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July 16, 2021

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

One of the success stories of the COVID-19 pandemic has been the speed at which safe and effective COVID-19 vaccines went from bench to bedside. The partnerships among federal government agencies and the private sector, made possible by robust funding from Congress on behalf of the American people, have produced vaccines more effective than we dared to predict and at a speed more quickly than we could have even imagined. The FDA must now work to approve Biologics License Applications for COVID-19 vaccines as quickly as possible as the pandemic continues and many remain unvaccinated because of their EUA status. Lives are at stake.

FDA's prompt issuance of Emergency Use Authorization designations for multiple COVID-19 vaccines has saved as many as 279,000 lives and prevented 1.25 million hospitalizations in the United States.[1] However, every day in this country people are still hospitalized and dying from COVID-19. On July 14, approximately 284 people died of COVID-19 and 20,305 were hospitalized. That hospitalization rate is 22% higher than two weeks prior and deaths—a lagging indicator—were up 5%.[2] And most tragically, nearly all recent COVID-19 hospitalizations and deaths are individuals who are not fully vaccinated. The Associated Press examined COVID-19 hospitalizations and deaths in the United States in May and found that those fully vaccinated were only 1.1% of hospitalizations and 0.8% of deaths.[3] This means nearly all hospitalizations and deaths from COVID-19 are preventable, and so working to encourage individuals to get vaccinated must be everyone's top priority.

[1] https://news.yale.edu/2021/07/08/us-vaccination-campaign-prevented-279000-covid-19-deaths
[2] https://www.nytimes.com/interactive/2021/us/covid-cases.html
[3] https://apnews.com/article/coronavirus-pandemic-health-941fcf43d9731c76c16e7354f5d5e187

One meaningful way to increase COVID-19 vaccination rates is for FDA to grant full approval to one or more COVID-19 vaccines. Kaiser Family Foundation, which has been conducting tracking polls about COVID-19 vaccinations, found in May that 32% of unvaccinated adults, including 44% of those who say they want to "wait and see" how the vaccines are working for others before getting it themselves, say they would be more likely to get vaccinated if a vaccine received full FDA approval.[4] And I have heard this directly from health care providers on the front lines, who tell me that unvaccinated individuals they talk to sometimes think the phrase is "experimental" use authorization and who are fearful of getting a vaccine that's not fully approved. Many of these individuals are from historically marginalized groups that *have* been experimented on, so we can understand why many of them are now in the "wait-and-see" group.

I am proud of FDA's commitment to ensuring the safety and efficacy of everything you authorize and approve. And I don't agree with those who charge that FDA is not working fast enough. Indeed, I am saying the current EUAs and our situation are unique and FDA must work differently: FDA set a high bar for manufacturers to meet in order to be granted EUA, which led to overwhelmingly effective vaccines safe enough to not just allow but *recommend* almost universally with few surprises after more than 336 million doses administered. EUAs should be granted selectively, but once they are and if they are successful, the path to licensure should be different and take into consideration the real-world safety and efficacy data gained from that experience. And the experience of those 336 million doses has shown these authorized vaccines are "safe, potent, and pure,"[5] and should be approved.

FDA Center for Biologics Evaluation and Research Director Peter Marks rightly noted that "any vaccine approval without completion of the high-quality review and evaluation that Americans expect the agency to perform would undermine the F.D.A.'s statutory responsibilities [and] affect public trust in the agency…"[6] I don't disagree. I do believe, however, that the high-quality review and evaluation the FDA has already done is why vaccinated individuals trusted those 336 million doses. FDA must decide how much more review and evaluation is worth the lives of those unvaccinated individuals who are waiting for the FDA to act.

Sincerely,

Ami Bera, M.D.
Member of Congress

Cc: Peter Marks, M.D., Ph.D.
Director, Center for Biologics Evaluation and Research

[4] https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-may-2021/
[5] https://www.law.cornell.edu/uscode/text/42/262
[6] https://www.nytimes.com/2021/07/09/opinion/letters/fda-covid-vaccines.html