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Testimony Before the FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) Concerning the EUA of the Moderna-NIH COVID-19 Vaccine for the Prevention of COVID-19

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I am Dr. Sidney Wolfe, Founder and Senior Adviser of Public Citizen’s Health Research Group. I have no conflicts of interest.

During the October 22, 2020, meeting of this committee, before we had seen the data from either the Pfizer-BioNTech or Moderna-NIH vaccines, the Food and Drug Administration’s (FDA’s) Dr. Doran Fink from the Center for Biologics Evaluation and Research pointed out that “deployment of a weakly effective COVID-19 vaccine could result in more harm than good. It could do so by providing a false sense of security that interferes with measures to reduce SARS-CoV transmission, such as wearing of masks and other PPE and social distancing.”¹

Even with current evidence that both vaccines are highly efficacious, there is still understandable concern about the danger of a false sense of security, if those getting vaccinated no longer adhere to proven, preventive public health measures such as wearing masks and appropriate social distancing.

The FDA’s 2017 Emergency Use Authorization (EUA) guidance² included a requirement for an FDA-approved patient Fact Sheet to accompany the use of any EUA product “to ensure that recipients are informed about the [product] they receive under an EUA” and to inform them “[o]f any available alternatives to the product and of the risks and benefits of available alternatives.” Other information would include a description of the disease/condition for which the product is authorized and an explanation of the intended use of the product.

Since 2017, no EUA for a vaccine had been granted, prior to the Pfizer-BioNTech vaccine, but providing written information about proven public health measures such as wearing masks and appropriate social distancing is necessary and appropriate for COVID-19 vaccine recipients.

¹ Food and Drug Administration. Transcript of 161st Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting. October 22, 2020. <https://www.fda.gov/media/143982/download>. Accessed December 16, 2020. PDF page 182.

² Food and Drug Administration. Emergency use authorization of medical products and related authorities. January 2017. <https://www.fda.gov/media/97321/download>. Accessed December 16, 2020.

Less than 24 hours after the EUA for the Pfizer-BioNTech vaccine was granted last Friday, the FDA posted a Pfizer-BioNTech FACT SHEET FOR RECIPIENTS AND CAREGIVERS for recipients of their vaccine.³ The fact sheet accurately states: “The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.”

Unfortunately, it contains no mention of the need for wearing masks and appropriate social distancing. For further information, the fact sheet suggests asking the vaccination provider or “your local or state public health department” and lists web sites that do not state such preventive measures should accompany vaccination.

A separate, longer Pfizer FACT SHEET FOR VACCINATION PROVIDERS⁴ states “As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the ‘Fact Sheet for Recipients and Caregivers’.

Though necessary as part of companies’ EUA submissions, such fact sheets were not included in briefing packages provided to the public or, possibly the advisory committee for either today’s or last week’s advisory committee meetings. Such important public health additions to the fact sheets must immediately be made before millions more people are vaccinated.

³ 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 16, 2020.

⁴ Pfizer and BioNTech. Fact sheet for healthcare providers administering vaccine (vaccination providers): Emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). December 2020. <https://www.fda.gov/media/144413/download>. Accessed December 16, 2020.