

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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Dr. Walensky and Dr. Woodcock:

As members of the Committee on Science, Space, and Technology, we are concerned that conflicting messages from federal health officials since the booster rollout was first announced is confusing the public and undermining confidence in the effectiveness of COVID-19 vaccines. We are also concerned that these conflicting messages will increase vaccine hesitancy and further fuel misinformation about the safety, effectiveness, and need for COVID-19 vaccines. Although evidence continues to show that COVID-19 vaccines are safe and effective at preventing illness and death from COVID-19, vaccine hesitancy remains a significant public health problem. While progress has been made to educate the public about the benefits of vaccination, only 57.2 percent of the eligible U.S. population is fully vaccinated to date.¹

Additionally, we are also dismayed that the Administration has again failed to “follow the science,” which it has repeatedly promised to do. To increase vaccine uptake, it is critical that the Administration takes a deliberate, scientific approach to its vaccine recommendations, and communicates its decisions clearly and consistently to the public. That has not been the case with the booster shots. On August 18, 2021, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released a joint statement announcing a plan to begin offering booster shots of the Pfizer and Moderna vaccines for all Americans beginning the week of September 20, starting eight months after an individual’s second vaccine dose.²

¹ *COVID-19 Vaccinations in the United States*, CENTERS FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (last visited October. 22, 2021).

² *Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots*, U.S. DEPT. OF HEALTH & HUMAN SERVICES, (August 18, 2021), <https://www.hhs.gov/about/news/2021/08/18/joint-statement-hhs-public-health-and-medical-experts-covid-19-booster-shots.html>.

Following the HHS joint statement, President Biden reiterated the booster rollout plan for the week of September 20, and the eight-month time frame.³

Just over two weeks after the August 18 announcement, a meeting took place at the White House with the CDC and FDA suggesting that the Administration scale back the plan to offer COVID-19 booster shots to the general public to give regulators more time to collect and review necessary data to inform the recommendation.⁴ Following the meeting, a White House spokesperson stated that “we always said we would follow the science, and this is all part of a process that is now underway.”⁵

On August 26, the Wall Street Journal reported that the Administration would likely approve booster shots to be administered at least six months after an individual’s second dose as opposed to the eight-month period previously announced. An unnamed source familiar with the plan stated that “data from vaccine manufacturers and other countries under review by the FDA is based on boosters being given at six months.”⁶ The next day, President Biden met with Israeli Prime Minister Naftali Bennett at the White House and stated that the Administration was considering shortening the timeline to five months after an individual’s second dose, based on Israeli data on the effectiveness of COVID-19 vaccines over time.⁷ Later that afternoon, the White House walked back the President’s comments, stating that “the President would rely on any guidance by the CDC and the FDA and his health and medical experts. That guidance continues to be eight months. That has not changed.”⁸

Adding further to the confusion, on September 13, *The Lancet* medical journal published an opinion piece—signed by two senior FDA officials—that stated, “current evidence does not...appear to show a need for boosting in the general population, in which efficacy against severe disease remains high,” and that “widespread boosting should be undertaken only if there is clear evidence that it is appropriate.”⁹

³ *Remarks by President Biden on Fighting the COVID-19 Pandemic*, THE WHITE HOUSE, (August 18, 2021), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/18/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-2/>.

⁴ Sharon LeFraniere & Noah Weiland, *Health Officials Advise White House to Scale Back Booster Plan for Now*, NEW YORK TIMES, (Sept. 3, 2021), <https://www.nytimes.com/2021/09/03/us/politics/coronavirus-booster-shots.html>.

⁵ *Id.*

⁶ Stephanie Armour & Jared S. Hopkins, *Biden Administration Likely to Approve Covid-19 Boosters at Six Months*, WALL STREET JOURNAL, (August 26, 2021), <https://www.wsj.com/articles/biden-administration-plans-covid-19-vaccine-boosters-at-six-months-instead-of-eight-11629919356>.

