CATHY McMORRIS RODGERS, WASHINGTON
CHAIR

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3641
Minority (202) 225-2927

June 29, 2023

Mary Denigan-Macauley, PH.D.
Director
Health Care
Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20226

Dear Dr. Denigan-Macauley:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, June 7, 2023, at the hearing entitled, "Looking Back Before Moving Forward: Assessing CDC's Failures in Fulfilling its Mission Safety."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on July 13, 2023**.** Your responses should be e-mailed in Word format to lauren.eriksen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

H. Morgan Griffith
Chairman
Subcommittee on Oversight and Investigations

cc: Representative Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations.

Additional Questions for the Record

Mary Denigan-Macauley, PhD, Director of Public Health, U.S. Government Accountability Office

The Honorable Michael Burgess

1. **Ms. Denigan-Macauley, in your written testimony, you mentioned that the lack of clearly defined roles within our public health agencies lead to putting more communities at risk during the COVID-19 pandemic, specifically.**

- Has this been a common theme you have seen throughout your analysis of different emergency health events?

The lack of clear roles and responsibilities within the Department of Health and Human Services (HHS) and between it and its key partners has been a longstanding concern that we have identified not just with the COVID-19 pandemic, but also during past events. For example, in August 2007, we reported that federal leadership roles and responsibilities, including HHS's, needed to be rigorously and robustly tested as they evolve to ensure clarity in how relationships should work during emergencies. We also reported that because initial actions may help limit the spread of a virus, such as influenza, the effective exercise of shared leadership roles and responsibilities could substantially shape the outcome of a pandemic.

The unprecedented scale of the COVID-19 pandemic, and the whole-of-nation response required to address it, highlight the critical importance of clearly defining the roles and responsibilities for the wide range of federal departments and other key partners involved when preparing for pandemics and addressing unforeseen emergencies. For example, in April 2021, we reported that when HHS helped repatriate U.S. citizens from abroad and quarantine them domestically at the beginning of the COVID-19 pandemic to prevent the spread of the virus, significant confusion ensued. As a result, HHS put repatriates, its own personnel, and nearby communities at risk due to a lack of clarity as to which HHS agency was in charge, including which HHS agency was responsible for managing infection prevention.

2. **What are your suggestions to make our public health agencies' roles more clearly defined?**

Regularly exercising preparedness plans with all response partners is a key practice. Response partners can include not only other federal agencies, but tribal, state, local, territorial and private sector, depending on the type of response. It allows all involved parties to practice operationalizing the plans to help identify any gaps in procedures or barriers to plan implementation so that these can be addressed and plans revised before an actual event occurs. For example, in April 2021, we recommended that HHS agencies—Administration for Strategic Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), and the Administration for Children and Families—revise or develop new plans that clarify agency roles and responsibilities during a pandemic, and regularly exercise these plans with key partners.

You also mentioned the limitations of ASPR, the Administration for Strategic Preparedness and Response, and its limited response activities.

3. **What advantage would an increase of public-private partnerships within ASPR have to ensure advanced readiness for any future pandemic?**

A whole-of-nation multidisciplinary approach to preparedness and response is essential. HHS partnership and engagement with nonfederal entities, including tribal, state, local, and territorial governments, and the private sector are key elements of this approach. It has the potential to enhance capacity and capabilities to help move more expediently during emergencies. Operation Warp Speed and HHS efforts to work with pharmaceutical companies to accelerate the development of COVID-19 therapeutics and vaccines are examples of federal collaboration with the private sector. In addition, with HHS support, groups of health care and response organizations—known as health care coalitions—partner to prepare health care systems to respond to emergencies and disasters in order to increase local and regional resilience. Given the many public and private entities that must come together to ensure community preparedness, HHS-supported health care coalitions serve an important mechanism for communicating and coordinating during emergencies and disasters.

