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ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives

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SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS

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<https://coronavirus.house.gov>

December 16, 2020

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Mr. Christopher C. Miller
Acting Secretary
Department of Defense
1000 Defense Pentagon
Washington, D.C. 2030

Dear Secretary Azar and Acting Secretary Miller:

We applaud the Food and Drug Administration's (FDA) recent emergency authorization of a coronavirus vaccine developed by Pfizer and BioNTech based in part on techniques pioneered by the National Institutes of Health. This historic development is the culmination of countless hours of work by dedicated scientists and public servants, and the new vaccine—along with others in development—has the potential to save hundreds of thousands of American lives. However, recent public reports raise troubling questions about whether the Trump Administration missed opportunities as recently as November 2020 to purchase additional vaccine doses, which could lead to significant delays in vaccinations across the United States. We write today to seek more information on the Administration's efforts to acquire and distribute vaccines to protect Americans from coronavirus infection.

More than 300,000 Americans have lost their lives during the coronavirus pandemic¹—more than in any other nation on Earth—and experts predict that the total could exceed 500,000 by April 2021.² The successful development and swift distribution of an effective coronavirus vaccine is critical to minimizing the death toll. A vaccine is especially important in light of the Administration's failure to take other steps recommended by public health experts to contain the spread of the virus—like ensuring all Americans wear masks, avoid crowds, and have access to rapid and reliable testing.

In July 2020, the Department of Health and Human Services (HHS) and the Department of Defense (DOD) agreed to purchase 100 million doses of Pfizer's vaccine candidate following

¹ Centers for Disease Control and Prevention, *CDC COVID Data Tracker* (online at covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days) (accessed on Dec. 13, 2020).

² *Most U.S. COVID Deaths in One Day (3,100) as Latest Model Projects 539,000 by April*, Forbes (Dec. 5, 2020) (online at www.forbes.com/sites/tommybeer/2020/12/05/most-us-covid-deaths-in-one-day-3100-as-latest-model-projects-539000-by-april/?sh=44b7446c786d).

approval or emergency use authorization by FDA. Because two doses are needed per person, the purchased doses can inoculate up to 50 million Americans.³

This agreement included an option to purchase up to 500 million additional doses. However, public reporting indicates that the Trump Administration declined repeatedly to exercise this option. According to the *New York Times*:

The government was in July given the option to request 100 million to 500 million additional doses. But despite repeated warnings from Pfizer officials that demand could vastly outstrip supply and amid urges to pre-order more doses, the Trump administration turned down the offer, according to several people familiar with the discussions.⁴

Pfizer board member Dr. Scott Gottlieb, who served as FDA Commissioner under President Trump from 2017 to 2019, said the Administration declined to exercise this option even after the vaccine was shown to be over 90 percent effective on November 9, 2020.⁵ That same day, Pfizer announced that due to supply chain issues, it would only be able to produce half of initial vaccine estimates by the end of 2020—50 million doses rather than 100 million.⁶ Administration officials reportedly went back to Pfizer more recently to attempt to purchase more doses, but Pfizer told the Administration that it would not be able to provide substantial quantities of vaccine until the second quarter of 2021.⁷ According to Dr. Gottlieb:

This is an American company. We want to work with the U.S. government but this has been a challenging process because there have been multiple conversations happening as recently as November and now they're coming back and wanting to restart those conversations when other commitments have been made in the interim.⁸

The Administration's apparent decision to forego additional doses of the Pfizer vaccine raises questions about whether HHS and DOD will be able to deploy vaccinations to all who

³ *Trump Administration Officials Passed When Pfizer Offered Months Ago to Sell U.S. More Vaccine Doses*, New York Times (Dec. 7, 2020) (online at www.nytimes.com/2020/12/07/us/trump-covid-vaccine-pfizer.html).

⁴ *Id.*

⁵ *U.S. Could Have Bought Additional Pfizer Vaccines in November but Passed, Says Pfizer Board Member*, CNBC (Dec. 14, 2020) (online at www.cnbc.com/2020/12/14/covid-vaccine-us-passed-on-more-pfizer-doses-in-november-says-board-member-gottlieb.html).

⁶ *Supply-Chain Obstacles Led to Last Month's Cut to Pfizer's COVID-19 Vaccine-Rollout Target*, Wall Street Journal (Dec. 3, 2020) (online at www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787).

⁷ *Pfizer Tells U.S. Officials it Cannot Supply Substantial Additional Vaccine Until Late June or July*, Washington Post (Dec. 8, 2020) (online at www.washingtonpost.com/health/2020/12/07/pfizer-vaccine-doses-trump/).

⁸ *U.S. Could Have Bought Additional Pfizer Vaccines in November But Passed, Says Pfizer Board Member*, CNBC (Dec. 14, 2020) (online at www.cnbc.com/2020/12/14/covid-vaccine-us-passed-on-more-pfizer-doses-in-november-says-board-member-gottlieb.html).

need them.⁹ So far, one vaccine candidate has been approved and two others have shown promising results, but the Administration has not yet made clear how or when sufficient doses will be available to most Americans.

