JAMES E. CLYBURN
CHAIRMAN
MAXINE WATERS
CAROLYN B. MALONEY
NYDIA M. VELÁZQUEZ
BILL FOSTER
JAMIE RASKIN
ANDY KIM

#### ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS

2157 RAYBURN HOUSE OFFICE BUILDING

Washington, DC 20515-6143

PHONE (202) 225-4400

https://coronavirus.house.gov

August 12, 2020

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

Dear Secretary Azar:

The Select Subcommittee on the Coronavirus Crisis is examining the actions of Operation Warp Speed, the Trump Administration's program to develop, manufacture, and distribute coronavirus vaccines, therapeutics, and diagnostics, as well as the potential conflicts of interest of the program's chief adviser, Dr. Moncef Slaoui. Public health experts agree that the development and equitable distribution of a safe and effective coronavirus vaccine is critical to stemming the tide of new infections and deaths from the coronavirus. Successful development of a vaccine requires scientific rigor and an open and transparent process that is free from financial and political conflicts of interest. This is especially true of a vaccine developed on an accelerated basis. The Select Subcommittee strongly supports efforts to develop and distribute a life-saving coronavirus vaccine, but I am concerned that the selection of candidate vaccines for Operation Warp Speed lacked transparency and excluded many vaccine experts. I am also concerned that Dr. Slaoui's financial interests in companies receiving federal funding—which he has referred to as "my retirement"—raise serious ethical issues and could undermine public confidence in this process.<sup>3</sup>

In early 2020, President Trump and others in his Administration downplayed the risks to Americans from the coronavirus outbreak, even as the virus spread throughout the United

STEVE SCALISE RANKING MEMBER JIM JORDAN BLAINE LUETKEMEYER JACKIE WALORSKI MARK E. GREEN, M.D.

 $<sup>^{1} \</sup>textit{Ending the COVID-19 Pandemic Requires Effective Multilateralism}, Health Affairs (May 27, 2020) \\ (online at www.healthaffairs.org/do/10.1377/hblog20200522.123995/full/).$ 

<sup>&</sup>lt;sup>2</sup> Eric M. Prager, et al., *Improving Transparency and Scientific Rigor in Academic Publishing*, Brain and Behavior (Jan. 9, 2019) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC6346653/).

<sup>&</sup>lt;sup>3</sup> Operation Warp Speed Is Fueling Vaccine Fears, Top Experts Worry, CNN (June 5, 2020) (online at www.cnn.com/2020/06/05/health/warp-speed-coronavirus-vaccine-worries/index.html); Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflict of Interest, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html).

States. As the devastating impact of the virus became clear, the President pivoted to promises of a quick resolution via the development of a novel vaccine. On May 2, 2020, the President said he was "very confident" a vaccine would be developed by the end of 2020. He repeated the claim in an interview on August 6, 2020, saying a vaccine would be ready "sooner than the end of the year, could be much sooner." The same day, the President asserted the vaccine may be ready prior to the November 3 election, stating, "I'm optimistic that it'll be probably around that date." Many experts, however, have argued that these projections are unrealistic.

On May 15, 2020, the Administration announced Operation Warp Speed and asserted that "[f]ourteen promising candidates" for vaccines had already been chosen for further review "from the 100+ vaccine candidates currently in development."

On June 3, 2020, the White House announced that Operation Warp Speed had selected five vaccine candidates to receive federal financial and operational support as they proceed to the next phase of development. As of August 7, 2020, the Department of Health and Human Services (HHS) had publicly identified eight candidates selected to receive a total of more than \$9 billion in federal development support.

The process followed to select these candidates has been opaque. On July 2, 2020, Director of the National Institutes of Health (NIH) Dr. Francis Collins stated that a group of vaccine experts working with Operation Warp Speed conducted a scientific review of 50

<sup>&</sup>lt;sup>4</sup> Trump Downplayed Coronavirus Threat Throughout February, Voice of America News (Apr. 14, 2020) (online at www.voanews.com/science-health/coronavirus-outbreak/trump-downplayed-coronavirus-threat-throughout-february); 'T'm Not Concerned at All': Trump Says He's Not Worried as Coronavirus Arrives in DC Area, USA Today (Mar. 9, 2020) (online at www.usatoday.com/story/news/politics/2020/03/08/trump-response-coronavirus-washington-dc/4994189002/).

