

Congress of the United States

Washington, DC 20510

November 16, 2020

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

Christopher C. Miller
Acting Secretary
U.S. Department of Defense
1000 Defense Pentagon
Washington, D.C. 20301

The Honorable Francis S. Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Gary Disbrow, Ph.D.
Acting Director
Biomedical Advanced Research
and Development Authority
200 Independence Ave. SW
Washington, D.C. 20201

Chad F. Wolf
Acting Secretary
Department of Homeland Security
2707 Martin Luther King Jr. Ave. SE
Washington, D.C. 20528

Pete Gaynor
Administrator
Federal Emergency Management Agency
500 C St. SW
Washington, D.C. 20472

Dear Secretary Azar, Acting Secretary Miller, Director Collins, Acting Director Disbrow, Acting Secretary Wolf, and Administrator Gaynor:

We write to request information and documents for all federal contracts issued for the development, manufacture, and distribution of therapeutics, vaccines, diagnostics, and other medical products procured to identify, mitigate, treat, cure, and prevent the spread of coronavirus disease 2019 (COVID-19), including all contracts associated with Operation Warp Speed (OWS), the public-private partnership established to “accelerate the development, manufacturing, and distribution of [coronavirus disease 2019 (COVID-19)] vaccines, therapeutics, and diagnostics”;¹ the Biomedical Advanced Research and Development Authority (BARDA); the National Institutes of Health (NIH); the Federal Emergency Management Agency (FEMA), and the Department of Defense (DoD). To date, OWS has awarded over \$13 billion in contracts to nearly 20 companies in pursuit of its goal “to have substantial quantities of a safe

¹ U.S. Department of Health and Human Services, “Trump Administration Announces Framework and Leadership for ‘Operation Warp Speed,’” press release, May 15, 2020, <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>.

and effective vaccine available for Americans by January 2021;”² NIH has awarded over \$1.65 billion to nearly 740 recipients;³ FEMA has spent billions to procure medical supplies;⁴ and BARDA, in conjunction with OWS, has spent over \$14.5 billion to advance COVID-19 tests, treatments, and vaccines.⁵ The terms of many these contracts, however, have been kept secret. The American people deserve to know that the federal government is using their tax dollars to develop COVID-19 medical products at the best possible price for the public—not to line the pockets of wealthy companies by cutting corners in consumer protection, pricing, and quality. Even the documents released by the federal government in response to Freedom of Information Act requests have been heavily redacted.⁶ These contracts, and affiliated documents, must be made available for public inspection.

The Trump Administration has a long history of cronyism and conflicts of interest—patterns that have continued throughout the COVID-19 pandemic. Earlier this year, for example, former director of BARDA, Dr. Rick Bright, filed a federal whistleblower complaint detailing pressure from the White House and Administration officials to direct resources toward an unproven and ineffective treatment for COVID-19.⁷ Dr. Bright also alleged he witnessed senior U.S. Department of Health and Human Services officials improperly steering taxpayer dollars toward friends or “cronies” or “for political purposes.”⁸ And the head of OWS, Dr. Moncef Slaoui, has entered into a complicated ethical arrangement that allows him to maintain investments in companies with a financial interest in OWS, in a clear attempt to circumvent federal ethics laws.⁹ To date, Dr. Slaoui has refused to address these conflicts of interest posed by his financial ties to companies of vaccine candidates and has insulted those who point them out.¹⁰

As a result, transparency into federal COVID-19 contracts is needed to ensure fair pricing, speed, effectiveness, and quality for the American people. After Americans have invested billions of taxpayer dollars, they deserve to know, for example, whether the federal government’s deals have preserved its public interest protections under the *Bayh-Dole Act*, such as march-in rights, which provide the federal government “with the ability to ‘march in’ and

² *Id.*; U.S. Department of Health and Human Services, “Fact Sheet: Explaining Operation Warp Speed,” <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>.

³ U.S. Department of Health and Human Services, Tracking Accountability in Government Grants System, “HHS COVID-19 Awards,” viewed October 25, 2020, <https://taggs.hhs.gov/Coronavirus>.

