RON JOHNSON, WISCONSIN JAMES LANKFORD, OKLAHOMA RICK SCOTT, FLORIDA JOSH HAWLEY, MISSOURI BERNIE MORENO, OHIO JONI ERNST, IOWA ASHLEY MOODY, FLORIDA

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United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS WASHINGTON, DC 20510–6250

April 2, 2025

Mr. Joaquin Duato Chief Executive Officer Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933

Dear Mr. Duato:

On May 15, 2020, the White House announced the federal government would invest in a partnership with vaccine manufacturers—an endeavor formally named Operation Warp Speed ("OWS")—in order to swiftly deliver a COVID-19 vaccine.¹ Prior investments, including \$456 million in federal funding awarded to Johnson & Johnson ("J&J")² on March 30, 2020, by the Department of Health and Human Services ("HHS") to support the development of a COVID-19 vaccine, would later be characterized as actions taken by OWS to support vaccine manufacturing.³ On August 5, 2020, the Department of Defense ("DoD") announced that J&J was to be paid an additional \$1 billion for its delivery of 100 million vaccine doses to the federal government.⁴ On February 27, 2021, J&J's COVID-19 vaccine ("Janssen") became the third to receive Emergency Use Authorization ("EUA") from the Food and Drug Administration ("FDA") but never received full approval.⁵ Instead, J&J ultimately requested a voluntary withdrawal of its EUA on May 22, 2023.⁶ Janssen, as with other COVID-19 vaccines, has since

¹ Lauran Neergaard & Zeke Miller, *US begins 'warp speed' vaccine push as studies ramp up*, AP News (May 15, 2020), https://apnews.com/article/virus-outbreak-donald-trump-us-news-international-news-politics-756e5b743058701c4a2ebefd0af1ade4.

² For the purposes of this letter, Johnson & Johnson shall also mean any subsidiary owned or controlled by Johnson & Johnson, whether in whole or in part, including, but not limited to, Janssen Pharmaceuticals.

³ Fact Sheet, U.S. Department of Health and Human Services, *Explaining Operation Warp Speed*,

https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus-lpha/pdf/fact-sheet-operation-warp-speed.pdf.

⁴ Press Release, U.S. Department of Defense, *HHS, DOD Collaborate With Johnson & Johnson to Produce Millions of COVID-19 Investigational Vaccine Doses* (Aug. 5, 2020),

https://www.defense.gov/News/Releases/Release/article/2301220/hhs-dod-collaborate-with-johnson-johnson-to-produce-millions-of-covid-19-invest/.

⁵ Press Release, Food & Drug Administration, *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine* (Feb. 27, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine; *Janssen COVID-19 Vaccine*, Food & Drug Administration, https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/janssen-covid-19-vaccine.

⁶ Id.

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been associated with reports of adverse events following vaccination, such as Guillain-Barré Syndrome and Thrombosis with Thrombocytopenia Syndrome.⁷

Pursuant to Senate Resolution 94 (119th Cong.), the United States Senate Permanent Subcommittee on Investigations (the "Subcommittee") is conducting a review of the development and deployment of COVID-19 vaccines, as well as the adverse events and injuries associated with these vaccines.⁸ In order to assist the Subcommittee in its review, please provide the following information and records regarding the development and administration of J&J's COVID-19 vaccine.

I expect you to fully comply with this request, but I am mindful that your company may choose to mimic HHS's past efforts to conceal records about the development, safety, and efficacy of the COVID-19 vaccines.⁹ Any attempt to obstruct or delay responses to this request will result in compulsory process.

Please note, in the requests below, the term Janssen shall include all versions of the J&J COVID-19 vaccine, including, but not limited to, the version approved under the EUA in February 2021 and any subsequent booster or variant-specific COVID-19 vaccines. Unless otherwise stated, the time period for the records requested shall be January 1, 2020 to present.

