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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

The Honorable Xavier Becerra, J.D.
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

We write today seeking information and documents regarding a no-bid contract awarded to KPMG by the U.S. Department of Health and Human Services (HHS) to develop a “novel prototype process” that would “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 entered into on March 1, 2021 and initially funded to \$75,000,000. The contract was 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

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 for KPMG to develop a “novel prototype process.” It is also unclear what KPMG is actually doing to

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).

“accelerate access” to mAb treatments.⁴ As of September 27, 2021, HHS reported to the Committee that only 16,461 mAb treatments had been administered as a result of the KPMG contract since March, 2021. For reference, by September 2, 2021, Florida alone had administered over 40,000 mAb treatments.⁵ HHS has not provided updated mAb treatment numbers.

Beyond the small number of infusions administered, the website KPMG developed under the contract is not well designed to “accelerate access” to mAb treatment and, worse, is potentially misleading to the public. Other than testimonial videos and general information about mAbs, KPMG’s crushcovid.com lists the name, phone number, and address of mAb infusion centers. Individuals are told to contact the infusion sites and schedule an appointment on their own.⁶ Unlike many infusion center websites, there is no online scheduling application.

One of KPMG’s objectives under the contract is to support efforts “to focus on the unique needs of government-selected geographies.”⁷ Thus, it appears KPMG is operating in regions at the direction of HHS. Given the focus on outreach, crushcovid.com’s geographical coverage is woefully inadequate, encompassing only eighteen states.⁸ More troublingly still, the infusion centers listed are only a tiny fraction of the total number of mAb infusion centers in a given state. For example, crushcovid.com lists only two mAb infusion centers in Arkansas, both in the eastern half of the state.⁹ By contrast, the Arkansas Department of Health lists one hundred twenty nine mAb infusion centers.¹⁰ Crushcovid.com’s incomplete list of states and infusion centers could actually discourage individuals from seeking treatment. It gives the erroneous impression that mAbs are not available in most states and communities. The public would be better informed if crushcovid.com simply provided links to state public health departments’ websites.

It is also unclear how KPMG identified infusion centers for listing on crushcovid.com. Under the contract, KPMG is supposed to work to “expand access to mAbs in ... targeted, underserved communities.” Unvaccinated individuals are the most at risk of infection, illness, and death from COVID-19 and are the primary users of mAbs. The virus has also had a disproportionate impact on racial and ethnic minorities and low income Americans. Accordingly, KPMG’s contract emphasizes the importance of increasing awareness of and access to mAb treatment availability in “high-risk communities.”

How KPMG determined what constitutes a “high-risk” community is not readily apparent. Nor is it clear what criteria KPMG used when deciding which mAb treatment centers in a given state should be listed on crushcovid.com and which should not. For most states, crushcovid.com only lists one or two healthcare providers, seemingly without regard for whether the provider has locations in “high-risk” communities. For example, one of the first infusion sites posted to crushcovid.com was in Barnstable County, Massachusetts off Cape Cod. As of November 4, 2021, 91% of Barnstable County residents had at least one COVID-19 vaccination. Barnstable County is 92.2% white with a median household income of over \$74,500. In short, by most measures of COVID-19 risk, Barnstable County is not a “high risk community.”

⁴ *Supra*, note 1.

⁵ <https://www.orlandosentinel.com/coronavirus/os-ne-coronavirus-regeneron-treatment-20210902-5eup4jp6efglhcxx73grc42tpq-story.html>

⁶ <https://crushcovid.com/>

⁷ <https://info.kpmg.us/news-perspectives/public-policy/federal-covid19-therapeutic-access-program.html>

⁸ *Id.*

⁹ https://crushcovid.com/?wpv-state=arkansas&wpv_aux_current_post_id=55&wpv_aux_parent_post_id=55&wpv_view_count=73.

¹⁰ <https://www.healthy.arkansas.gov/programs-services/topics/covid-19-guidance-about-mono-clonal-antibodies>.

To date the Ranking Member's oversight staff 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 Department of Defense (DoD), who executed the contract on HHS's behalf, for complicating interagency review of the contract.

The next day, November 4, 2021, the 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. However, recently, KPMG informed the Committee that HHS ordered it not to cooperate with the Committee's investigation and that HHS must approve KPMG's release of information to the Committee. We sincerely hope that HHS is not coercing KPMG into obstructing a congressional investigation and that this is a misunderstanding.

For these reasons 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 the "novel prototype process" developed by KPMG.
2. Explain in detail the justification for using DoD's other transaction authority for prototype projects¹¹ and identify the nontraditional defense contractors participation in the contract.
3. 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. Explain in detail the negotiations with KPMG, including who initiated negotiations, and identify any federal employee, official, political appointee, agent, representative, or volunteer, including but not limited to any White House, DoD, or HHS employee that participated in negotiations.
5. Explain in detail the review process the KPMG contract is currently undergoing, include the following information:
 - a. How is HHS reviewing KPMG's "overall performance" and "milestone achievement"?
 - b. Does HHS consider KPMG to be in breach of contract or to have failed to meet contract milestones? If so, why?
 - c. What "changes in COVID-19 therapeutic landscape" contributed to HHS initiating a review of the KPMG contract?
 - d. What role does DoD play in reviewing the KPMG contract?
 - e. When does HHS expect the review to be finished?
6. Explain in detail the instructions, advice, or directives HHS has given KPMG concerning KPMG's interactions with the Committee and identify any HHS, White House, and DoD employee, official, political appointee, agent, representative, or volunteer who gave such instructions, advice, or directives.

¹¹ 10 U.S.C. § 2371b

7. Provide updated information on the following:
 - a. A list of infusion sites participating in the KPMG prototype program;
 - b. The number of mAb treatments that have been administered to date as a result of the contract, include an explanation of how HHS determines that a mAb treatment is the result of the KPMG contract; and
 - c. The amount KPMG has been reimbursed for costs incurred as a result of the contract.

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. All projections, forecasts, models, and estimates, including underlying data, relating to the demand for mAb treatments from February 1, 2021 to the present.
4. All documents and communications regarding the contract award, performance, and review, including internal HHS communications and HHS communications with KPMG, the White House, and DoD. Priority custodians of interest to the Committee include, but are not limited to, the following:
 - a. David Kessler, Chief Science Officer, COVID Response;
 - b. Dawn O'Connell, Assistant Secretary for Preparedness and Response, formerly Senior Counselor, COVID Response;
 - c. AJ Pearlman, Chief of Staff, COVID Response;
 - d. Kathryn Alvarez, Deputy Chief of Staff, COVID Response;
 - e. Norris Cochran, Acting Assistant Secretary for Financial Resources, formerly Acting Secretary;
 - f. Ian Sams, Deputy Assistant Secretary for Public Affairs, COVID Response;
 - g. Kirsten Allen, National Press Secretary, COVID Response;
 - h. Kacey Wulff, Chief of Staff, Office of the Assistant Secretary for Preparedness and Response;
 - i. Jonathan Warsh, Senior Policy Advisor COVID Response, Office of the Assistant Secretary for Preparedness and Response;
 - j. Kristin Avery, White House Liaison;
 - k. Marvin Figueroa, Director, Office of Intergovernmental and External Affairs; and
 - l. Yvanna Cancela, Principal Deputy Director, Office of Intergovernmental and External Affairs.
5. 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.

Secretary Xavier Becerra

November 18, 2021

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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:

Mr. Jeffery Zients
White House Coronavirus Response Coordinator

Mr. S. Lawrence Kocot
Principal and National Leader of the Center for Healthcare Regulatory Insight, KPMG