<sup>&</sup>lt;sup>5</sup> *Trump Claims U.S. Will Have Coronavirus Vaccine by End of 2020*, Axios (May 3, 2020) (online at www.axios.com/trump-coronavirus-vaccine-2020-town-hall-748ed518-d037-4624-810c-eddcb123bdda.html).

<sup>&</sup>lt;sup>6</sup> Trump Says Coronavirus Vaccine Possible Before Nov. 3, Reuters (Aug. 6, 2020) (online at www.reuters.com/article/us-health-coronavirus-trump-vaccine/trump-says-coronavirus-vaccine-possible-before-nov-3-idUSKCN25221Q).

<sup>&</sup>lt;sup>7</sup> The White House, *Remarks by President Trump Before Marine One Departure* (Aug. 6, 2020) (online at www.whitehouse.gov/briefings-statements/remarks-president-trump-marine-one-departure-080620/).

<sup>&</sup>lt;sup>8</sup> Moderna's Clinical Trial Numbers Show There's 'No Way' Trump Can Have a Vaccine By Election Day, CNN (August 10, 2020) (online at www.cnn.com/2020/08/10/health/covid-vaccine-election-moderna-clinical-trials/index.html); Is Trump On Track for an October Vaccine Surprise?, Politico (July 22, 2020) (online at www.politico.com/news/2020/07/22/trump-october-vaccine-surprise-coronavirus-379278).

 $<sup>^9</sup>$  Department of Health and Human Services,  $Trump\,Administration\,Announces\,Framework\,and\,Leadership for\, 'Operation Warp Speed' (May 15, 2020) (on line at www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html).$ 

<sup>&</sup>lt;sup>10</sup> Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists, New York Times (June 9, 2020) (online at www.nytimes.com/2020/06/03/us/politics/coronavirus-vaccine-trump-moderna.html).

<sup>&</sup>lt;sup>11</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Aug. 7, 2020) (online at www.hhs.gov/about/news/2020/08/07/fact-sheet-explaining-operation-warp-speed.html).

candidate coronavirus vaccines. <sup>12</sup> However, the Administration has not released the list of vaccine candidates reviewed, the reasons for selecting or rejecting particular candidates, or the identity of the individuals who conducted the analysis or were responsible for selection decisions. <sup>13</sup> Members of a scientific committee called Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), organized by NIH to advise on the design and operation of clinical trials related to Operation Warp Speed, stated that they were left out of the selection process for vaccine candidates. One member of the committee stated, "We're sort of like two parallel universes." <sup>14</sup>

A lack of transparency in the development of a coronavirus vaccine, especially on an accelerated timeline, could contribute to the growth of anti-vaccination sentiment. <sup>15</sup> Recent surveys indicate that as few as half of Americans are committed to taking a coronavirus vaccine when it becomes available. <sup>16</sup>

Operation Warp Speed's chief advisor, Dr. Slaoui, is a venture capitalist and former pharmaceutical company executive. His financial interests in for-profit companies receiving federal funding to develop vaccines raise serious ethical concerns that could undermine public trust in the Administration's vaccine efforts. As of May 2020, Dr. Slaoui reportedly held approximately \$10 million in GlaxoSmithKline securities. He refused to sell the shares when he was named as one of the "leaders" of Operation Warp Speed, stating: "This is my retirement.

<sup>&</sup>lt;sup>12</sup> Senate Committee on Appropriations, Subcommittee on Labor, Health, and Human Services, Education, and Related Agencies, *Review of Operation Warp Speed: Researching, Manufacturing, & Distributing a Safe & Effective Coronavirus Vaccine* (July 2, 2020) (online at www.appropriations.senate.gov/hearings/review-of-operation-warp-speed-researching-manufacturing-and-distributing-a-safe\_effective-coronavirus-vaccine).

<sup>&</sup>lt;sup>13</sup> Operation Warp Speed's Opaque Choices of COVID-19 Vaccines Draw Senate Scrutiny, Science (July 2, 2020) (online at www.sciencemag.org/news/2020/07/operation-warp-speed-s-opaque-choices-covid-19-vaccines-draw-senate-scrutiny).

