United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

April 2, 2025

Mr. Albert Bourla
Chief Executive Officer
Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001-2192

Dear Mr. Bourla:

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] On July 22, 2020, through OWS, Pfizer Inc. ("Pfizer")[2] and BioNTech SE ("BioNTech")[3] entered into a $1.95 billion advance-purchase agreement with the federal government, to be paid upon Pfizer's delivery of 100 million vaccine doses.[4] On December 11, 2020, the Pfizer-BioNTech COVID-19 vaccine became the first to receive Emergency Use Authorization ("EUA") from the Food and Drug Administration ("FDA"), but it would not receive full FDA approval until August 23, 2021, under the brand name Comirnaty.[5] Comirnaty, as with other COVID-19 vaccines, has since been associated with reports of adverse events following vaccination, such as myocarditis and pericarditis.[6]

Pursuant to Senate Resolution 94 (119th Cong.), the United States Senate Permanent Subcommittee on Investigations (the "Subcommittee") is conducting a review of the

[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, Pfizer Inc. shall also mean any subsidiary owned or controlled by Pfizer Inc., whether owned in whole or in part.

[3] For the purposes of this letter, BioNTech SE shall also mean any subsidiary owned or controlled by BioNTech SE, whether owned in whole or in part.

[4] *Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2* (Jul. 22, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600; *Was the Pfizer vaccine part of the government's Operation Warp Speed?* New York Times (Nov. 10, 2020), https://www.nytimes.com/2020/11/10/health/was-the-pfizer-vaccine-part-of-the-governments-operation-warp-speed.html; Emily Czachor, *Pfizer Avoided R&D Funding From Trump's Operation Warp Speed Because of Bureaucracy, Politics*, Newsweek (Nov. 9, 2020), https://www.newsweek.com/pfizer-avoided-rd-funding-trumps-operation-warp-speed-because-bureaucracy-politics-1546110.

[5] Press Release, Food & Drug Administration, *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine#:~:text=The%20first%20EUA%2C%20issued%20Dec,trial%20of%20thousands%20of%20individuals.

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

development and deployment of COVID-19 vaccines, as well as the adverse events and injuries associated with these vaccines.[7] In order to assist the Subcommittee in its review, please provide the following information and records regarding the development and administration of Pfizer-BioNTech's COVID-19 vaccine.

I expect you to fully comply with this request, but I am mindful that your company may choose to mimic the Department of Health and Human Services' ("HHS") past efforts to conceal records about the development, safety, and efficacy of the COVID-19 vaccines.[8] Any attempt to obstruct or delay responses to this request will result in compulsory process.

Please note, in the requests below, the term Comirnaty shall include all versions of the Pfizer-BioNTech COVID-19 vaccine, including, but not limited to, the version approved under the December 2020 EUA and the final fully licensed COVID-19 vaccine. 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 Pfizer employee involved in the development[9] of Comirnaty;

2. A complete list of entities Pfizer contracted, collaborated, or otherwise worked with on the development and testing of Comirnaty, including, but not limited to, the surveillance or testing of SARS-CoV-2 variants;

3. All communications[10] referring or relating to the development of Comirnaty, including, but not limited to, all communications between or among Pfizer 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:

    a. clinical trials for Comirnaty, including, but not limited to, all communications between or among Pfizer, BioNTech or external entities involved in the clinical trials;
    b. the approval of Comirnaty, including, but not limited to, all communications sent to or by HHS, 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 the Department of Defense;
    d. adverse events associated with Comirnaty;

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[7] S. Res. 94, 119th Cong. (2025).
[8] 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/.
[9] 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 mRNA vaccines.
[10] 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).

e. adverse events associated with any COVID-19 vaccine, including, but not limited to, all communications with Johnson & Johnson, Moderna, Inc., or any of their subsidiaries;
f. the testing of Comirnaty against SARS-CoV-2 variants; and
g. vaccine-associated enhanced disease(s) and Comirnaty.[11]

4. All communications with search engines and social media platforms referring or relating to adverse events and Comirnaty, including, but not limited to, the following:

   a. Alphabet Inc.; [12]
   b. Meta Platforms, Inc.;[13] and
   c. X Corp. (formerly known as Twitter Inc.).[14]

5. A complete response to my December 29, 2021 letter (enclosed).

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 Pfizer's production.