⁷ Rich Mendez, *Biden says U.S. health officials are considering Covid booster shots at 5 months, moving up timeline of third shot*, CNBC, (August 27, 2021), <https://www.cnbc.com/2021/08/27/biden-says-us-health-officials-are-considering-covid-booster-shots-within-5-months.html>.

⁸ *Press Briefing by Press Secretary Jen Psaki, August 27, 2021*, THE WHITE HOUSE, (August 27, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/08/27/press-briefing-by-press-secretary-jen-psaki-august-27-2021/>.

⁹ Philip R. Krause, MD et al., *Considerations in boosting COVID-19 vaccine immune responses*, THE LANCET, (Sept. 13, 2021), available at: <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902046-8>.

On September 17, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to consider Pfizer's application to authorize booster shots for all adult recipients of the Pfizer vaccine.¹⁰ The VRBPAC recommended an emergency use authorization (EUA) for boosters to recipients ages 65 and older and those at high risk of COVID-19 six months after their second dose. The VRBPAC rejected the broader application to recommend boosters for all adults.

Shortly after the VRBPAC made its recommendation, National Institutes of Health (NIH) Director Francis Collins and National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony Fauci publicly endorsed the FDA's recommendation to limit boosters to individuals 65 and older and individuals at high risk for severe disease, despite initially suggesting boosters for all previously vaccinated adults.¹¹

On September 22, the FDA issued an EUA for Pfizer boosters to be administered at least six months after completion of primary vaccination to individuals 65 years of age and older; individuals 18-64 years of age at high risk of severe COVID-19; and individuals 18-64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.¹²

On September 23, the CDC Advisory Committee on Immunization Practices (ACIP) voted to recommend Pfizer boosters six months after primary vaccination to individuals 65 years of age and older; individuals 50-64 years of age with underlying medical conditions; and individuals 18-49 years of age with underlying medical conditions.¹³ However, the ACIP voted against recommending booster shots for individuals 18-64 at increased risk of COVID-19 exposure and transmission because of occupational or institutional setting, contrary to the VRBPAC's recommendation. The next day, CDC Director Rochelle Walensky overruled the ACIP's decision not to recommend boosters for individuals in high risk occupational and institutional settings, to align with the FDA EUA and expand eligibility of the Pfizer booster to more populations.¹⁴

On October 14, the VRBPAC met to consider amending the EUA of the Moderna COVID-19 vaccine for the administration of a booster dose in individuals 18 years of age and older.¹⁵

¹⁰ *Vaccines and Related Biological Products Advisory Committee September 17, 2021 Meeting Announcement*, U.S. FOOD AND DRUG ADMIN., (Sept. 17, 2021), <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement>.

¹¹ Brianna Crummy, *Collins, Fauci endorse and explain FDA's recommendation for limited use of boosters*, POLITICO, (Sept. 19, 2021), <https://www.politico.com/news/2021/09/19/collins-fauci-endorse-fda-vaccine-boosters-512749>.

¹² FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations, U.S. FOOD AND DRUG ADMIN., (Sept. 22, 2021), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations>.

¹³ Emma Bowman, *A CDC Panel Backs Booster Shots For Older Adults, A Step Toward Making Them Available*, NPR, (Sept. 23, 2021), <https://www.npr.org/sections/coronavirus-live-updates/2021/09/23/1040078971/cdc-covid-19-pfizer-boosters-adults-guidance>.

¹⁴ *CDC Statement on ACIP Booster Recommendations*, CENTERS FOR DISEASE CONTROL & PREVENTION, (Sept. 24, 2021), <https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html>.

¹⁵ *Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Announcement*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement>.