<sup>&</sup>lt;sup>14</sup> Top U.S. Scientists Left Out of White House Selection of COVID-19 Vaccine Short List, Science (June 4, 2020) (online at www.sciencemag.org/news/2020/06/top-us-scientists-left-out-white-house-selection-covid-19-vaccine-shortlist).

<sup>&</sup>lt;sup>15</sup> Some Worry 'Operation Warp Speed' Plays into Anti-Vaccination Movement Hands, The Hill (May 31,2020) (online at the hill.com/policy/healthcare/500213-some-worry-operation-warp-speed-plays-into-anti-vaccination-movements-hands).

<sup>&</sup>lt;sup>16</sup> Just 50% of Americans Plan to Get a COVID-19 Vaccine. Here's How to Win Over the Rest, Science (June 30, 2020) (online at www.sciencemag.org/news/2020/06/just-50-americans-plan-get-covid-19-vaccine-here-show-win-over-rest).

<sup>&</sup>lt;sup>17</sup> Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflict of Interest, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html); Chief of White House's 'Operation Warp Speed' Vaccine Effort Can Keep Investing In Pharma Firms, Under IG Ruling, Washington Post (July 14, 2020) (online at www.washingtonpost.com/business/2020/07/14/chief-white-houses-operation-warp-speed-vaccine-effort-can-keep-investing-pharma-firms-under-ig-ruling/).

<sup>&</sup>lt;sup>18</sup> Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflict of Interest, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html).

What I said regarding the GSK [GlaxoSmithKline] shares, I said I cannot take the job if I have to sell them." <sup>19</sup>

On July 31, 2020, GSK and Sanofi jointly secured an agreement of up to \$2.1 billion to supply the federal government with 100 million doses of an experimental coronavirus vaccine, the largest such deal announced to date.<sup>20</sup> Dr. Slaoui has asserted that he will donate a portion of GSK stock gains after he leaves Operation Warp Speed to NIH. However, it is unclear whether there is any enforceable requirement for him to do so, and he appears poised to continue reaping financial benefits from any gains in GSK stock value that accrue in the future, even if they relate to the company's federal contract awarded during Dr. Slaoui's tenure at Operation Warp Speed.

From 2017 to 2020, Dr. Slaoui sat on the board of Moderna, a biotechnology firm that is pursuing a coronavirus vaccine. Dr. Slaoui also held significant holdings in Moderna, the value of which rose to nearly \$12.4 million following the release of preliminary, partial data from an early phase of Moderna's coronavirus vaccine trial. On April 16, 2020, the federal government awarded \$483 million in support to Moderna in pursuit of a coronavirus vaccine. On May 18, 2020, after joining Operation Warp Speed and amid widespread public pressure, Dr. Slaoui agreed to divest his holdings in Moderna. The federal government awarded another \$472 million in support for Moderna on July 26, 2020.

Although I am pleased that Dr. Slaoui agreed to divest his Moderna holdings, I am concerned that this conflict of interest was not addressed before he was appointed to lead Operation Warp Speed. I am also concerned by reports that he and other consultants with ties to the pharmaceutical industry, including Carlo de Notaristefani, William Erhardt, and Rachel Harrigan, are advising Operation Warp Speed without disclosing other possible conflicts of interest. <sup>25</sup>

<sup>&</sup>lt;sup>19</sup> Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflicts, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html); Department of Health and Human Services, Trump Administration Announces Framework and Leadership for 'Operation Warp Speed' (May 15, 2020) (online at www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html).

<sup>&</sup>lt;sup>20</sup> Sanofi and GlaxoSmithKline Snag Biggest Coronavirus Vaccine Deal Yet, New York Times (July 31, 2020) (online at www.nytimes.com/2020/07/31/health/covid-19-vaccine-sanofi-gsk.html).

 $<sup>^{21} \</sup>textit{Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflicts}, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html).$ 

<sup>&</sup>lt;sup>22</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Aug. 7, 2020) (online at www.hhs.gov/about/news/2020/08/07/fact-sheet-explaining-operation-warp-speed.html).