Congress has been investigating plans for vaccine acquisition and distribution for months, but the Administration has not been transparent. On July 24, 2020, the Select Subcommittee submitted a bipartisan request for the Government Accountability Office (GAO) to conduct a comprehensive review of Operation Warp Speed and related vaccine development efforts. Among other goals, this review aimed to “enhance the organization and management of the projects and reduce the risk of delays and other setbacks in this endeavor.”¹⁰

On September 15, 2020, two of us wrote to your Departments that it is “critical” for you to provide GAO “with real-time, ongoing access to information, documents, and officials” as part of this review.¹¹ Unfortunately, your Departments have not fully cooperated with GAO’s review. GAO requested information regarding Operation Warp Speed contracts in August 2020 but did not receive the Pfizer contract until late November 2020, and has still not received all the documents it requested. Had GAO been given access in a timely manner, Congress may have had notice of potential shortages of this vaccine. We urge you to provide GAO with full and immediate access to all requested documents and information so that it can conduct its review and help identify and address other potential problems.

Our nation stands at a critical juncture in the fight against coronavirus. The emergency use authorization of the first coronavirus vaccine is a remarkable breakthrough, but critical questions must be answered regarding how HHS and DOD plans to acquire and distribute sufficient vaccines to protect all Americans.

For these reasons, we request that you provide responses to the following questions by December 23, 2020. In addition, we request a briefing by December 23, 2020 regarding these matters.

⁹ Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (accessed on Dec. 13, 2020) (online at www.hhs.gov/about/news/2020/08/07/fact-sheet-explaining-operation-warp-speed.html).

¹⁰ Letter from Chairman James E. Clyburn, Rep. Mark E. Green, M.D., and Rep. Bill Foster, Select Subcommittee on the Coronavirus Crisis, to Comptroller General Gene L. Dodaro, Government Accountability Office, (July 24, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-07-24.Select%20Cmte%20to%20Dodaro-GAO%20re%20OWS%20.pdf).

¹¹ Letter from Chairman James E. Clyburn and Rep. Bill Foster, Select Subcommittee on the Coronavirus Crisis, to Secretary of Health and Human Services Alex M. Azar II (Sept. 15, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-09-15.Clyburn%20to%20Azar%20re%20OWS%20GAO%20Access%20Letter%20HHS_%20%28002%29.pdf); Letter from Chairman James E. Clyburn and Rep. Bill Foster, Select Subcommittee on the Coronavirus Crisis, to Secretary of Defense Mark T. Esper (Sept. 15, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-09-15.Clyburn%20to%20Esper%20re%20OWS%20GAO%20Access%20Letter%20DOD_%20%28002%29.pdf).

1. Did HHS and DOD decline to exercise an option to purchase between 100 million and 500 million additional doses of Pfizer's coronavirus vaccine, and if so, why?
2. Did HHS and DOD decline an opportunity to purchase additional doses of Pfizer's vaccine after it demonstrated over 90 percent efficacy in November 2020, and if so, why?
3. Did HHS and DOD recently seek to purchase additional doses of Pfizer's coronavirus vaccine, and if so, what were the results of that effort?
4. Please describe how many doses of any vaccine or vaccine candidate HHS and DOD have agreed to purchase from each manufacturer. For each purchase agreement, please identify the manufacturer, the contract vehicle, the cost, the number of doses, and the dates when the doses will be available.
5. Please explain how HHS and DOD determined the appropriate number of doses to purchase, including any data and metrics applied to these decisions.
6. Please describe any plans HHS and DOD have to purchase additional doses of any vaccine candidate and the steps being taken to ensure that additional doses will be available.
7. Do HHS and DOD plan to secure enough vaccine doses to inoculate the entire adult American population? If not, why not?

These requests are consistent with House Resolution 935, which established the Select Subcommittee on the Coronavirus Crisis "to conduct a full and complete investigation" of "issues related to the coronavirus crisis," including the "preparedness for and response to the coronavirus crisis," "the development of vaccines and treatments," and "executive branch policies, deliberations, decisions, activities, and internal and external communications related to the coronavirus crisis."

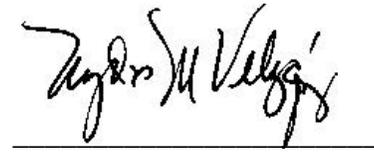
An attachment to this letter provides additional instructions for responding to the Select Subcommittee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-4400.

Sincerely,

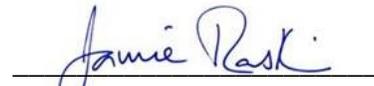

James E. Clyburn
Chairman

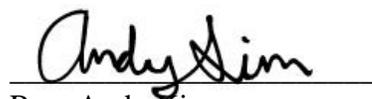

Rep. Maxine Waters


Rep. Carolyn B. Maloney


Rep. Nydia M. Velázquez


Rep. Bill Foster


Rep. Jamie Raskin


Rep. Andy Kim

cc: The Honorable Steve Scalise, Ranking Member

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.
2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.
3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.
4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.
5. Documents produced in electronic format should be organized, identified, and indexed electronically.
6. Electronic document productions should be prepared according to the following standards:
 - a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - b. Document numbers in the load file should match document Bates numbers and TIF file names.
 - c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.
8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.
9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.
10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.
11. The pendency of or potential for litigation shall not be a basis to withhold any information.
12. In accordance with 5 U.S.C. § 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.
13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.
14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.
16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.
17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.
19. All documents shall be Bates-stamped sequentially and produced sequentially.
20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.
21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.
4. The term “including” shall be construed broadly to mean “including, but not limited to.”
5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.
6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.
7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.
8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.
9. The term “individual” means all natural persons and all persons or entities acting on their behalf.