



United States Senate
Washington D.C. 20510

August 20, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Joe Biden
U.S. President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

President Biden:

Thank you for your contribution in helping to address the COVID-19 pandemic. This week, you took an additional step forward in America's vaccine strategy by declaring a plan to offer COVID-19 booster shots to fully vaccinated individuals, beginning the week of September 20.¹ This plan, if implemented, would bring us one step further on our road to recovery. However, time is of the essence. As each week passes, so increases the risk exposure for individuals with an insufficient level of protection getting infected from the delta variant. Therefore, I strongly urge you to direct the U.S. Department of Health and Human Services (HHS) and its relevant sub-operating agencies to consider real-world evidence and other clinical data to ensure all seniors are prioritized immediately.

America's seniors, ranging from the Greatest Generation to the early Baby Boomers, make up a considerable percent of our population and an even greater percent of those most vulnerable to COVID-19. 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 representing patients 65 years of age and older.² It is especially concerning for seniors in long-term care facilities as data shows COVID-19 efficacy against the delta variant has declined from 74.7 percent to 53.1 percent.³ Other data shows similar

¹ The White House, Fact Sheet: President Biden to Announce New Actions to Protect Americans from COVID-19 and Help State and Local Leaders Fight the Virus, August 18, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/18/fact-sheet-president-biden-to-announce-new-actions-to-protect-americans-from-covid-19-and-help-state-and-local-leaders-fight-the-virus/>.

² 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>.

³ U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Resident Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant – National Healthcare Safety Network, March 1-August 1, 2021, August 18, 2021 (Early Release), <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm>.

declines in efficacy for seniors.⁴ Across the state of Kansas, seniors have been calling my office, imploring the federal government to take further action and reconsider the availability of booster shots to be available sooner than announced.

Current dosing and administration for booster shots vary across patient populations in the U.S. and across the world. On August 12, the U.S. Food and Drug Administration (FDA) authorized a booster shot for certain immunocompromised individuals 28 days or more after completing the initial two-dose regimen.⁵ Overseas, Israel, United Kingdom, Canada, France, Hungary, Germany, and other countries have issued various strategies for boosters. In early July, Israel announced they would offer booster shots to immunocompromised individuals, and later in the month, their health ministry authorized booster shots to patients over 60 at least five months following a two-dose regimen.⁶ This past week, they extended the boosters to patients over 40 and teachers. This is after they dropped the eligibility age to 50 earlier this month, and their strategy followed a thorough review of vaccine and breakthrough infection data.^{7, 8, 9} The United Kingdom and Germany also 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 Hungary began their booster shot campaign early this month for seniors and certain immunocompromised individuals four months after their two-dose regimen.¹² Many of these countries' health agencies justified their recommendations based on data including the risk of complications, exposure, waning immunity, and the risk of the virus' variants. And the overwhelming majority of these agencies began or will begin with their seniors and immunocompromised patients.

Given the above, I ask you have the CDC publish and provide additional rationale as to why our dosing regimens vary across our global allies. If we are following and applying the science, why is the U.S. coming up with such dissimilar conclusions on clinical appropriateness on boosters? In

⁴ U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status – New York, May 3-July 25, 2021, August 18, 2021, <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm>.

⁵ U.S. Food and Drug Administration, Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals, August 12, 2021, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised>.

⁶ Bloomberg, Israel to Offer 3rd Covid Dose to Those With Weak Immune Systems, by Alisa Odenheimer, July 12, 2021, <https://www.bloomberg.com/news/articles/2021-07-12/israel-approves-3rd-vaccine-dose-for-immunocompromised-tv-says>. See also Wall Street Journal, Israel Begins Pfizer Booster Shots for At-Risk Adults as Delta Cases Rise, by Dov Leiber, July 12, 2021, https://www.wsj.com/articles/israel-begins-pfizer-booster-shots-for-at-risk-adults-as-delta-cases-rise-11626110100?mod=article_inline.

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, Second Quarter 2021 Earnings Teleconference, 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 Hungary Today, Hungary Starts Third “Booster” Vaccination Campaign Amid Serious Debate, July 30, 2021, <https://hungarytoday.hu/hungary-third-booster-vaccination-campaign-debate/>.

medicine, recommendations and labeling for routine vaccines are not so dissimilar across countries. And while it is not always the case, we are utilizing clinical data and other real-world evidence across other countries to inform our COVID-19 vaccine strategy. To end the pandemic, we should be working as a global community to come up with a common understanding of what the dosing and administration of COVID-19 boosters should be. And I urge to you to have the CDC Advisory Committee on Immunization Practices (ACIP) take into account international data when making recommendations, particularly for the boosters.

The ACIP, our nation's counsel tasked with issuing recommendations on vaccines, released information last Friday on what should be considered for boosters.¹³ While I question the inconsistency on the dosing timeline and patient population for the boosters, it appears ACIP is considering data the potential need for boosters for residents of long-term care facilities, seniors over 65 years of age, and health care personnel. ACIP was scheduled to meet on Tuesday, August 24 to discuss these policy considerations, however, it was announced yesterday on their website that this meeting has been delayed until August 30.¹⁴ While no additional details were provided, this lag between your announcement and the appropriate scientific review, approval, and recommendations to support boosters adds increased confusion among these vulnerable populations. I urge you to ensure that as further recommendations and prioritizations are made, our seniors and other vulnerable populations remain at the front of the line.

The now-dominant delta variant is surging and in order to combat it, federal agencies must remain committed to providing expeditious, consistent, and complementary patient-centered solutions. As you consider my concerns, please also work to ensure that the FDA remains laser-focused on prioritizing the full approval of the vaccines. This 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 have an insufficient level of protection. Thank you for considering this urgent request. I look forward to your reply.

Sincerely,

A handwritten signature in blue ink that reads "R. W. Marshall". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

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

Cc: The Honorable Xavier Becerra, Secretary, HHS
Dr. Rochelle Walensky, Director, CDC
Dr. Janet Woodcock, Acting Director, FDA
Dr. David Kessler, Chief Scientific Officer for COVID-19 Task Force, HHS

¹³ U.S. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices Committee, Considerations for Booster Doses of COVID-19 vaccines, August 13, 2021, slides 15-17,

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-13/05-COVID-Oliver-508.pdf>

¹⁴ U.S. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices, <https://www.cdc.gov/vaccines/acip/index.html?source=email..>