<sup>&</sup>lt;sup>23</sup> White House Coronavirus Vaccine Advisor Moncef Slaoui to Divest \$12.4 Million of Moderna Holdings, CNBC (May 19, 2020) (online at www.cnbc.com/2020/05/18/coronavirus-vaccine-adviser-moncef-slaoui-to-divest-12point4-million-of-moderna-holdings.html).

<sup>&</sup>lt;sup>24</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Aug. 7, 2020) (online at www.hhs.gov/about/news/2020/08/07/fact-sheet-explaining-operation-warp-speed.html).

<sup>&</sup>lt;sup>25</sup> Vaccine Project Contract Raises Transparency Questions, Politico (July 31, 2020) (online at www.politico.com/news/2020/07/31/vaccine-project-contract-raises-transparency-questions-389822).

It remains unclear whether Dr. Slaoui or other consultants working for Operation Warp speed have undisclosed conflicts of interest because the Administration has structured their contracts to avoid the ethics rules and requirements to disclose outside positions, stock holdings, and other potential conflicts that are applicable to federal employees. <sup>26</sup> Dr. Slaoui has been hired as a federal contractor with an annual salary of one dollar, although he is reportedly being compensated for housing and other expenses. <sup>27</sup> The Administration has refused to disclose any ethics restrictions in Dr. Slaoui's contract. <sup>28</sup> The Administration also has not explained whether the contractual arrangement with Dr. Slaoui is consistent with federal regulations restricting the use of contractors to make policy decisions, direct and control federal employees, or hold positions that resemble those of government employees. <sup>29</sup>

Addressing potential conflicts of interest is critical to assure the public that decisions pertaining to the manufacturing and distribution of a coronavirus vaccine are made with a sound scientific basis, not for political reasons or for the financial benefit of any individual.

For all these reasons, the Select Subcommittee requests that you produce the following documents and information by August 26, 2020. 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, including … the development of vaccines and treatments."

- 1. Documents sufficient to identify the names, titles, and roles of all individuals formally or informally involved in Operation Warp Speed, including federal employees, contractors, advisors, and others.
- 2. All organizational charts for Operation Warp Speed.
- 3. A list of all vaccine candidates considered by Operation Warp Speed, including the steps taken to consider each candidate, the status of that consideration, whether the vaccine was selected for further federal support, and any additional steps planned.
- 4. A list of all individuals responsible for reviewing and selecting vaccine candidates for further federal support.

<sup>&</sup>lt;sup>26</sup> 18 U.S.C. § 208; Pub.L. 95–521 (1978).

<sup>&</sup>lt;sup>27</sup> Vaccine Project Contract Raises Transparency Questions, Politico (July 31, 2020) (online at www.politico.com/news/2020/07/31/vaccine-project-contract-raises-transparency-questions-389822).

<sup>&</sup>lt;sup>28</sup> Ethics Groups Call on Coronavirus 'Vaccine Czar' to Disclose Potential Conflicts, ABC News (May 29, 2020) (online at a benews.go.com/Politics/ethics-groups-call-coronavirus-vaccine-czar-disclose-potential/story?id=70935155).

<sup>&</sup>lt;sup>29</sup> See 48 C.F.R. § 7.503(a)(5); 48 C.F.R. § 37.104(a)-(b).

- 5. All documents regarding the criteria used to select candidate vaccines for potential development and distribution through Operation Warp Speed including the performance work statement, technical evaluation criteria, and technical evaluation plan.
- 6. All documents and communications regarding the selection of candidate vaccines for potential development and distribution through Operation Warp Speed, including internal communications and communications with the technical evaluation panel, the source selection committee, pharmaceutical companies, the White House, other federal agencies, and other third parties.
- 7. All documents related to contracts for vaccine development or manufacturing, including but not limited to solicitations, requests for proposals or information, contracts, task orders, justifications for other than full and open competition, responsibility determinations, documentation of acceptance or performance, and verification of price reasonableness, with any company that has been selected to receive funding through Operation Warp Speed, including but not limited to the following:
  - a. Johnson & Johnson;
  - b. Moderna Inc.;
  - c. AstraZeneca Plc;
  - d. Merck & Co., Inc.;
  - e. Sanofi:
  - f. GlaxoSmithKline;
  - g. Pfizer, Inc.;
  - h. Regeneron Pharmaceuticals;
  - i. Emergent BioSolutions; and
  - j. Novovax, Inc.
- 8. Documents sufficient to show the anticipated schedule for the development and distribution of a coronavirus vaccine by Operation Warp Speed.
- 9. A detailed list of all financial interests and outside positions held by Moncef Slaoui, Carlo de Notaristefani, William Erhardt, Rachel Harrigan, and any other consultants to Operation Warp Speed.
- 10. All documents and communications regarding actual or potential conflicts of interest of Dr. Moncef Slaoui, Carlo de Notaristefani, William Erhardt, Rachel Harrigan, and any other consultants to Operation Warp Speed, including steps taken to address any conflicts of interest.
- 11. All policies and procedures related to conflicts of interest applicable to Operation Warp Speed; and