⁴ Government Technology, “Disaster Funding?” Eric Holdeman, July 30, 2020, <https://www.govtech.com/em/emergency-blogs/disaster-zone/which-states-depend-the-most-on-femas-disaster-funding.html>.

⁵ Public Citizen, “BARDA Funding Tracker,” Zain Rizvi, July 5, 2020 (updated September 24, 2020), <https://www.citizen.org/article/barda-funding-tracker/>.

⁶ <https://www.npr.org/sections/health-shots/2020/10/24/927474041/a-federal-coronavirus-vaccine-contract-released-at-last-but-redactions-obscure-t>

⁷ Science, “Emails offer look into whistleblower charges of cronyism behind potential COVID-19 drug,” Jon Cohen, Charles Piller, May 13, 2020, <https://www.sciencemag.org/news/2020/05/emails-offer-look-whistleblower-charges-cronyism-behind-potential-covid-19-drug>.

⁸ *Id.*

⁹ Letter from Senator Elizabeth Warren, et. al to HHS Secretary Alex Azar, August 24, 2020, <https://www.warren.senate.gov/imo/media/doc/2020.08.24%20Letter%20to%20HHS%20re%20Dr.%20Slaoui%2020.pdf>.

¹⁰ *Id.*

grant licenses for patents that result from publicly-funded R&D,”¹¹ allowing it to license the drug to a generic manufacturer for production at a lower cost, “if necessary to alleviate health or safety needs”¹² and under other circumstances—or whether the federal government caved to pharmaceutical corporations and wrote out these fair pricing mechanisms.

We, therefore, request all of the following information:

1. Please provide all contracts, grants, funding agreements, cooperative research and development agreements, licensing agreements, other transactions, and any other arrangements (including those entered into by a Third Party on behalf of the Government) related to the development, manufacture, and distribution of therapeutics, vaccines, diagnostics, and other medical products procured to identify, mitigate, treat, cure, and prevent the spread of COVID-19, including all contracts associated with OWS, NIH, FEMA, BARDA, and DoD, which may include any of the following:
 - a. Licenses of federally-owned inventions, issued pursuant to 35 USC 207 and 35 USC 209;
 - b. Cooperative Research and Development Agreements (CRADAs) and exclusive licenses issued pursuant to 15 USC 3710a;
 - c. Funding agreements, as defined under 35 USC 201;
 - d. Contracts, grants, cooperative agreements, and other transactions entered into or awarded pursuant to 42 USC 247d-7e through BARDA;
 - e. Contracts and other transactions entered into or awarded pursuant to 42 USC 284n through NIH;
 - f. Contracts, grants, and cooperative agreements pursuant to 42 USC 287a through Cures Acceleration Network (CAN);
 - g. Contracts, leases, cooperative agreements or other transactions to fulfil the functions of the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program;
 - h. Contracts, cooperative agreements, or grants entered pursuant to 10 USC 2358;
 - i. Other transactions pursuant to 10 USC 2371 through DoD;
 - j. Contracts or other transactions entered pursuant to 10 USC 2373;
 - k. Grants and contracts entered into pursuant to 42 USC 241.
2. Please provide the following:
 - a. Any and all documents relating to selection of proposals for awarding federal COVID-19 contracts or other transactions, including from intermediaries involved in any selection processes;
 - b. Any records of related discussions between HHS and nongovernmental participants in Operation Warp Speed related to therapeutics and vaccines for Covid-19; and
 - c. Any documents setting forth HHS policy, positions, and costing models specifically with respect to Operation Warp Speed, including but not limited to issues related to intellectual property, technology transfer, manufacturing capacity, pricing, and award determinations.

¹¹ Congressional Research Service, “March-In Rights Under the Bayh-Dole Act,” John R. Thomas, August 22, 2016, <https://crsreports.congress.gov/product/pdf/R/R44597>.

¹² *Id.*

We appreciate your consideration of this important request.

Sincerely,


Elizabeth Warren
United States Senator


Katie Porter
Member of Congress