

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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April 20, 2021

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Dr. Janet Woodcock
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Food and Drug Administration
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Dr. Walensky and Dr. Woodcock:

We write to request a briefing on the Biden administration's recent decision to pause the use of the Johnson & Johnson (J&J) COVID-19 vaccine, as well as the science, data, information, and other considerations that the administration relied on to support its decision.

On February 27, 2021, U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the J&J vaccine for the prevention of COVID-19.¹ Since then, more than 7.9 million doses of the vaccine have been administered in the United States.² On April 13, 2021, the Centers for Disease Control and Prevention (CDC) and the FDA announced in a joint statement that they are reviewing data involving six reported cases of a rare and severe type of blood clot called cerebral venous sinus thrombosis (CVST) that was seen in combination with low levels of blood platelets in women between ages 18 and 48 after receiving the J&J vaccine.³ In response to these six reported adverse events, the CDC and FDA jointly recommended a "pause in the use of [the J&J] vaccine out of an abundance of caution."⁴ All 50 states, Puerto

¹ *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Feb. 27, 2021), <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine>.

² *COVID Data Tracker*, CENTERS FOR DISEASE CONTROL & PREVENTION, <https://covid.cdc.gov/covid-data-tracker/#vaccinations> (last visited Apr. 16, 2021).

³ *Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Apr. 13, 2021), <https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine>.

⁴ *Id.*

Rico, and Washington, D.C., have headed the recommendation to “pause” the use of the J&J vaccine as of April 13, 2021.⁵

According to reports the pause was initiated to permit the CDC and the FDA to assess, investigate, and recommend whether, and if so, how and under what conditions use of the J&J vaccine should continue.⁶ The Biden administration has indicated that it will rely on the Advisory Committee on Immunization Practices (ACIP) and the FDA to investigate and review the cases prior to lifting the pause,⁷ but thus far has not provided information on how or a clear timeline for when this will be accomplished.

The ACIP convened an emergency meeting on April 14, 2021, to review and discuss the safety data around the J&J vaccine, analyze the clinical information about the six reported adverse events, and to deliberate on any updates to recommendations and uses of the vaccine.⁸ The ACIP adjourned its emergency meeting without reaching a determination as to whether use of the vaccine should be continued, discontinued, or otherwise limited based on certain demographics, citing a lack of information to support an informed decision.⁹ The ACIP is set to reconvene on April 23 to consider additional data from J&J on the six reported adverse events that may be linked to the vaccine.¹⁰ To date, no causal connection between the CVST events and the J&J vaccine have been established.

We are concerned that the pause could ultimately do more harm than good. Fewer than one case per million reported developing the rare blood clot after receiving the J&J vaccine, which raises concern that the “pause” may be an overreaction with unintended, adverse consequences. In particular, we are concerned that this decision could further increase vaccine hesitancy and fuel conspiracy theories and disinformation about the benefits of getting vaccinated. Vaccine hesitancy is one of the biggest challenges for vaccination efforts, and progress has been made to educate Americans about the benefits of vaccines and counter such misinformation.¹¹ The longer it takes to resolve this situation, the greater the risk that vaccine hesitancy and disinformation about vaccines will increase as a result.

⁵ Noah Weiland, Sharon LaFraniere & Carl Zimmer, *Johnson & Johnson Vaccinations Paused After Rare Clotting Cases Emerge*, N.Y. TIMES (Apr. 13, 2021), <https://www.nytimes.com/2021/04/13/us/politics/johnson-johnson-vaccine-blood-clots-fda-cdc.html>.

⁶ *Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Apr. 13, 2021), <https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html>.

⁷ *Id.*

⁸ *Press Briefing by White House COVID-19 Response Team and Public Health Officials*, THE WHITE HOUSE (Apr. 14, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/04/14/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-28/>.

⁹ Betsy McKay & Peter Loftus, *U.S. Vaccine Panel Delays Vote on J&J Covid-19 Shot’s Blood-Clotting Risk*, WALL ST. J. (Apr. 14, 2021), <https://www.wsj.com/articles/federal-advisory-panel-to-meet-wednesday-on-j-j-vaccine-11618392603>.

¹⁰ Erin Banco, *CDC Vaccine Panel to Hold Emergency Meeting Next Week On J&J Vaccine*, POLITICO (Apr. 16, 2021), <https://subscriber.politicopro.com/article/2021/04/cdc-vaccine-panel-to-hold-emergency-meeting-next-week-on-j-j-vaccine-2049205>.

¹¹ Jared S. Hopkins, *J&J Covid-19 Vaccine Blood-Clot Cases Could Stir Vaccine Hesitancy*, WALL ST. J. (Apr. 14, 2021), <https://www.wsj.com/articles/j-j-covid-19-vaccine-blood-clot-cases-could-stir-vaccine-hesitancy-11618425733>.

Additionally, we are concerned the Administration has failed to “follow the science,” as it has frequently promised to do. Since President Biden took office, he has stated that “[his] Administration will lead with science and scientists.”¹² His Administration remains adamant that leading with science will boost public confidence in the vaccine rollout and show that the Federal government is tracking adverse effects in real time.¹³ But there is no indication as to what “science” was considered in making the decision to pause use of the J&J vaccine.

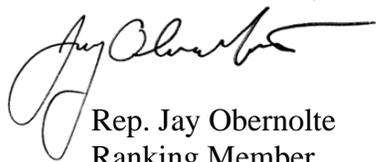
For example, did the Administration consider the science regarding the social and societal impact of sending mixed messages about vaccine safety? Did anyone in the Administration assess or analyze the data concerning vaccine hesitancy and what impact its decision to pause use of the vaccine could have on efforts to improve vaccine uptake? Was there any consideration of the potential impact that pausing the only single-dose COVID-19 vaccine could have on rural and underserved communities, including the homeless? These are important questions that to date remain unanswered.

The Science Committee has held several hearings and a series of briefings on COVID-19 since the onset of the pandemic. To help further the Committee’s efforts in this regard, we request a Member-level briefing on the decision to pause use of the J&J vaccine, as well as the science, data, and information that was used to support this decision. We ask that you please provide this briefing as soon as possible, but in any event, no later than May 3, 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. Thank you for your attention to this matter.

Sincerely,



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



Rep. Jay Obernolte
Ranking Member
Investigations and Oversight Subcommittee

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

¹² @JoeBiden, TWITTER (Jan. 18, 2021, 1:02 PM), <https://twitter.com/JoeBiden/status/1351228360123318272?s=20>.

¹³ Rachel Roubein & Dan Goldberg, *Sharpening Resistance: States Fret Pause in J&J Vaccine Could Drive Up Hesitancy*, POLITICO (Apr. 14, 2021), <https://www.politico.com/news/2021/04/14/states-j-j-vaccine-hesitancy-481601>.