The Honorable Alex M. Azar II Page 7

12. All documents and communications regarding the decision to engage Dr. Moncef Slaoui as a contractor, rather than a federal employee.

In addition, the Select Subcommittee requests a staff briefing regarding these issues by August 26, 2020.

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 Select Subcommittee staff at (202) 225-4400.

Sincerely,

anes E. Clyburn

(Kairman

Enclosure

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.

JAMES E. CLYBURN
CHAIRMAN
MAXINE WATERS
CAROLYN B. MALONEY
NYDIA M. VELÁZQUEZ
BILL FOSTER
JAMIE RASKIN
ANDY KIM

#### ONE HUNDRED SIXTEENTH CONGRESS

RANKING MEMBER

JIM JORDAN

BLAINE LUETKEMEYER

JACKIE WALORSKI

MARK E. GREEN, M.D.

STEVE SCALISE

# Congress of the United States

# House of Representatives

# SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS 2157 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6143

PHONE (202) 225-4400

https://coronavirus.house.gov

August 12, 2020

Mr. David S. Harris President and Chief Executive Officer Advanced Decision Vectors LLC 5270 Shawnee Road, Suite 104 Alexandria, VA 22312-2380

Dear Mr. Harris:

The Select Subcommittee on the Coronavirus Crisis is examining the role of private contractors in advising Operation Warp Speed, the Trump Administration's program to develop, manufacture, and distribute coronavirus vaccines, therapeutics, and diagnostics. Successful development of a coronavirus vaccine requires scientific rigor and an open and transparent process that is free from financial and political conflicts of interest. I am concerned that a lack of transparency in the use of consultants to advise Operation Warp Speed could undermine public confidence in this process. I am writing to request documents and information regarding your company's role in this process.

On May 15, 2020, Advanced Decision Vectors was awarded a contract by the National Institutes of Health (NIH) to "provide expert advice regarding development and mass production of new COVID-19 vaccine candidates, therapeutics, and diagnostics," and to provide advice to the Department of Health and Human Services on coordination among the Assistant Secretary for Preparedness and Response, NIH, and the Food and Drug Administration. Your company was originally awarded \$100,000, which was increased to \$611,000 on May 29, 2020.<sup>2</sup> This contract has reportedly been used in part to compensate independent consultants advising Operation Warp Speed, many of whom are former pharmaceutical industry executives.<sup>3</sup> Your company received a related award for \$465,000 on July 28, 2020.<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020) (online at www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html).

<sup>&</sup>lt;sup>2</sup> USASpending.gov, Delivery Order No. 75N98020F00001 (May 15, 2020) (online at www.usaspending.gov/#/award/CONT\_AWD\_75N98020F00001\_7529\_75N98019D00020\_7529).

<sup>&</sup>lt;sup>3</sup> Vaccine Project Contract Raises Transparency Questions, Politico (July 31, 2020) (online at www.politico.com/news/2020/07/31/vaccine-project-contract-raises-transparency-questions-389822).

<sup>&</sup>lt;sup>4</sup> USASpending.gov, Delivery Order No. 75N98020F00002 (July 28, 2020) (online at www.usaspending.gov/#/award/CONT\_AWD\_75N98020F00002\_7529\_75N98019D00020\_7529).