The VRBPAC unanimously recommended an EUA for boosters to recipients ages 65 and older and those at high risk of COVID-19 due to underlying conditions or due to institutional or occupation exposure six months after their second dose.¹⁶

On October 15, the VRBPAC met to consider amending the EUA of the J&J COVID-19 vaccine for the administration of a booster dose in individuals 18 years of age and older.¹⁷ The VRBPAC also heard a presentation from the NIH and NIAID on the heterologous (or “mix and match”) use of booster doses following the primary series of the Pfizer, Moderna, and J&J COVID-19 vaccines.¹⁸ The VRBPAC unanimously recommended an EUA for J&J boosters to everyone 18 years of age and older who have already received the single-shot J&J vaccine at least two months after initial vaccination.¹⁹

Just days before the October 15 VRBPAC meeting, FDA scientists published an analysis on J&J’s application for a booster shot questioning the strength of the data provided by J&J to support booster shots and stated that the FDA had not yet verified all of the available data.²⁰ Before the October 15 VRBPAC vote, some committee members asked the FDA if they could postpone a decision on J&J boosters and others wondered why the FDA presented the J&J application before the VRBPAC before conducting an independent assessment of the data, as it customarily does.²¹ The New York Times reported that VRBPAC members were ultimately swayed by the argument that it would “be unfair to deny [J&J] recipients an additional shot after endorsing boosters for recipients of the other two vaccines, especially in the face of evidence that [J&J] offers the weakest protection of the three.”²²

On October 18, the New York Times reported that the FDA was planning to allow individuals to receive a different COVID-19 vaccine booster shot than what they received for their initial vaccination.²³ This reporting came days after the NIH and NIAID briefed the VRBPAC on early findings from a study on “mix and match” booster shots.

[and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement](#) (last visited Oct. 21, 2021).

¹⁶ Sharon LaFraniere and Noah Weiland, *F.D.A. Panel Recommends Booster for Many Moderna Vaccine Recipients*, NEW YORK TIMES, (Oct. 14, 2021), <https://www.nytimes.com/2021/10/14/us/politics/fda-moderna-vaccine-booster.html>.

¹⁷ *Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Announcement*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement> (last visited Oct. 21, 2021).

¹⁸ *DMID 21-0012 - Heterologous Platform Boost Study*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/media/153128/download> (last visited Oct. 21, 2021).

¹⁹ Berkeley Lovelace Jr. and Robert Towey, *FDA panel unanimously recommends J&J Covid booster shots to adults who already got the first dose*, CNBC, (Oct. 15, 2021), <https://www.cnbc.com/2021/10/15/fda-panel-unanimously-recommends-jj-covid-booster-shots-to-millions-of-americans.html>.

²⁰ *Id.*

²¹ *Id.*

²² Sharon LaFraniere, Noah Weiland and Carl Zimmer, *F.D.A. Panel Unanimously Recommends Johnson & Johnson Booster Shots*, NEW YORK TIMES, (Oct. 15, 2021), <https://www.nytimes.com/2021/10/15/health/johnson-johnson-vaccine-booster.html>.

²³ Sharon LeFraniere and Noah Weiland, *F.D.A. to Allow ‘Mix and Match’ Approach for Covid Booster Shots*, NEW YORK TIMES, (Oct. 18, 2021), <https://www.nytimes.com/2021/10/18/us/politics/fda-mix-and-match-boosters.html>

The study suggested that J&J recipients may benefit more from a Moderna or Pfizer booster in lieu of the J&J booster, due to higher antibody levels derived from the former relative to the latter. Researchers at the meeting emphasized that these findings were preliminary, based on a small group of volunteers and short-term findings, and used antibody levels as the sole measure for calculating immune response.²⁴

On October 20, the FDA authorized EUAs for Moderna and J&J booster doses as well as “mix and match” booster doses.²⁵ The Moderna EUA authorizes a single booster dose of the vaccine at least six months after completion of the primary series to individuals 65 years of age and older; individuals 18-64 years of age at high risk of severe COVID-19; and individuals 18-64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.²⁶ The J&J EUA authorizes a single booster dose of the vaccine to be administered at least two months after completion of the single-dose primary regimen to individuals 18 years of age and older.²⁷ For “mix and match” doses, the FDA issued an EUA authorizing the use of each available COVID-19 vaccine as a heterologous booster dose in eligible individuals following the completion of primary vaccination with a different COVID-19 vaccine.²⁸