While such partnerships can be beneficial, we found that HHS can be challenged incentivizing private sector involvement and maintaining a state of readiness. For example, we reported in February 2023 the reluctance of the private sector to get involved with medical countermeasure development and the subsequent challenges this resulted in during the COVID-19 pandemic. Specifically, we reported that one reason manufacturing sites in one program faced challenges reliably producing products during the pandemic was that they lacked regular manufacturing work leading up to pandemic, in part because they faced challenges attracting private sector partners. We concluded that, looking ahead, if HHS does not develop an effective program model for medical countermeasure development, it may not secure the private sector partnerships necessary to provide countermeasure surge manufacturing capacity and capability during future public health emergencies. We recommended that HHS systematically assess and respond to known challenges and future risks associated with advanced development and manufacturing of countermeasures. Such an approach should clearly document program risks, ensure that progress in addressing risks is tracked, estimate needed program resources, and communicate this information to key decision makers so that HHS is better prepared for future events. By implementing our recommendation, HHS would be better positioned to ensure advanced readiness of its partnership programs for future public health threats.

<u>The Honorable Miller-Meeks</u>

1. During the Public Health Emergency, the CDC set up processes to ensure patient access to COVID vaccinations quickly following the recommendation by the Advisory Committee on Immunization Practices (ACIP).
    a. Can the CDC also set up the appropriate strategy to ensure patient access isn't impeded for new vaccines by developing and implementing processes to allow for rapid publication of the MMWR shortly after ACIP votes and recommends a new vaccine? Publication in the MMWR occurred only hours after the ACIP recommendation but can otherwise take months. This coordination would be beneficial to ensure patients have access to new vaccines, especially those that have an epidemiological seasonality. It would directly support the implementation of the CDC's Moving Forward Project and Data Modernization Initiative (DMI) with one of the focuses being timeliness of policy guidance.

GAO response: ACIP recommendations are reviewed by the CDC Director, and if adopted, are published as official CDC recommendations in the Morbidity and Mortality Weekly Report (MMWR). However, our previous work on COVID-19 vaccinations has shown that CDC can adopt ACIP's recommendations prior to publication in the MMWR. In particular, our November 2021 report on COVID-19 Vaccine Distribution and Communication (https://www.gao.gov/products/gao-22-104457) includes a timeline of key events for COVID-19 vaccine implementation, with examples of when CDC adopted ACIP's recommendations before MMWR publication. For example, ACIP made recommendations for COVID-19 booster doses on October 21, 2021. On the same day, CDC adopted these recommendations and issued a public statement with information about them. The recommendations were later posted online as an MMWR Early Release on October 29, 2021 and published in the November 5 issue of the MMWR. See https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e2.htm.

More recently, CDC has also followed this practice for other vaccines. For example, on June 27, 2023, the CDC Director reviewed and adopted ACIP's recommendations from its June 21-23 meeting, and these recommendations are now official, according to CDC's website (https://www.cdc.gov/vaccines/acip/recommendations.html). The website includes details on the recommendations—which relate to RSV (Respiratory Syncytial Virus), Polio, Influenza, and Pneumococcal vaccines—and states (as of June 30) that they will be published in the MMWR in the coming months. In addition to sharing information on the website and through the MMWR, ACIP also includes non-voting representatives of liaison organizations, such as American Medical Association and the Association of State and Territorial Health Officials, who help to disseminate ACIP's recommendations to their membership (https://www.cdc.gov/vaccines/acip/members/index.html).

The Honorable Jan Schakowsky

2. The U.S Government Accountability Office has done extensive work assessing COVID-19 in nursing home facilities. Since the start of the pandemic, over 200,000 residents and staff in long-term care facilities have died from COVID-19.
    a. What recommendations has the Government Accountability Office made in response to this issue?

GAO Response: GAO has examined COVID-19 in nursing homes in multiple studies from 2020 through 2022 and made 11 recommendations. Please see the table below for an overview of these studies.

Table 1: Description of Selected GAO Reports on COVID-19 in Nursing Homes with Recommendations, September 2020 through September 2022

