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SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS

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September 21, 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:

As you know, the Select Subcommittee on the Coronavirus Crisis is investigating the Trump Administration's handling of Operation Warp Speed, including whether top advisors to this program who were hired through your company have conflicts of interest that could undermine the integrity of the Administration's process for developing coronavirus vaccines. Documents recently obtained by the Select Subcommittee have heightened concerns that these advisors may have significant undisclosed financial conflicts of interest that, contrary to the Administration's public statements, have not been adequately addressed. Despite the gravity of these concerns, Advanced Decision Vectors LLC (ADV) has refused to cooperate with the Select Subcommittee's requests. I am writing today to offer you another opportunity to comply before the Select Subcommittee considers compulsory process.

On August 12, 2020, the Select Subcommittee sent you a letter requesting documents and information regarding contracts that ADV entered into with the Department of Health and Human Services (HHS) related to Operation Warp Speed, the Trump Administration's program to develop, manufacture, and distribute coronavirus vaccines, therapeutics, and diagnostics.¹ The Select Subcommittee asked ADV to produce four categories of documents by August 26, 2020. Select Subcommittee staff subsequently agreed to a one-week extension that you requested. On September 2, 2020, your counsel sent the Select Subcommittee an incomplete production consisting of four documents, totaling just 18 pages.²

¹ Letter from Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Mr. David S. Harris, President and Chief Executive Officer, Advanced Decision Vectors LLC (Aug. 12, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-08-12.Clyburn%20to%20Harris%20re%20Operation%20Warp%20Speed.pdf).

² Letter from Devon E. Hewett to Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/20200902%20ADV%20Response%20to%20Rep%20Clyburn%20%2800082539xC0F9E%29.pdf).

This limited document production heightens the Select Subcommittee’s concern that top advisors to Operation Warp Speed may have conflicts of interest that could bias the Administration’s vaccine development process. The documents consist of “Financial Holdings and Non-Disclosure Statement[s],” written on HHS letterhead, for four advisors hired through your company: Dr. Moncef Slaoui, Dr. Carlo de Notaristefani, Dr. William Erhardt, and Dr. Rachel Harrigan.³

The document related to Dr. Slaoui, the Chief Scientific Advisor to Operation Warp Speed, shows that, as of May 16, 2020, he held securities in Moderna, GlaxoSmithKline (GSK), and Lonza Group. Both Moderna and GSK are developing coronavirus vaccines that have been selected by Operation Warp Speed for federal investment.⁴ Although Dr. Slaoui reportedly agreed to divest his shares of Moderna, he refused to sell \$10 million in GSK securities, calling this “my retirement.”⁵ Lonza is a biotechnology company that in May 2020 entered into a ten-year agreement to manufacture Moderna’s experimental coronavirus vaccine.⁶ Although Dr. Slaoui announced in May 2020 that he would step down from his position on Lonza’s board, his financial holdings in Lonza have not previously been disclosed publicly.⁷

The Administration claimed that Dr. Slaoui addressed the clear conflicts of interest from his investments through “robust supplemental contract provisions” requiring him to “donate any increase in the value” of these holdings to the National Institutes of Health (NIH).⁸ However, the document obtained by the Select Subcommittee shows that this requirement is toothless. Dr. Slaoui is not required to donate any of his profits from companies involved in Operation

³ Department of Health and Human Services, *Financial Holdings and Non-Disclosure Statement of Dr. Moncef Slaoui* (May 16, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/HHS%20NDA_FE_Dr.%20Slaoui_05.18.2020.pdf); *Financial Holdings and Non-Disclosure Statement of Dr. Carlo de Notaristefani* (May 28, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/NDA_FE_HHS_Dr.%20de%20Notaristefani_05.28.20.pdf); *Financial Holdings and Non-Disclosure Statement of Dr. Rachel Harrigan* (May 28, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/NDA_FE_HHS_Harrigan_05.28.20.pdf); *Financial Holdings and Non-Disclosure Statement of Dr. William Erhardt* (May 28, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/NDA_FE_HHS_ERHARDT_05.28.20.pdf). These documents purport to come from the “National Institute of Health” within HHS, although the correct name for this agency is the “National Institutes of Health.”

⁴ *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); *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).

⁵ *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).

⁶ *Moderna Signs Ten-Year Vaccine Manufacturing Deal with Lonza*, Pharmaceutical Technology (May 1, 2020) (online at www.pharmaceutical-technology.com/news/moderna-lonza-manufacturing-deal/).

⁷ *Lonza: Moncef Slaoui to Step Down as Member of the Board of Directors of Lonza Group*, Market Screener (May 19, 2020) (online at www.marketscreener.com/quote/stock/LONZA-GROUP-2956013/news/Lonza-Moncef-Slaoui-to-Step-Down-as-Member-of-the-Board-of-Directors-of-Lonza-Group-30635505/).