Sincerely,

Ron Johnson
Chairman
Permanent Subcommittee on Investigations

Enclosure

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

[11] 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 of related terms.
[12] 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.
[13] 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.
[14] 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.

Enclosure

United States Senate
WASHINGTON, DC 20510

December 29, 2021

Albert Bourla, DVM, Ph.D.
Chief Executive Officer
Pfizer
235 East 42nd Street
New York, NY 10017

Dear Dr. Bourla:

Due to the unprecedented number of adverse events and deaths associated with the COVID-19 vaccines on the Vaccine Adverse Event Reporting System (VAERS), independent researchers have downloaded VAERS data and begun analyzing the apparent variation in the distribution of adverse events between vaccine lots. If the production of vaccines were under control, with quality systems working properly, one would expect to see relatively even distribution of adverse events and deaths across all lots.

According to these researchers, the variation of adverse events among COVID-19 vaccine lots stands in stark contrast to a much lower degree of variation of adverse events associated with seasonal flu vaccine lots reported over a 30-year period. Furthermore, the total number of adverse events reported in COVID-19 vaccine lots appear to be much higher than the total number of adverse events reported in the context of seasonal flu vaccine lots.

Using VAERS data, these researchers found that for the past 30 years, seasonal flu vaccines have never had more than 137 adverse events reported for a single lot in VAERS. In stark contrast, in less than one year, 5,297 adverse events were associated with a single COVID-19 vaccine lot. In addition, 186 lots of COVID-19 vaccine had over 1,000 reports of adverse events, and an additional 70 lots between 500-999 reports. The researchers' analysis further shows that approximately 80% of U.S.-only adverse events reported to VAERS for COVID-19 vaccines are associated with approximately 1% of vaccine lots reported to VAERS, and approximately 80% of serious adverse events (those involving emergency room visits, hospitalization, or death) are associated with approximately 5% of specific vaccine lots reported to VAERS.

According to the researchers, as of December 3, 2021, the data comparing COVID-19 vaccine lots to seasonal flu vaccine lots spanning 30 years show the following:

	COVID-19 Vaccines	Seasonal Flu Vaccines
Total # of lots reported:	24,945	22,334
Highest # Adverse Events in one lot:		
(COVID-19: Moderna lot# 039K20A)	5,297	
(Flu: Novartis lot # 1514501)		137
# of lots with Adverse Events totaling between:		
3,000 to 5,297:	12	0
1,000 to 2,999:	174	0
500 to 999:	70	0
100 to 499:	109	10
50 to 99:	73	150
10 to 49:	695	3,779
5 to 9:	1,136	2,588
1 to 4:	22,676	15,807

Over the last year, public reporting has revealed instances where specific COVID-19 vaccine doses or lots were contaminated or linked to safety concerns. For example, in January 2021, California temporarily paused administering doses from a Moderna COVID-19 vaccine lot following reports of people having severe allergic reactions to the doses from that lot.[1] It is unclear how the California Department of Public Health made the decision to lift the pause and whether individuals from the other states that received doses from this lot experienced similar severe allergic reactions.[2]

Reports also revealed that in March 2021, Johnson & Johnson confirmed that "one vaccine batch was discarded over production issues."[3] In August 2021, Moderna reportedly recalled three lots of its vaccine in Japan after detecting a contaminant in vaccine vials.[4] These examples underscore concerns about potential problems with specific vaccine lots.

In addition, the total number of adverse events and deaths reported to VAERS for the COVID-19 vaccines should have prompted serious investigations and corrective action many months ago. As noted by federal health agencies, the reports on VAERS are "only a small

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[1] John Bonifield, *UPDATE: California pauses giving out shots from one lot of coronavirus vaccine*, CNN, Jan. 19, 2021, https://www.cnn.com/2021/01/18/health/ca-vaccine-lot-pause/index.html.

[2] According to reports, 37 states received shipments from this vaccine lot. *Id.*

[3] *Johnson & Johnson Confirms One Vaccine Batch Was Discarded Over Production Issues*, NBC News, Mar. 31, 2021, https://www nbcchicago.com/news/coronavirus/johnson-johnson-confirms-one-vaccine-batch-was-discarded-over-production-issues/2476078/.

