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December 22, 2020

Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Peter Marks, M.D., Ph.D.
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 2099

Frances Collins, M.D.
Director
National Institutes of Health
U.S. Department of Health and Human Services
9000 Rockville Pike
Bethesda, Maryland 20892

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
U.S. Department of Health and Human Services
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Commissioner Hahn, Dr. Marks, Dr. Collins, and Dr. Fauci:

As you know, in the past 11 days the first two COVID-19 vaccines were granted emergency use authorization (EUA) by the Food and Drug Administration (FDA). The announcement of each authorization was accompanied by the first public disclosure of the FDA-required patient fact sheet, to be given out when vaccination occurs.^{1,2} Because studies on the vaccines are continuing, the fact sheets accurately state that the vaccines “may not protect everyone.” Other information about the vaccine itself also includes accurate reviews of the benefits and risks of vaccination with each vaccine. But the fact sheets unacceptably fail to include any mention of the crucial relationship between vaccination and the other proven public health measures needed to contain the pandemic, now almost a year after it began. This must be promptly remedied.

It would be impossible to disagree with either of the following helpful answers to questions people must have when considering vaccination in the context of current public health measures. However, none of this critically important indisputable advice is mentioned in the FDA-approved patient fact sheets:

Why would a vaccine be needed if we can do other things, like social distancing and wearing masks, to prevent the virus that causes COVID-19 from spreading?

Stopping a pandemic requires using all the tools available. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Other steps, like covering

¹ Pfizer and BioNTech. Fact sheet for recipients and caregivers: Emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19) in individuals 16 years of age and older. December 2020. <https://www.fda.gov/media/144414/download>. Accessed December 22, 2020.

² Moderna TX. Fact sheet for recipients and caregivers: Emergency use authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19) in individuals 18 years of age and older. December 2020. <https://www.fda.gov/media/144638/download>. Accessed December 22, 2020.

your mouth and nose with a mask and staying at least 6 feet away from others, help reduce your chance of being exposed to the virus or spreading it to others. Together, COVID-19 vaccination and following CDC's recommendations [to protect yourself and others](#) will offer the best protection from COVID-19.

Do I need to wear a mask and avoid close contact with others if I have received 2 doses of the vaccine?

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real life conditions, it will be important for everyone to continue using **all the tools** available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following CDC's recommendations for [how to protect yourself and others](#) will offer the best protection from getting and spreading COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.³

These answers to such frequently asked important questions appear to have been first posted on the Centers for Disease Control and Prevention's (CDC's) website on Friday, December 18, the day the Moderna-National Institutes of Health (NIH) vaccine's EUA was announced along with the release of another FDA-approved, but deficient fact sheet that was similar to the patient fact sheet for the Pfizer-BioNTech vaccine released a week earlier. However, the FDA leadership has long been aware of the importance of continuing these proven public health measures in individuals receiving COVID-19 vaccines and was quite negligent in failing to require that such information be incorporated into the patient fact sheets of these vaccines.

Faced with a deadly surge of COVID-19 in this country, everyone is being urged to wear masks and engage in social distancing. The glaring absence of this successful public health advice in the FDA-approved patient vaccine fact sheets feeds dangerous inclinations that once people are vaccinated, being less careful is justified. Despite current evidence that both vaccines are highly effective, there is still understandable concern about the danger of such a false sense of security. If those getting vaccinated do not adhere to proven, preventive public health measures such as wearing masks and appropriate social distancing, the vaccine alone might be less protective of the public's health.

The FDA must promptly update the Pfizer-BioNTech and Moderna-NIH COVID-19 vaccine fact sheets to include this critical information. The agency must also ensure that subsequent fact sheets for other vaccines include the importance of continuing these practices. The probability of a typical vaccine recipient later getting this information only from the CDC web site pales in comparison with the certainty of getting the fact sheet when vaccinated. FDA failure to promptly update the fact sheets would likely increase the dangerous public health laxity that has plagued earlier, pre-vaccine efforts to reduce the magnitude of the pandemic.

³ Centers for Disease Control and Prevention. Frequently asked questions about COVID-19 vaccines. December 20, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>. Accessed December 22, 2020.

I look forward to a prompt response to this urgent letter.

A handwritten signature in black ink that reads "Sidney Wolfe M.D." in a cursive style.

Sidney Wolfe, M.D.
Founder, Senior Advisor
Public Citizen Health Research Group