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September 15, 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:

We are writing to urge you to provide the Government Accountability Office (GAO) with all of the access and information that it needs to conduct an effective ongoing review of Operation Warp Speed, the Administration's initiative for developing, manufacturing, and distributing a safe, effective vaccine for the coronavirus. GAO's review aims to help Operation Warp Speed accomplish its goals by providing an independent perspective and conveying clear and complete information to Congress and the public. To succeed, it will be critical that the Department provides GAO with real-time, ongoing access to information, documents, and officials.

On July 24, 2020, the Select Subcommittee on the Coronavirus Crisis sent a bipartisan letter to GAO requesting "that GAO conduct a comprehensive, ongoing review of Operation Warp Speed and the vaccine and therapeutic development initiatives that are being coordinated through it." The Select Subcommittee's letter emphasized the critical importance of developing safe and effective treatments and vaccines as soon as possible, explaining:

It is our genuine, bipartisan belief that Congress' and GAO's participation is critical to ensure this endeavor succeeds. These efforts should include real-time oversight by GAO's experienced project management experts and periodic assessment reports to both HHS and Congress in a joint fashion. Oversight by GAO would also add transparency to the development of coronavirus vaccines and therapeutics, increasing public confidence in products developed through this process.¹

¹ Letter from Chairman James E. Clyburn, Rep. Mark E. Green, M.D., and Rep. Bill Foster, Select Subcommittee on the Coronavirus Crisis, to Comptroller General Gene L. Dodaro, Government Accountability Office, (July 24, 2020) (online at coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-07-24.Select%20Cmte%20to%20Dodaro-GAO%20re%20OWS%20.pdf).

On July 28, 2020, GAO accepted this review request, explaining that the review is “within the scope of its authority.”²

Congress appropriated significant taxpayer funds through the Coronavirus Aid, Relief, and Economic Security (CARES) Act and other laws that have been used for Operation Warp Speed and other vaccine-development initiatives. We seek to work with the Department of Health and Human Services to ensure these tax dollars are used effectively, efficiently, and equitably in pursuit of vaccines and treatments for the coronavirus.

Providing GAO with access to information, documents, and officials is not only critical to conducting this review—it is also required by law. Congress provided GAO with specific access authorities with respect to coronavirus-related oversight. Specifically, the CARES Act provides that GAO “shall conduct monitoring and oversight” pertaining to federal efforts related to the pandemic and “shall have access to records” relating to these efforts. This access authority extends not only to federal agencies, but also to state and local agencies, contractors, grantees, recipients, and subrecipients, including private entities. Congress also empowered GAO to make copies of records, interview staff, and inspect facilities “[a]s determined necessary by the Comptroller General.”³

These authorities are in addition to GAO’s traditional access authorities, specifically its authority to examine any contractor or subcontractor records that directly pertain to, and involve, transactions relating to the contract and subcontract, as well as the right to interview any current contractor employee regarding those transactions. Federal law authorizes the Comptroller General “to obtain such agency records as the Comptroller General requires to discharge the duties of the Comptroller General (including audit, evaluation, and investigative duties).” Under the law, each agency is required to “give the Comptroller General information the Comptroller General requires about the duties, powers, activities, organization, and financial transactions of the agency.”⁴

Conducting ongoing, real-time oversight of key federal programs is not novel. GAO has used similar approaches for previous and ongoing GAO work, such as reviewing the Department of Defense’s planning for replacing intercontinental ballistic missiles and the Army’s Next-Generation Combat Vehicle. Directly observing activities can help to minimize the support GAO needs from federal agencies. For example, attending a key meeting or observing a contractor’s presentation can help to minimize the need for federal officials to respond to GAO’s questions about these efforts. We hope that you will view GAO as a resource to aid Operation Warp Speed in reaching its goals.

² Letter from Managing Director Orice Williams Brown, Government Accountability Office, to Chairman James E. Clyburn, House Select Subcommittee on the Coronavirus Crisis (July 28, 2020).

³ P.L. 116-136, § 19010.

⁴ 41 U.S.C. § 4706(d); Federal Acquisition Regulation § 52.215-2

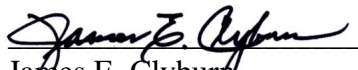
Specifically, we request that GAO receive access to all the information necessary to evaluate the progress of Operation Warp Speed, including but not limited to:

- Attendance at key Operation Warp Speed meetings, including weekly briefings to the Board of Directors, as observers. This access requires GAO to be made aware of when key meetings are scheduled to take place;
- Ongoing access to key officials to ask questions or hear considerations or decisions in real-time (either during meetings or separately);
- The ability to review documents as they are being developed and used, including documents in “pre-decisional” or draft form;
- Access to records and officials from private companies participating in Operation Warp Speed; and
- The ability to visit selected facilities to observe key activities, such as vaccine production.

Please respond by September 22, 2020, to confirm that the Department will provide this access to GAO so it can conduct this critical review.

If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-4400.

Sincerely,


James E. Clyburn
Chairman


Rep. Bill Foster

cc: The Honorable Steve Scalise, Ranking Member

The Honorable Gene L. Dodaro, Comptroller General