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August 2, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dr. Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, M.D. 20993

Secretary Becerra and Acting Commissioner Woodcock:

Thank you for your contribution in addressing the COVID-19 pandemic. As of today, over 164 million Americans have been fully vaccinated and/or have gained immunity through natural infection.[1] However, the delta variant now poses a threat to undo the significant progress we made to restore our way of life. In order to combat the delta variant, federal agencies must remain committed to providing expeditious and complementary patient-centered solutions. To this end, I urge the Food and Drug Administration (FDA) to work expeditiously in approving Biologics License Applications (BLA) for COVID-19 vaccines.

In early May, Pfizer announced the initiation of the BLA for the approval of their vaccine for patients 16 years and older.[2] It was completed in a matter of weeks, and FDA formally accepted the application and granted it a Priority Review designation in mid-July.[3] Similarly, Moderna announced its initiation of the rolling BLA application for patients 18 years and older in June.[4] The goal date for a decision on Pfizer's BLA is January 2022, however, it is my understanding that there are no regulatory constraints to fully approve their application before this deadline. Success may be right

[1] U.S. Centers for Disease Control and Prevention, COVID-19 Vaccinations in the United States, accessed August 2, 2021, https://covid.cdc.gov/covid-data-tracker/#vaccinations.
[2] Pfizer, Pfizer and Biotech Initiate Rolling Submission of Biologics License Application for U.S. FDA Approval of Their COVID-19 Vaccine, May 7, 2021, https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-biologics.
[3] BioNTech, U.S. FDA Grants Priority Review for the Biologics License Application for Pfizer-BioNTech COVID-19 Vaccine, July 16, 2021, https://investors.biontech.de/news-releases/news-release-details/us-fda-grants-priority-review-biologics-license-application.
[4] Moderna, Moderna Announces Initiation of Rolling Submission of Biologics License Application (BLA) with U.S. FDA for the Moderna COVID-19 Vaccine, June 1, 2021, https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-initiation-rolling-submission-biologics.

around the corner as robust amounts of clinical data and real-world evidence can substantiate the clinical benefit of the vaccine for various patient populations.

As the FDA considers these applications, I also urge the FDA and other HHS agencies to strongly consider emerging real-world evidence and conduct its own research that will increase the level of protection for our most vulnerable patient populations. As you know, COVID-19 disproportionately impacts senior citizens and patients with underlying health conditions.[5] Specifically, 95 percent of COVID-19 deaths in the U.S. occurred for patients over 50 years of age with about 8 in 10 deaths over 65 years, and 83 percent of all deaths occurred in patients with pre-existing comorbidities.[6] Recognizing the need to prioritize efforts on the most vulnerable patients, several countries have or are planning to give booster shots. The Israel health ministry implemented a plan to give booster shots to patients over 60 following a review of vaccine and breakthrough infection data.[7, 8, 9] The United Kingdom and Germany recently announced that their health agencies are preparing to offer COVID-19 vaccine boosters as early as next month.[10] The United Kingdom released a report on their potential booster program prioritizing vulnerable patients as noted above, but also included household contacts for immunosuppressed patients.[11]

I urge the FDA to reach a decision as quickly as possible because full approval will help get more shots into arms. The BLA review involves a deeper dive of data for safety and effectiveness, and across the country, unvaccinated Americans say that the FDA approval could be the deciding factor in them choosing to receive the vaccine.[12, 13, 14] A recent Kaiser Family Foundation poll found that over 30 percent of unvaccinated Americans were waiting for vaccines to receive full approval.[15] While there is no single silver bullet to address vaccine hesitancy, I do know that patients are more willing to accept a fully approved medical product.

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[5] David Yanez, Noel Weiss, and Miriam Treggiari, "COVID-19 mortality risk for older men and women," *BMC Public Health*, 20:1742 (2020), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09826-8. *See also* Seung-Ji Kang and Sook In Jung, "Age-Related Morbidity and Mortality among Patients with COVID-19," June 2020, 52(2), pp 154-164, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7335648/.

[6] AJMC, Contributor: Links Between COVID-19 Comorbidities, Mortality Detailed in FAIR Health Study, by Robin Gelburd, November 11, 2020, https://www.ajmc.com/view/contributor-links-between-covid-19-comorbidities-mortality-detailed-in-fair-health-study.

[7] NPR, Israel Is Offering Its Older Citizens A 3rd COVID-19 Shot As Infections Rise, July 29, 2021, https://www.npr.org/sections/coronavirus-live-updates/2021/07/29/1022334531/israel-covid-booster-shot-vaccine-coronavirus.

[8] Pfizer, page 25, https://s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-Earnings-Charts-FINAL.pdf.

[9] Foreign Policy, The Science Says Everyone Needs a COVID-19 Booster Shot—and Soon, by Laurie Garrett, July 30, 2021, https://foreignpolicy.com/2021/07/30/booster-shot-coronavirus-covid-science/.

[10] Barron's, Countries Are Preparing to Offer Booster Shots. What It Means for Vaccine Makers, by Callum Keown, August 2, 2021, https://www.barrons.com/articles/countries-are-preparing-to-offer-booster-shots-what-it-means-for-vaccine-makers-51627920318.

[11] United Kingdom Department of Health & Social Care, *Independent Report: VCVI Interim Advice: Potential COVID-19 Booster Vaccine Programme Winter 2021 to 2022*, June 30, 2021, https://www.gov.uk/government/publications/jcvi-interim-advice-on-a-potential-coronavirus-covid-19-booster-vaccine-programme-for-winter-2021-to-2022/jcvi-interim-advice-potential-covid-19-booster-vaccine-programme-winter-2021-to-2022.

[12] TIME, Too Many Americans Still Mistrust the COVID-19 Vaccines. Here's Why, by Jeffrey Kluger, January 5, 2021, https://time.com/5925467/covid-19-vaccine-hesitancy/.

[13] Fox News, Full FDA approval for COVID-19 vaccines could ease vaccine hesitancy: expert, by Jeanette Settembre, July 21, 2021, https://www.foxnews.com/health/full-fda-approval-for-covid-19-vaccines-could-ease-vaccine-hesitancy-expert.

[14] Wall Street Journal, Opinion: Full FDA Approval Is Needed to Overcome Vaccine Hesitancy, by Howard J. Zeft, M.D., July 26, 2021, https://www.wsj.com/articles/fda-approval-vaccine-hesitancy-emergency-use-delta-variant-11627078633.

[15] Kaiser Family Foundation, KFF COVID-19 Vaccine Monitor: June 2021, https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/.

As a physician, I practice evidence-based medicine and rely on the FDA's rigorous gold-level standards in ensuring the safety, efficacy and security of all medical products I use and prescribe. Full approval of the vaccines can help physicians and other health care providers better serve their patients in discussing the benefits of the vaccines, and the benefits of boosters for patients who might fail to generate a sufficient immune response. Thank you for considering this urgent request quickly issue a full approval while remaining transparent and ensuring patient safety. I look forward to your reply.

Sincerely,

Roger Marshall, M.D.
U.S. Senator