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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

November 18, 2021

Delivered via E-Mail

Mr. Gregory M. Kausner
Acting Under Secretary of Defense for Acquisition and Sustainment
The Pentagon
Washington, D.C. 20310

Dear Mr. Kausner:

On March 1, 2021, the Department of Defense's (DoD) Army Contracting Command entered into another transaction authority prototype project contract with KPMG on behalf of the DoD's Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense and the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services (HHS). Under the contract, KPMG was to develop a "novel prototype process" to help "accelerate access to monoclonal antibody (mAb) treatments for COVID-19 patients who are at high risk for hospitalization or death from the coronavirus, with a focus on ensuring more equitable access to treatment."¹ The one-year contract was initially worth \$75,000,000. The contract was then finalized on June 17, 2021 for a total value of \$142,703,946.²

Less than three months after the contract was finalized, on September 13, 2021, HHS announced a nationwide shortage of mAb treatments and began rationing access to the therapeutic. These potentially life-threatening shortages were the result of the Biden Administration's decision, in April and June, 2021, to cancel mAb manufacturing contracts. Rationing of mAb treatments remains in effect. It is hard to understand why the Biden Administration would enter into a contract with KPMG, worth over \$142,000,000, to promote mAb treatments at the same time it was cancelling mAb manufacturing contracts.

The shortage of mAb treatments and rationing calls into question the origin, rationale, and performance of the KPMG contract. One month after the mAb shortages were announced and just four months after the KPMG contract was finalized, HHS informed the Committee that the contract was under review for "overall performance milestone achievement" and "changes in the COVID-19 therapeutic landscape."³

¹ Other Transaction Authority For Prototype Agreement, W912CG-21-9-0001 (on file with Committee).

² *Id.*

³ Email from HHS-ASPR Office of External Affairs to Committee oversight staff (Oct. 4, 2021).

We have had serious concerns about the KPMG contract since its inception. Our investigation into the contract began just weeks after it was signed when the Committee received information suggesting irregularities in the contract award process. The Ranking Member's oversight staff have tried to work with HHS to better understand the circumstances around the formation of the contract, KPMG's performance, and how the contract fits into the government's COVID-19 therapeutics plan. Regrettably, those efforts have not been successful.

Simply put, it is unclear why the Biden Administration decided to spend over \$142,000,000 on KPMG to develop a "novel prototype process." It is also unclear what KPMG is actually doing to "accelerate access" to mAb treatments.⁴ To date we have received inconsistent and inadequate answers to even basic questions about this contract. On October 7, 2021, HHS declined a Committee request for a briefing stating that the Department was reviewing the KPMG contract for "overall performance, milestone achievement, and changes in the therapeutics landscape." On November 3, 2021, HHS told the Committee that the review was taking longer than expected, blaming the DoD for slowing the interagency review of the contract.

The next day, November 4, 2021, the HHS Assistant Secretary for Preparedness and Response Dawn O'Connell contradicted her agency's representations from the day before in testimony at a Committee hearing. Ms. O'Connell testified that the "review is underway right now. I'm expecting a memo any day with the team's recommendations on whether to keep that funding going." As of the date of this letter, there is no indication that Assistant Secretary O'Connell has reached a decision and HHS staff continue to tell the Committee that their Department is waiting on DoD's review.

Given HHS's representations on DoD's involvement in the KPMG contract, we request the following information and documents by November 24, 2021. When responding, please include a response below each question rather than in a narrative format.

Interrogatories

1. Explain in detail DoD's role in negotiating and managing the KPMG contract, including DoD's role in the ongoing review being conducted by HHS.
2. Explain in detail the "novel prototype process" developed by KPMG.
3. Explain in detail the justification for using DoD's other transaction authority for prototype projects⁵ and identify the nontraditional defense contractors participating in the contract.
4. Explain in detail the requirements development process for the KPMG contract, including, the rationale for entering into the KPMG contract while cancelling mAb manufacturing contracts.

⁴ *Supra*, note 1.

⁵ 10 U.S.C. § 2371b

Document Requests

1. The complete contract file, including but not limited to all solicitations, contracts, task orders, justifications for other than full and open competition, responsibility determinations, documentation of acceptance or performance, and any documentation supporting the use of prototype other transaction authority.
2. All documents reflecting any bids or proposals received in connection with the KPMG contract, including all analyses of these bids and proposals.
3. A list of all meetings or phone conferences between KPMG and any HHS, White House, and DoD employee, official, political appointee, agent, representative, or volunteer, regarding the KPMG contract. Please include the date and time of the meeting or phone conference, names of all participants, and a brief description of the topics discussed.

Thank you in advance for your time and attention to this matter.

Sincerely,



Richard Burr



Susan Collins



Bill Cassidy, M.D.



Mike Braun



Roger Marshall, M.D.



Mitt Romney



Tommy Tuberville

Cc:

The Honorable Xavier Becerra, J.D.
Secretary of Health and Human Services

Mr. Gregory M. Kausner

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Mr. Jeffery Zients

White House Coronavirus Response Coordinator

Mr. S. Lawrence Kocot

Principal and National Leader of the Center for Healthcare Regulatory Insight, KPMG