Public reporting has raised questions about potential conflicts of interest among consultants engaged through Advanced Decision Vectors, including Operation Warp Speed's chief adviser Dr. Moncef Slaoui and other former pharmaceutical industry executives such as Carlo de Notaristefani, William Erhardt, and Rachel Harrigan.<sup>5</sup>

As of May 2020, Dr. Slaoui reportedly held approximately \$10 million in securities of GlaxoSmithKline, a company that, in partnership with Sanofi, was awarded \$2.1 billion to supply the federal government with 100 million doses of its experimental coronavirus vaccine. Until recently, Dr. Slaoui also held significant shares in Moderna, a company that has received significant federal funding to develop a coronavirus vaccine. Dr. Slaoui ultimately agreed to divest his shares in Moderna following significant public pressure. Other consultants may also have potential conflicts of interest. For example, Mr. Erhardt and Dr. Harrigan are former Pfizer executives. On July 22, 2020, the Administration placed an order for a coronavirus vaccine, jointly developed by Pfizer and BioNTech, worth \$1.95 billion upon the vaccine's successful production and distribution.

It remains unclear whether consultants advising Operation Warp Speed have other, undisclosed conflicts of interest. The Administration has structured these consulting agreements in a manner that avoids the ethics rules and requirements to disclose outside positions, stock holdings, and other potential conflicts that are applicable to federal employees. <sup>10</sup> Dr. Slaoui was reportedly hired as a federal contractor with an annual salary of one dollar, although he is reportedly being compensated for housing and other expenses through your company's contract. <sup>11</sup> The Administration has not disclosed any ethics restrictions in Dr. Slaoui's contract. <sup>12</sup> The Administration also has not explained whether the contract arrangement with Dr. Slaoui is consistent with federal regulations restricting the use of contractors to make policy

<sup>&</sup>lt;sup>5</sup> *Vaccine Project Contract Raises Transparency Questions*, Politico (July 31, 2020) (online at www.politico.com/news/2020/07/31/vaccine-project-contract-raises-transparency-questions-389822).

<sup>&</sup>lt;sup>6</sup> Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflict of Interest, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html); Sanofi and GlaxoSmithKlineSnag Biggest Coronavirus Vaccine Deal Yet, New York Times (July 31, 2020) (online at www.nytimes.com/2020/07/31/health/covid-19-vaccine-sanofi-gsk.html).

<sup>&</sup>lt;sup>7</sup> White House Coronavirus Vaccine Advisor Moncef Slaoui to Divest \$12.4 Million of Moderna Holdings, CNBC (May 19, 2020) (online at www.cnbc.com/2020/05/18/coronavirus-vaccine-adviser-moncef-slaoui-to-divest-12point4-million-of-moderna-holdings.html).

<sup>&</sup>lt;sup>8</sup> Vaccine Project Contract Raises Transparency Questions, Politico (July 31, 2020) (online at www.politico.com/news/2020/07/31/vaccine-project-contract-raises-transparency-questions-389822).

<sup>&</sup>lt;sup>9</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Aug. 7, 2020) (online at www.hhs.gov/about/news/2020/08/07/fact-sheet-explaining-operation-warp-speed.html).

<sup>&</sup>lt;sup>10</sup> 18 U.S.C. § 208; Pub.L. 95–521 (1978).

<sup>&</sup>lt;sup>11</sup> Vaccine Project Contract Raises Transparency Questions, Politico (July 31, 2020) (online at www.politico.com/news/2020/07/31/vaccine-project-contract-raises-transparency-questions-389822).

<sup>&</sup>lt;sup>12</sup> Ethics Groups Call on Coronavirus 'Vaccine Czar' to Disclose Potential Conflicts, ABC News (May 29, 2020) (online at a bcnews.go.com/Politics/ethics-groups-call-coronavirus-vaccine-czar-disclose-potential/story?id=70935155).

decisions, direct and control federal employees, or hold positions that resemble government employees. <sup>13</sup>

Addressing potential conflicts of interest is critical to assure the public that decisions pertaining to the manufacturing and distribution of a coronavirus vaccine are made with a sound scientific basis, not for political reasons or for the financial benefit of any individual.

For all these reasons, the Select Subcommittee requests that you produce the following documents and information by August 26, 2020. 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, including … the development of vaccines and treatments."

