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July 24, 2020

The Honorable Gene L. Dodaro  
Comptroller General  
Government Accountability Office  
441 G Street, N.W.  
Washington, D.C. 20548

Dear Comptroller General Dodaro:

We write on a bipartisan basis to request that the Government Accountability Office (GAO) conduct periodic and ongoing reviews of Operation Warp Speed, the coronavirus treatment and vaccine development project at the Department of Health and Human Services (HHS), and related efforts for the duration of those projects. Given the critical importance of developing safe and effective treatments and vaccines as soon as possible, real-time monitoring by GAO has the potential to augment the scientific and project management expertise of the staff at Operation Warp Speed, serve as a non-partisan interface to Congressional oversight, enhance the organization and management of the projects, and reduce the risk of delays and other setbacks in this endeavor.

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 alongside HHS to ensure these tax dollars are used effectively and efficiently in pursuit of vaccines and treatments for the coronavirus. Timely and objective reporting on the status of these efforts is crucial to Congress as it both partners in this endeavor and plans future legislation in response to the crisis, to state and local officials as they plan their public health response, and to the American public.

A primary goal of Operation Warp Speed is to develop, manufacture, and distribute 300 million doses of a safe, effective vaccine for the coronavirus by January 2021. This project is complex, involving multiple executive branch agencies, private corporations, and billions of dollars in taxpayer funding.<sup>1</sup> The program is intended to coordinate efforts between components of HHS, including the Centers for Disease Control and Prevention, Food and Drug Administration (FDA), National Institutes of Health (NIH), and Biomedical Advanced Research and Development Agency (BARDA), as well as the Department of Defense, other federal

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<sup>1</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (June 16, 2020) (online at [www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html](http://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html)).

agencies, and private firms.<sup>2</sup> Related initiatives at NIH include the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, the Rapid Acceleration of Diagnostics (RADx) initiative, and the COVID-19 Prevention Trials Network (COVPN).<sup>3</sup>

The process of developing a vaccine is extraordinarily challenging under any circumstances, but especially when being done under enormous time pressure. Most existing vaccines were in development for between 10 and 30 years from the beginning of clinical trials to approval. The majority of potential vaccines fail in preclinical and clinical trials, and fewer than one in 15 vaccine candidates that enter Phase 2 clinical trials ultimately gain FDA approval.<sup>4</sup>

Even if a coronavirus vaccine candidate proves effective in a compressed timeframe, other serious challenges will be presented in manufacturing and distributing the vaccine. FDA authorization of a coronavirus vaccine would permit the manufacturer to market the vaccine but does not guarantee that the vaccine will be widely available. Manufacturers may not be able to produce an adequate supply of the vaccine rapidly to protect the entire U.S. population.<sup>5</sup> The coronavirus pandemic has exposed weaknesses in America's pharmaceutical supply and distribution chains, and the success of Operation Warp Speed depends on navigating these significant hurdles.<sup>6</sup>

At the same time that Operation Warp Speed and initiatives such as ACTIV work to develop a vaccine, they also seek to accelerate the development, manufacturing, and distribution of coronavirus therapeutics and diagnostics.<sup>7</sup> The biomedical community has been working to develop new therapies and repurpose existing therapeutics to prevent coronavirus infections or reduce severe outcomes in patients. For example, researchers are testing whether antibodies can confer temporary immunity from coronavirus infection to use as treatment or prophylactic therapy until the development of a safe and effective vaccine. However, limitations in manufacturing capacity could impact the potential utility of this treatment.<sup>8</sup>

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<sup>2</sup> Congressional Research Service, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions* (June 25, 2020) (online at [www.crs.gov/Reports/R46427?source=search&guid=8be11f5774584169864e3e0795f45fc0&index=1](http://www.crs.gov/Reports/R46427?source=search&guid=8be11f5774584169864e3e0795f45fc0&index=1)).

