccine has been identified. Reasonable people can disagree over whether study subjects should have priority access to a product whose efficacy they helped demonstrate. But we ought to be able to agree on this: no subject who has put their body on the line in a vaccine study should be at a disadvantage in terms of vaccine access as a result of their participation. Yet some observers appear to be advocating for extended periods of blinded follow-up even after authorization. This position is hard to justify ethically, if it is inconsistent with public health recommendations, particularly with rapidly rising case rates and the reported levels of effectiveness for the Pfizer/BioNTech and Moderna vaccines.

Let me propose the following framework:

1. Subjects should be informed if any candidate vaccine is authorized (not just the vaccine in their own study)

2. Like any study subjects, those in vaccine trials should be given the opportunity to leave the trial at any time
3. Given the shortages of available product, subjects should be offered vaccination with an authorized vaccine as soon as it is offered to those in their clinical or demographic group, in accordance with federal/state guidelines
4. Those for whom the product is not yet recommended can continue to be followed in blinded fashion (up to six months in the Pfizer trial)
5. If vaccination is recommended for an individual, a good option is to do so in a blinded crossover manner (those in the placebo group get the vaccine/those in the vaccine group get a placebo; neither is told what they have received) to facilitate blinded follow-up for long-term safety and efficacy outcomes.

I believe that this will facilitate the collection of essential data while honoring the contributions of the tens of thousands of people whose altruistic efforts have brought us to where we are today.