On October 21, the CDC ACIP voted unanimously to recommend Moderna and J&J boosters as well as “mix and match” booster doses for certain populations with CDC Director Walenky’s sign off later that evening.²⁹ The CDC formally expanded booster shot eligibility for recipients of the Pfizer and Moderna vaccine six months or more after their initial vaccination series for individuals 65 years of age and older; individuals 18 years of age and older in long-term care settings, individuals 18 years of age and older with underlying medical conditions; and individuals 18 years of age and older who work or live in high-risk settings.³⁰ The CDC also formally recommended booster shots for recipients of the J&J vaccine 18 years of age and older who were vaccinated two or more months ago.³¹ Additionally, the CDC stated that individuals eligible for a booster shot may choose whichever vaccine they prefer for their booster shot and that they receive a different vaccine than they originally received if they prefer to allow for mix and match dosing for booster shots.³²

Announcing the booster rollout before regulators had the chance to properly and thoroughly review data to determine whether boosters were safe and necessary undermines the Administration’s supposed commitment to “following the science,” and ultimately could weaken public trust in recommendations and decisions from the CDC and FDA.

²⁴ *Id.*

²⁵ Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines>.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ Manas Mishra and Julie Steenhuyzen, *U.S. CDC signs off on Moderna, J&J COVID-19 vaccine boosters, mix-and-match shots*, REUTERS, (Oct. 21, 2021), <https://www.reuters.com/world/us/us-cdc-advisers-weigh-moderna-jj-covid-19-vaccine-boosters-mix-and-match-shots-2021-10-21/>.

³⁰ *CDC Expands Eligibility for COVID-19 Booster Shots*, CENTERS FOR DISEASE CONTROL & PREVENTION, (Oct. 21, 2021), <https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html>.

³¹ *Id.*

³² *Id.*

Moreover, recent reporting has indicated that, contrary to the Administration's commitment to "follow the science," the initial push to announce a broad booster rollout was based in part on fears about supply chain disruptions.³³ While supply concerns are an appropriate policy consideration, such concerns should not usurp a rigorous scientific analysis of the efficacy and necessity of boosters. Unfortunately, it appears that is precisely what occurred in this case.

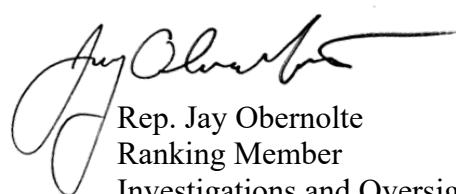
The Science Committee has held several oversight hearings and briefings on COVID-19 since the pandemic began. To further aid the Committee's efforts in this regard, we request a Member-level briefing on the Biden Administration's process surrounding the recommendation for booster shots of the Pfizer-BioNTech, Moderna, and J&J COVID-19 vaccines, as well as the science, data, information, and other considerations that the Administration relied on to support these decisions.

We ask that you please provide this briefing as soon as possible, but no later than November 5, 2021. Please contact Ms. Anna Ferrara of the Science Committee minority staff with any questions related to this request at Anna.Ferrara@mail.house.gov.

Finally, we would be remiss if we neglected to note our disappointment that the FDA remains without a permanent leader due to President Biden's failure to nominate a Commissioner, despite being in the middle of a public health emergency. President Biden should immediately nominate a Commissioner to provide the FDA with the leadership needed to get through this pandemic with scientifically informed decision-making.

Thank you for your attention to this matter.

Sincerely,



Rep. Jay Obernolte
Ranking Member
Investigations and Oversight
Subcommittee



Rep. Frank D. Lucas
Ranking Member
Committee on Science, Space
and Technology

cc: Rep. Bill Foster, Chairman, Investigations and Oversight Subcommittee
Rep. Eddie Bernice Johnson, Chairwoman, Committee on Science, Space, and Technology

³³ Erin Banco, *Vaccine supply fears motivated White House booster push*, POLITICO, (Sept. 20, 2021), <https://www.politico.com/news/2021/09/20/biden-vaccine-booster-supply-513134>.