- 1. The names and titles, along with the dates they held those titles, of each J&J employee involved in the development¹⁰ of Janssen;
- 2. A complete list of entities J&J contracted, collaborated, or otherwise worked with on the development and testing of Janssen, including, but not limited to, the surveillance or testing of SARS-CoV-2 variants;
- 3. All communications¹¹ referring or relating to the development of Janssen, including, but not limited to, all communications between or among J&J employees or contractors and all communications sent to or by any federal entity, employee, or contractor. This request includes, but is not limited to, communications referring or relating to:

⁷ CDC, Coronavirus Disease 2019 (COVID-19) Vaccine Safety, (Jan. 31, 2025), https://www.cdc.gov/vaccine-safety/vaccines/covid-19.html.

⁸ S. Res. 94, 119th Cong. (2025).

⁹ Kaelan Deese, Judge scraps 75-year FDA timeline to release Pfizer vaccine safety data, giving agency eight months, Wash. Examiner, Jan. 7, 2022, https://www.washingtonexaminer.com/news/2381224/judge-scraps-75-year-fda-timeline-to-release-pfizer-vaccine-safety-data-giving-agency-eight-months/.

¹⁰ For the purposes of this request, the term "development" refers to any supporting funds, research, analysis, design, or experimentation that contributed to the formulation, testing, and evaluation of COVID-19 vaccines.

¹¹ The term "communications" includes any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

- a. clinical trials for Janssen, including, but not limited to, all communications between or among J&J or external entities involved in the clinical trials;
- b. the approval of Janssen, including, but not limited to, all communications sent to or by HHS, the Centers for Disease Control and Prevention, FDA, National Institutes of Health, Vaccine Research Center at the National Institute of Allergy and Infectious Diseases, or any other federal health agency or department;
- c. all communications with DoD;
- d. adverse events associated with Janssen;
- e. adverse events associated with any COVID-19 vaccine, including, but not limited to, all communications with Moderna, Inc., Pfizer Inc., or any of their subsidiaries;
- f. the testing of Janssen against SARS-CoV-2 variants;
- g. vaccine-associated enhanced disease(s) and Janssen;¹² and
- h. the withdrawal and revocation of Janssen's EUA, including, but not limited to, the decision to voluntarily withdraw.
- 4. All communications with search engines and social media platforms referring or relating to adverse events and Janssen, including, but not limited to, the following:
 - a. Alphabet Inc.;¹³
 - b. Meta Platforms, Inc.;¹⁴ and
 - c. X Corp. (formerly known as Twitter Inc.).¹⁵

¹² For the purposes of this request, records referring or relating to "vaccine-associated enhanced disease(s)" shall include all related terms, including, but not limited to, vaccine associated respiratory enhanced disease, enhanced respiratory disease or enhanced disease, enhanced illness or enhanced illness syndrome, antibody-dependent enhancement, and all associated acronyms, abbreviations, or permutations of these and other related terms.

¹³ For the purposes of this request, Alphabet Inc. shall also mean any subsidiary owned or controlled by Alphabet Inc., whether in whole or in part, including, but not limited to, Google and YouTube.

¹⁴ For the purposes of this request, Meta Platforms, Inc. shall also mean any subsidiary owned or controlled by Meta Platforms, Inc., whether in whole or in part, including, but not limited to, Facebook, Instagram, and WhatsApp.

¹⁵ For the purposes of this request, X Corp. shall also mean any subsidiary owned or controlled by X Corp., whether in whole or in part, including, but not limited to, any predecessor or successor entity.

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Please provide the information and records requested by April 16, 2025. To expedite the Subcommittee's review, please submit the information and records responsive to this request as they become available, rather than waiting to provide them all at once. To avoid any unnecessary delays, please carefully review the *Procedures for Transmitting Documents to the Permanent Subcommittee on Investigations* and contact the Subcommittee to discuss the method and timing of J&J's production.

Sincerely,

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Ron Johnson Chairman Permanent Subcommittee on Investigations

cc: The Honorable Richard Blumenthal Ranking Member Permanent Subcommittee on Investigations