<sup>3</sup> *Id.*

<sup>4</sup> R. Gordon Douglas and Vijay B. Samant, "The Vaccine Industry," in Plotkin's *Vaccines*, 7th ed. (2017); see also Tung Thanh Le, et al., *The COVID-19 Vaccine Development Landscape*, *Nature Reviews Drug Discovery* (Apr. 9, 2020) (online at [www.nature.com/articles/d41573-020-00073-5](http://www.nature.com/articles/d41573-020-00073-5)).

<sup>5</sup> Congressional Research Service, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020) (online at [www.crs.gov/Reports/R46399?source=search&guid=0440b0739f7a419695b594c842972c81&index=1](http://www.crs.gov/Reports/R46399?source=search&guid=0440b0739f7a419695b594c842972c81&index=1)).

<sup>6</sup> *If a Coronavirus Vaccine Arrives, Can the World Make Enough?*, *Nature* (Apr. 9, 2020) (online at [www.nature.com/articles/d41586-020-01063-8](http://www.nature.com/articles/d41586-020-01063-8)).

<sup>7</sup> Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (June 16, 2020) (online at [www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html](http://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html)); *Five Coronavirus Treatments in Development*, *National Public Radio* (June 11, 2020) (online at [www.npr.org/sections/health-shots/2020/06/11/873399184/five-coronavirus-treatments-in-development](http://www.npr.org/sections/health-shots/2020/06/11/873399184/five-coronavirus-treatments-in-development)).

<sup>8</sup> Congressional Research Service, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions* (June 25, 2020) (online at [www.crs.gov/Reports/R46427?source=search&guid=8be11f5774584169864e3e0795f45fc0&index=1](http://www.crs.gov/Reports/R46427?source=search&guid=8be11f5774584169864e3e0795f45fc0&index=1)).

A safe, effective, and widely available vaccine or therapeutic has the potential to save lives and allow Americans to return safely to their jobs and schools. We believe that GAO’s involvement could provide real-time actionable items to facilitate Congress’ assistance in these projects, and allow us to provide rigorous and objective oversight of Operation Warp Speed and other vaccine and therapeutic development initiatives. 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.

During your testimony before the Select Subcommittee on June 26, 2020, you confirmed that GAO has the capacity to conduct real-time oversight of vaccine and therapeutic development using both “in-house capabilities” and “standing arrangements to get additional expertise.”<sup>9</sup> GAO has conducted real-time oversight of other major scientific projects.<sup>10</sup>

For all these reasons, we request that GAO conduct a comprehensive, ongoing review of Operation Warp Speed and the vaccine and therapeutic development initiatives that are being coordinated through it. This oversight should be intended to inform the process as it happens and create an elite delivery of service to the American people. We believe this oversight will be most effectively conducted by embedding appropriate subject matter experts—including scientific experts, project management experts, and others—within Operation Warp Speed and requesting immediate access to key documents and personnel from the relevant agencies.

We request that GAO provide the Select Subcommittee and the relevant departments with monthly bipartisan staff briefings beginning in August 2020 and written reports every three months beginning in September 2020, until Operation Warp Speed is disbanded. As a means for creating a template for future endeavors, the reports and briefings should detail observations of best practices that should be sustained and highlight lessons learned that should be improved upon in the next crisis. In other words, GAO should detail what has been done well and should be repeated and what should be learned from and not repeated. Ideally, the reports would follow each category listed below and describe observations to “Improve” and “Sustain” in each one.

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[www.crs.gov/Reports/R46427?source=search&guid=ce2b74e58cb54ebdaed080a267c2badd&index=1](http://www.crs.gov/Reports/R46427?source=search&guid=ce2b74e58cb54ebdaed080a267c2badd&index=1)); *The Race Is on for Antibodies that Stop the New Coronavirus*, Science (May 5, 2020) (online at [www.sciencemag.org/news/2020/05/race-antibodies-stop-new-coronavirus](http://www.sciencemag.org/news/2020/05/race-antibodies-stop-new-coronavirus)); Duke-Margolis Center for Health Policy, *COVID-19 Manufacturing for Monoclonal Antibodies* (June 2020) (online at [healthpolicy.duke.edu/sites/default/files/2020-06/Issue%20Brief%20-%20COVID-19%20Manufacturing%20of%20Monoclonal%20Antibodies\\_0.pdf](http://healthpolicy.duke.edu/sites/default/files/2020-06/Issue%20Brief%20-%20COVID-19%20Manufacturing%20of%20Monoclonal%20Antibodies_0.pdf)).

