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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, 2020.² This contract has reportedly been used in part to compensate independent consultants advising Operation Warp Speed, many of whom are former pharmaceutical industry executives.³ Your company received a related award for \$465,000 on July 28, 2020.⁴

¹ 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).

² USASpending.gov, Delivery Order No. 75N98020F00001 (May 15, 2020) (online at www.usaspending.gov/#/award/CONT_AWD_75N98020F00001_7529_75N98019D00020_7529).

³ 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).

⁴ 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.⁵

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. ¹⁰ 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. ¹¹ The Administration has not disclosed any ethics restrictions in Dr. Slaoui's contract. ¹² 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

⁵ *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).

⁶ 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).

⁷ 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).

⁸ 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).

⁹ 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).

¹⁰ 18 U.S.C. § 208; Pub.L. 95–521 (1978).

¹¹ 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).

¹² 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. ¹³

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.

¹³ 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.