- 1. All documents related to contracts with the Department of Health and Human Services, the National Institutes of Health, or any other federal agency related to Operation Warp Speed or any other effort to develop a vaccine or treatment for the novel coronavirus, including but not limited to all solicitations, request for proposals or information, contracts, and task orders.
- 2. All communications with the Department of Health and Human Services, the National Institutes of Health, or any other federal agency regarding any contract responsive to Request 1, including all communications regarding any subcontractor, independent contractor, or consultant to be engaged in connection with the contract.
- 3. All agreements with any subcontractor, independent contractor, or consultant engaged in connection with any contract identified in response to Request 1, including but not limited to any agreement with the following individuals:
  - a. Moncef Slaoui:
  - b. Carlo de Notaristefani;
  - c. William Erhardt; and
  - d. Rachel Harrigan.
- 4. All documents and communications regarding the financial interests, outside positions, and actual or potential conflict of interest of any subcontractor, independent contractor, or consultant engaged in connection with any contract identified in response to Request 1.

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 Select Subcommittee staff at (202) 225-4400.

<sup>&</sup>lt;sup>13</sup> See 48 C.F.R. § 7.503(a)(5); 48 C.F.R. § 37.104(a)-(b).

Sincerely,

James E. Clyburn

Chairman

# Enclosure

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.

JAMES E. CLYBURN
CHAIRMAN
MAXINE WATERS
CAROLYN B. MALONEY
NYDIA M. YELÁZQUEZ
BILL FOSTER
JAMIE RASKIN
ANDY KIM

### ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6143

PHONE (202) 225-4400

https://coronavirus.house.gov

August 12, 2020

Dr. Moncef Slaoui Chief Advisor Operation Warp Speed

Dear Dr. Slaoui:

The Select Subcommittee on the Coronavirus Crisis is examining your role as chief advisor to Operation Warp Speed, the Trump Administration's program to develop, manufacture, and distribute coronavirus vaccines, therapeutics, and diagnostics. The Select Subcommittee strongly supports efforts to develop and distribute a life-saving coronavirus vaccine, but I am concerned that your financial interests in for-profit companies receiving federal funding to develop vaccines for the coronavirus raise serious ethical concems and could reduce public trust in the Administration's vaccine efforts.<sup>1</sup>

Prior to joining Operation Warp Speed, you were an executive at GlaxoSmithKline (GSK) for more than 30 years and a venture capitalist focused on investing in pharmaceutical companies. As of May 2020, you reportedly held approximately \$10 million in GSK securities. You refused to sell these shares when you joined Operation Warp Speed, stating: "This is my retirement. What I said regarding the GSK shares, I said I cannot take the job if I have to sell them." On July 31, 2020, GSK and Sanofi jointly secured an agreement of up to \$2.1 billion to supply the federal government with 100 million doses of its experimental coronavirus vaccine, the largest such deal announced to date. You have asserted that you will donate a portion of GSK stock gains to the National Institutes of Health (NIH) after you leave Operation Warp Speed. However, it is unclear whether there is any enforceable requirement for you to do so. You also appear poised to reap financial benefits from any gains in GSK stock value that accrue

STEVE SCALISE RANKING MEMBER JIM JORDAN BLAINE LUETKEMEYER JACKIE WALORSKI MARK E. GREEN, M.D.

<sup>&</sup>lt;sup>1</sup> Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflict of Interest, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html); Chief of White House's 'Operation Warp Speed' Vaccine Effort Can Keep Investing in Pharma Firms, Under IG Ruling, Washington Post (July 14, 2020) (online at www.washingtonpost.com/business/2020/07/14/chief-white-houses-operation-warp-speed-vaccine-effort-can-keep-investing-pharma-firms-under-ig-ruling/).

 $<sup>^2 \</sup>textit{Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflicts}, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html).$ 

<sup>&</sup>lt;sup>3</sup> Sanofi and Glaxo SmithKline Snag Biggest Coronavirus Vaccine Deal Yet, New York Times (July 31, 2020) (online at www.nytimes.com/2020/07/3 l/health/covid-19-vaccine-sanofi-gsk.html).

in the future, even if they relate to the company's federal contract awarded during your tenure at Operation Warp Speed.