[4] Miho Inada, *Moderna Says Covid-19 Vaccine Contaminant in Japan Was Stainless Steel*, Sees No Safety Issue, Wall Street Journal, Sept. 2, 2021, https://www.wsj.com/articles/moderna-says-covid-19-vaccine-contaminant-in-japan-was-stainless-steel-sees-no-safety-issue-11630596275.

fraction of actual adverse events."[5] Through December 17, 2021, there have been 983,758 total adverse events and 20,622 deaths reported worldwide associated with the COVID-19 vaccines. Of the 20,622 deaths, 6,232 (30%) have occurred on day 0,1, or 2 following vaccination. In contrast, over 30 years of reporting on seasonal flu vaccines, there have been a total of 200,264 adverse events and 2,078 deaths.

The significant differences between adverse event reports in the contexts of COVID-19 and seasonal flu vaccines, both in terms of absolute numbers and vaccine lot variation, should be raising major alarms with the vaccine manufacturers and federal health agencies. However, it remains unclear the extent to which vaccine manufacturers and federal health agencies have reviewed or conducted robust safety investigations based on the COVID-19-associated VAERS data.

Fortunately, VAERS data is publicly available, and these alarming safety signals have not remained totally hidden. Also fortunately, scientists and researchers have revealed, and continue to reveal, potential serious safety signals and are attempting to bring these revelations to the public and to the regulatory agencies. The experienced opinions of these independent researchers, some of whom are veterans of the pharmaceutical industry, is that the extent of variability in product safety between batches is completely outside of any normal boundaries of properly manufactured products of this highly-regulated sector.

The information detailed above raises a number of questions that need to be answered.

1. Is Pfizer aware of VAERS data showing certain COVID-19 vaccine lots with high numbers of adverse events?
    a. If so, please identify those lots.
    b. If so, what investigations or corrective action has Pfizer undertaken?
    c. If no action has been taken, please explain why.
    d. If not aware, please describe what action(s) Pfizer is taking to ensure it identifies such events in the future.
    e. In the past, has there ever been such a wide variability in the safety profile of any pharmaceutical product manufactured by Pfizer?

2. Please provide a definitive listing of all COVID-19 vaccine lots manufactured by Pfizer.

3. Does Pfizer manufacture COVID-19 vaccines in-house? If so, provide the number of manufacturing sites and the locations.

4. Does Pfizer contract with manufacturers to produce COVID-19 vaccines? If so, provide the names of those manufacturers, the number of manufacturing sites, and the locations of those sites.

[5] *Guide to Interpreting VAERS Data*, Centers for Disease Control and Prevention, Food and Drug Administration, accessed Dec. 22, 2021, https://vaers.hhs.gov/data/dataguide.html.

5. Identify the COVID-19 vaccine lots that:
    a. Have been discarded;
    b. Are no longer administered; and
    c. Are under investigation.

6. How many doses are in each COVID-19 vaccine lot?

7. If vaccine lots contain different numbers of doses, what is the range of doses across all vaccine lots?

8. How many FDA audits have been conducted at each COVID-19 vaccine manufacturing site since the vaccine received Emergency Use Authorization?
    a. Please provide the results and findings of those audits.

9. Were all COVID-19 vaccine manufacturing sites found to be in full FDA and Current Good Manufacturing Practice compliance?
    a. If not, have there been any instances where any amounts of drug substance or drug product have not been locatable at the time of the inspection? If so, how often has this occurred?

10. What specific quality control checks are performed on each vaccine lot?

11. What is the statistical sampling criteria for each quality check?

12. What quality control information does Pfizer provide federal health agencies regarding the manufacturing of its COVID-19 vaccine?
    a. On a routine basis?
    b. As part of Pfizer's ongoing quality surveillance requirements?

13. What do the numbers and alpha characters represent in Pfizer's lot numbering system?
    a. Can the manufacturing location be identified by the lot number? How?
    b. Can the manufacturing date be identified by the lot number? How?
    c. What other manufacturing information is captured in the lot number?

Please provide this information no later than January 12, 2022. Thank you for your attention to this important matter.

Sincerely,

Ron Johnson
United States Senator