⁸ Letter from Sarah Arbes, Assistant Secretary for Legislation, Department of Health and Human Services, to Senator Elizabeth Warren (July 30, 2020) (online at www.warren.senate.gov/imo/media/doc/July%2030%20HHS%20Letter%20to%20Sen%20Warren.pdf).

Warp Speed, including GSK, during his lifetime. Instead he can postpone his donation until the “last death” of Dr. Slaoui or his spouse. Dr. Slaoui’s agreement states that any increase in value in these holdings:

shall be donated to NIH either through an *inter vivos* donation or testamentary donation, at the discretion of the employee. A testamentary donation may occur on the last death of the employee and his or her spouse.⁹

The documents obtained by the Select Subcommittee also raise concerns that other Operation Warp Speed advisors hired through your company have conflicts of interest. On May 28, 2020, Dr. de Notaristefani, Dr. Erhardt, and Dr. Harrigan all reported financial interests in companies producing coronavirus vaccines, treatments, or diagnostics that have not previously been publicly disclosed in connection with Operation Warp Speed. Yet HHS appears to be permitting these advisors to keep these holdings, along with any profits, by certifying that “the Government has determined” the companies “are not involved in vaccines, therapeutics and diagnostic products developed to combat pandemic COVID-19.”¹⁰

These certifications appear to be inaccurate. Several companies listed in these documents have been actively involved in manufacturing or developing coronavirus vaccines, treatments, and diagnostic materials. For example:

- Both Dr. Erhardt and Dr. Harrigan reported holdings in Pfizer, which has been developing a coronavirus vaccine since at least March 2020. In July 2020, the federal government placed an order, worth approximately \$1.95 billion, for 100 million doses of Pfizer’s experimental coronavirus vaccine.¹¹

⁹ Department of Health and Human Services, *Financial Holdings and Non-Disclosure Statement of Dr. Moncef Slaoui* (May 16, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/HHS%20NDA_FE_Dr.%20Slaoui_05.18.2020.pdf) (emphasis added).

¹⁰*Id.*; Department of Health and Human Services, *Financial Holdings and Non-Disclosure Statements of Dr. Carlo de Notaristefani* (May 28, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/NDA_FE_HHS_Dr.%20de%20Notaristefani_05.28.20.pdf), *Dr. Rachel Harrigan* (May 28, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/NDA_FE_HHS_Harrigan_05.28.20.pdf), and *Dr. William Erhardt* (May 28, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/NDA_FE_HHS_ERHARDT_05.28.20.pdf). These documents purport to come from the “National Institute of Health” within HHS, although the correct name for

¹¹ Pfizer, *Press Release: Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine* (Mar. 17, 2020) (online at www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-co-develop-potential-covid-19-vaccine); Pfizer, *Press Release: Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-Based Vaccine Candidate Against Sars-CoV-2* (July 22, 2020) (online at www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600).

- Dr. Erhardt listed holdings in Thermo Fisher Scientific, Inc., a leading diagnostics manufacturer, that has received millions of dollars from the federal government for coronavirus testing materials.¹²
- Dr. Erhardt listed holdings in PhaseBio Pharmaceuticals, which has initiated at least two clinical trials of drugs that may be used to treat coronavirus patients.¹³
- Dr. Erhardt listed holdings in Incyte Pharmaceuticals, which is working with the Food and Drug Administration to conduct a study of its flagship product, Jakafi, in patients with cytokine storm associated with the coronavirus.¹⁴
- Dr. de Notaristefani listed a financial interest in Teva Pharmaceuticals, which has been involved in manufacturing at least one drug, hydroxychloroquine, that has been studied as a potential treatment for the coronavirus.¹⁵

These documents highlight the need for full cooperation with the Select Subcommittee's inquiry so Congress and the American people can understand the full scope of potential conflicts of interest in Operation Warp Speed, what steps have been taken to address them, and whether additional actions are needed.

Although ADV's September 2, 2020, letter to the Select Subcommittee stated, "ADV fully intends to and will do its best to cooperate with your committee in the committee's investigation of Operation Warp Speed,"¹⁶ your counsel subsequently stated that the company does not intend to produce additional documents voluntarily. On a September 8, 2020, telephone call, Select

¹² *Thermo Fisher Builds \$40M Coronavirus Test Tube Manufacturing Facility in 6 Weeks*, Fierce Biotech (Aug. 31, 2020) (online at www.fiercebiotech.com/medtech/thermo-fisher-builds-40m-coronavirus-test-tube-manufacturing-facility-6-weeks); Department of Health and Human Services, *Press Release: HHS Invests in Diagnostic Labs to Expand COVID-19 Testing Capacity in the United States* (Aug. 13, 2020) (online at www.hhs.gov/about/news/2020/08/13/hhs-invests-in-diagnostic-labs-to-expand-covid-19-testing-capacity-in-the-united-states.html).