From 2017 to 2020, you sat on the board of Moderna, a biotechnology firm that has received federal funding to pursue a coronavirus vaccine. <sup>4</sup> Until recently, you also held significant holdings in Moderna, the value of which rose to nearly \$12.4 million following the release of preliminary, partial data from an early phase of Moderna's coronavirus vaccine trial. <sup>5</sup> On April 16, 2020, the federal government awarded \$483 million in support to Moderna in pursuit of a coronavirus vaccine. <sup>6</sup> On May 18, 2020, after you joined Operation Warp Speed and following widespread public pressure, you agreed to divest your holdings in Moderna. <sup>7</sup> On June 3, 2020, it was reported that Operation Warp Speed had selected Moderna as a finalist. <sup>8</sup> The federal government awarded another \$472 million in support for Moderna on July 26, 2020. <sup>9</sup>

I am concerned that these conflicts of interests were not addressed before you were appointed to run Operation Warp Speed. It remains unclear whether you have undisclosed conflicts, as the Administration has structured your employment agreement to avoid the ethics rules and requirements to disclose outside positions, stock holdings, and other potential conflicts that are applicable to federal employees. You have been hired as a federal contractor with an annual salary of one dollar, rather than an employee, and the Administration has refused to disclose any ethics restrictions in your contract. He Administration also has not explained whether your contractual arrangement is consistent with federal regulations restricting the use of contractors to make policy decisions, direct and control federal employees, or hold positions that resemble those of government employees. 12

Addressing potential conflicts of interest is critical to assure the public that decisions pertaining to the manufacturing and distribution of a coronavirus vaccine are made with a sound scientific basis, not for political reasons or for the financial benefit of any individual.

 $<sup>^4</sup>$  Trump's Vaccine Chief Has Vast Ties to Drug Industry, Posing Possible Conflicts, New York Times (May 20, 2020) (online at www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html).

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Aug. 7, 2020) (online at www.hhs.gov/about/news/2020/08/07/fact-sheet-explaining-operation-warp-speed.html).

<sup>&</sup>lt;sup>7</sup> White House Coronavirus Vaccine Advisor Moncef Slaoui to Divest \$12.4 Million of Moderna Holdings, CNBC (May 19, 2020) (online at www.cnbc.com/2020/05/18/coronavirus-vaccine-adviser-moncef-slaoui-to-divest-12point4-million-of-moderna-holdings.html).

<sup>&</sup>lt;sup>8</sup> *Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists*, New York Times (June 3, 2020) (online at www.nytimes.com/2020/06/03/us/politics/coronavirus-vaccine-trump-moderna.html).

<sup>&</sup>lt;sup>9</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Aug. 7, 2020) (online at www.hhs.gov/about/news/2020/08/07/fact-sheet-explaining-operation-warp-speed.html).

<sup>&</sup>lt;sup>10</sup> 18 U.S.C. § 208; Pub.L. 95–521 (1978).

<sup>&</sup>lt;sup>11</sup> Ethics Groups Call on Coronavirus 'Vaccine Czar' to Disclose Potential Conflicts, ABC News (May 29, 2020) (online at a bcnews.go.com/Politics/ethics-groups-call-coronavirus-vaccine-czar-disclose-potential/story?id=70935155).

<sup>&</sup>lt;sup>12</sup> See 48 C.F.R. § 7.503(a)(5); 48 C.F.R. § 37.104(a)-(b).

For all these reasons, the Select Subcommittee requests that you produce the following documents and information by August 26, 2020. 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, including … the development of vaccines and treatments."

- 1. A detailed list of your financial interests and outside positions, including but not limited to interests and positions in entities that are developing vaccines or therapeutics for the coronavirus.
- 2. All documents and communications with any federal employee regarding your financial interests, outside positions, potential conflicts of interest, and steps to address potential conflicts of interest, in connection with your role at Operation Warp Speed.
- 3. All documents and communications with any federal employee regarding your role as chief adviser to Operation Warp Speed, including discussions regarding the terms or structure of your contract or the decision to hire you as a contractor rather than a federal employee.
- 4. All communications with any officer, director, or employee of any company in which you have a financial interest or hold an outside position regarding Operation Warp Speed or federal support for efforts to develop a vaccine or treatment for the coronavirus, including but not limited to communications with GlaxoSmithKline and Moderna.

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 Select Subcommittee staff at (202) 225-4400.

Sincerely,

James E. Clyburn

Enclosure

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.