Date	Title	Recommendation	Status
September 2022	*COVID-19 in Nursing Homes: CMS Needs to Continue to Strengthen Oversight of Infection Prevention and Control* (GAO-22-105133)	The Administrator of the Centers for Medicare & Medicaid Services (CMS) should establish minimum infection preventionist training standards. (Recommendation 1)	**Open.**
		The Administrator of CMS should collect infection preventionist staffing data and use these data to determine whether the current infection preventionist staffing requirement is sufficient. (Recommendation 2)	**Open.**
		The Administrator of CMS should provide additional guidance in the State Operations Manual on making scope and severity determinations for infection prevention and control (IPC)-related deficiencies. (Recommendation 3)	**Open.**
July 2021	*COVID-19:* *VA Should Assess Its Oversight of Infection Prevention and Control in Community Living Centers (GAO-21-559)*	The Department of Veterans Affairs (VA) Under Secretary for Health should conduct a retrospective assessment of VA's oversight of infection prevention and control in Community Living Centers (CLC) during the COVID-19 pandemic to identify lessons learned and be better prepared for future infectious disease outbreaks. (Recommendation 1)	**Closed – implemented.**
June 2021	*VA Health Care:* *Additional Data Needed to Inform the COVID- 19 Response in Community Living Centers (GAO-21-369r)*	The VA Under Secretary for Health should compile and review facility-specific COVID-19 data on CLC staff cases and deaths on a regular basis to inform the agency's response to the pandemic or future infectious disease outbreaks. (Recommendation 1)	**Open.**
March 2021	*COVID-19: Sustained Federal Action is Crucial as Pandemic Enters Its Second Year* (GAO-21-387)	The Secretary of the Department of Health and Human Services (HHS) should ensure that the Director of the Centers for Disease Control and Prevention (CDC) collects data specific to the COVID-19 vaccination rates in nursing homes and makes these data publicly available to better ensure transparency and that the necessary information is available to improve ongoing and future vaccination efforts for nursing home residents and staff. See Nursing Homes enclosure. (Recommendation 3)	**Closed – implemented.**
		The Secretary of HHS should ensure that the Administrator of CMS, in consultation with CDC, requires nursing homes to offer COVID-19 vaccinations to residents and staff and design and implement associated quality measures. See Nursing Homes enclosure. (Recommendation 4)	**Open – partially addressed.**
November 2020	*COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response* (GAO-21-191)	The Administrator of CMS should quickly develop a plan that further details how the agency intends to respond to and implement, as appropriate, the 27 recommendations in the final report of the Coronavirus Commission on Safety and Quality in Nursing Homes, which the Centers for Medicare & Medicaid Services released on September 16, 2020. Such a plan should	**Closed – implemented.**

		include milestones that allow the agency to track and report on the status of each recommendation; identify actions taken and planned, including areas where CMS determined not to take action; and identify areas where the agency could coordinate with other federal and nonfederal entities. (Recommendation 2)	
		The VA Under Secretary for Health should develop a plan to ensure inspections of state veterans homes occur during the COVID-19 pandemic—which may include using in-person, a mix of virtual and in-person, or fully virtual inspections. (Recommendation 3)	**Closed – implemented.**
		The VA Under Secretary for Health should collect timely data on COVID-19 cases and deaths in each state veterans home, which may include using data already collected by CMS. (Recommendation 4)	**Closed – implemented.**
September 2020	*COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions* (GAO-20-701)	The Secretary of HHS, in consultation with CMS and CDC, should develop a strategy to capture more complete data on confirmed COVID-19 cases and deaths in nursing homes retroactively back to January 1, 2020, and to clarify the extent to which nursing homes have reported data before May 8, 2020. To the extent feasible, this strategy to capture more complete data should incorporate information nursing homes previously reported to CDC or to state or local public health offices. (Recommendation 15)	**Open.**

Source: GAO

Note: The hyperlinks provide additional details about the report findings and recommendations.

b. What else is needed to protect nursing home residents and staff?

GAO response: A growing body of work shows that the COVID-19 pandemic exposed and worsened longstanding infection control problems in nursing homes. As the nation moves forward, proper infection prevention and control procedures will remain critical to protecting residents against not only the threat of COVID-19, but also other infectious diseases. In April 2022, GAO convened a roundtable of infectious disease specialists, nursing home staff, advocates, and other experts to examine infection control practices in nursing homes. These experts identified 14 actions for the Department of Health and Human Services (HHS) to continue, enhance, or discontinue—some of which are consistent with GAO's prior recommendations, including developing solutions to ensure adequate staffing. HHS's continued leadership in prioritizing infection prevention and control—in coordination with other federal, state, and private entities—is critical to better protecting nursing home residents from the enduring risks of declining health and premature death posed by infections.