<sup>9</sup> Select Subcommittee on the Coronavirus Crisis, *Hearing on Accountability in Crisis: GAO’s Recommendations to Improve the Federal Coronavirus Response* (June 26, 2020) (online at [coronavirus.house.gov/subcommittee-activity/hearings/accountability-crisis-ga-o-s-recommendations-improve-federal](http://coronavirus.house.gov/subcommittee-activity/hearings/accountability-crisis-ga-o-s-recommendations-improve-federal)).

<sup>10</sup> See, e.g., Government Accounting Office, *Super Collider Is Over Budget and Behind Schedule* (Feb. 12, 1993) (online at [www.gao.gov/products/RCED-93-87](http://www.gao.gov/products/RCED-93-87)); Government Accountability Office, *National Science Foundation: Cost and Schedule Performance of Large Facilities Construction Projects and Opportunities to Improve Project Management* (Mar. 2019) (online at [www.gao.gov/assets/700/697970.pdf](http://www.gao.gov/assets/700/697970.pdf)).

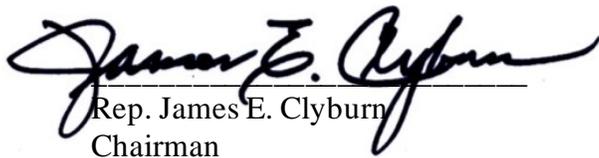
Specifically, we request that GAO examine the following issues:

1. The organizational structures of Operation Warp Speed and the vaccine and therapeutic development initiatives it coordinates, including key personnel and decision-making mechanisms.
2. The justifications and criteria used to assign funds and resources to various Operation Warp Speed projects, including projects designed to develop coronavirus vaccines, therapeutics, testing, and treatments.
3. The justification and criteria used to select coronavirus vaccine and treatment candidates eligible to receive support from Operation Warp Speed.
4. How Operation Warp Speed is coordinating efforts between and among other federal vaccine or therapeutic development initiatives, including but not limited to ACTIV, COVPN, RADX, and other initiatives run by HHS, BARDA, FDA, NIH, or other federal agencies
5. Operation Warp Speed's progress towards completing its stated objective to deliver 300 million doses of a safe, effective coronavirus vaccine to the American public by January 2021 and any significant challenges or impediments, including:
  - a. coordination with relevant federal agencies and other stakeholders and overall project management;
  - b. contracting protocols and procedures;
  - c. technology transfer protocols and procedures between government and private industry;
  - d. utilization of appropriate scientific analysis to assess program outcomes;
  - e. advanced manufacturing and distribution planning; and
  - f. appropriate use of the Defense Production Act to ensure that intellectual property, supply chain, and manufacturing capacity issues do not unnecessarily delay lifesaving treatments and vaccines.
6. Technology Readiness Assessments examining the various vaccine development platforms being used by entities funded through Operation Warp Speed to develop a novel coronavirus vaccine;
7. Review of projects funded by Operation Warp Speed and the initiatives it coordinates to develop testing and treatments for the coronavirus, including assessments of the management and coordination of federal and private research and development efforts;
8. Operation Warp Speed's adherence to federal conflict of interest regulations and whistleblower protections.

9. Whether appropriate schedule coordination, public transparency on likely delivery schedules, and hand-off to the agencies that will be responsible for vaccine prioritization and distribution are taking place.
10. Any other issues that arise during GAO's review and are relevant to the success of Operation Warp Speed or related vaccine and therapeutic development efforts.

Thank you for your prompt attention to this matter. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-4400.

Sincerely,

  
Rep. James E. Clyburn  
Chairman

  
Rep. Mark E. Green, M.D.

  
Rep. Bill Foster