¹³ PhaseBio Pharmaceuticals, *Press Release: PhaseBio Launches Clinical Trial to Evaluate PB1046 as a Treatment for Hospitalized COVID-19 Patients* (May 27, 2020) (online at investors.phasebio.com/news-releases/news-release-details/phasebio-launches-clinical-trial-evaluate-pb1046-treatment); PhaseBio Pharmaceuticals, *Press Release: PhaseBio Doses First Patient in VANGARD Phase 2 Clinical Trial to Evaluate PB1046 for Hospitalized COVID-19 Patients* (July 16, 2020) (online at investors.phasebio.com/news-releases/news-release-details/phasebio-doses-first-patient-vanguard-phase-2-clinical-trial).

¹⁴ *Wilmington-Based Incyte Looking to Repurpose Flagship Drug as COVID-19 Treatment*, Philadelphia Business Journal (Apr. 3, 2020) (online at www.bizjournals.com/philadelphia/news/2020/04/03/wilmington-based-incyte-looking-to-repurpose.html).

¹⁵ Teva Pharmaceuticals, *Press Release: Teva to Donate Potential COVID-19 Treatment, Hydroxychloroquine Sulfate Tablets to Hospitals Nationwide* (Mar. 20, 2020) (online at www.tevapharm.com/news-and-media/latest-news/teva-to-donate-potential-covid-19-treatment-hydroxychloroquine-sulfate-tablets-to-hospitals-nationwide).

¹⁶ Letter from Devon E. Hewett to Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/20200902%20ADV%20Response%20to%20Rep%20Clyburn%20%2800082539xC0F9E%29.pdf).

Subcommittee staff asked ADV's counsel whether the company would produce the remaining documents the Select Subcommittee requested. ADV's counsel responded that the company would not produce any further documents without a subpoena.

ADV's counsel stated that the company is subject to non-disclosure agreements and risks legal exposure if the company produced information voluntarily.¹⁷ As Select Subcommittee staff explained to your counsel, Congress' authority to conduct investigations derives from Article I of the Constitution and is not limited by non-disclosure agreements or other contracts, whether involving private parties or government agencies. As the Supreme Court has recognized, "The congressional power to obtain information is 'broad' and 'indispensable.'"¹⁸ This authority clearly extends to oversight of federal contractors, and congressional committees have routinely obtained documents from federal contractors for many years under both Republican and Democratic leadership.¹⁹

On September 8, your counsel also asserted that the Select Subcommittee's request is overly burdensome, notwithstanding the extension to which Select Subcommittee staff previously agreed. When Select Subcommittee staff offered to discuss the issue and seek additional accommodations to address this concern, your counsel refused to engage in a discussion. The Select Subcommittee is sensitive to the effort involved in responding to congressional requests and remains willing to engage in good-faith discussions to address any questions or concerns. However, given the strong public interest in addressing potential conflicts of interest among individuals leading the Administration's vaccine development initiative, it is imperative that the Select Subcommittee receive the information it needs to conduct this investigation without further delay.

House Resolution 935 authorizes the Chairman of the Select Subcommittee on the Coronavirus Crisis to issue subpoenas in furtherance of a "a full and complete investigation" of "issues related to the coronavirus crisis," including "the development of vaccines and treatments." Nevertheless, my preference is to obtain compliance with Select Subcommittee requests through voluntary cooperation and accommodation whenever possible. Please confirm by September 25, 2020, whether your company will voluntarily cooperate with the Select Subcommittee's requests, or whether the Select Subcommittee should issue a subpoena as requested by your counsel.

¹⁷ ADV's counsel did not identify the specific non-disclosure agreements, the parties to such agreements, or the responsive documents that the company believes are implicated by these agreements.

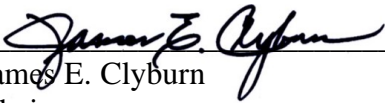
¹⁸ *Trump v. Mazars USA, LLP*, 591 U.S. ____ (2020) (quoting *Watkins v. United States*, 354 U.S. 178, 187, 215 (1957)).

¹⁹ For example, in May 2019, the Committee on Oversight and Reform received documents from a Department of Defense contractor. See Letter from John J. Deschauer, Jr., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 7, 2019) (online at oversight.house.gov/sites/democrats.oversight.house.gov/files/HORC%20LtrRedacted.pdf). In 2016, under then-Chairman Jason Chaffetz, the Committee received documents directly from contractors in connection with a data breach at the Office of Personnel Management. See Committee on Oversight and Government Reform, Republican Staff, *The OPM Data Breach: How the Government Jeopardized Our National Security for More than a Generation*, 114th Cong. (Sept. 7, 2016) (online at republicans-oversight.house.gov/report/opm-data-breach-government-jeopardized-national-security-generation/).

Mr. David S. Harris
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Thank you for your attention to this matter.

Sincerely,


James E. Clyburn
Chairman

cc: The Honorable Steve Scalise, Ranking Member