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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510–6300

WARREN GUNNELS, MAJORITY STAFF DIRECTOR AMANDA LINCOLN, REPUBLICAN STAFF DIRECTOR

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July 6, 2023

VIA ELECTRONIC TRANSMISSION

Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Ave., S.W. Washington, D.C. 20201

Dear Secretary Becerra:

On July 22, 2022, the Department of Health and Human Services (HHS) announced that it had elevated its Office of the Assistant Secretary for Preparedness and Response from a staff division to an operating division and renamed it the Administration for Strategic Preparedness and Response (ASPR). On February 16, 2023, HHS announced that it had completed a reorganization of ASPR. In light of the critical role ASPR plays in preparing for and responding to public health threats, I write to ensure that ASPR's recent reorganization places it in the best possible position to serve the American people in times of crisis.

One of the initial steps in the reorganization, completed in January 2022, involved moving the functions of the Countermeasures Acceleration Group, previously known as Operation Warp Speed, to the HHS Coordination Operations and Response Element (H-CORE).³ The Countermeasures Acceleration Group was formed out of a partnership between HHS and the U.S. Department of Defense and was responsible for developing, producing, and distributing COVID-19 vaccines.⁴ According to HHS's February 16, 2023 announcement regarding the reorganization, H-CORE is responsible for "deliver[ing] COVID-19 countermeasures to the American public while solidifying enhanced capability to respond to future public-health threats."⁵

¹ HHS Strengthens Country's Preparedness for Health Emergencies, Announces Administration for Strategic Preparedness and Response (ASPR), DEP'T OF HEALTH & HUM. SERVS., (July 22, 2022), https://www.hhs.gov/about/news/2022/07/22/hhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html.

² Statement of Organization, Functions and Delegations of Authority, 88 Fed. Reg. 10125 (Feb. 16, 2023).

³ https://www.help.senate.gov/imo/media/doc/O%27Connell3.pdf; see also Letter from Xavier Becerra, Sec'y, Dep't of Health & Hum. Servs., to Ranking Member, Subcomm. on Lab., Health & Hum. Servs., Educ. & Related Agencies, Comm. on Appropriations, U.S. Senate (Jan. 27, 2023).

⁴ See U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-104453, COVID-19: HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues (Jan. 2022), https://www.gao.gov/products/gao-22-104453.

⁵ Statement of Organization, Functions and Delegations of Authority, 88 Fed. Reg. 10125 (Feb. 16, 2023).

During the reorganization effort, HHS also made changes to the reporting structure for the Strategic National Stockpile (SNS) and the Office of Industrial Base Management and Supply Chain (IBMSC).⁶ These components, which were previously associated with other offices within the agency, now report directly to the Assistant Secretary for Preparedness and Response.⁷ In a January 27, 2023 letter, you explained that changes at the SNS "provide a direct line of communication to ASPR leadership for the important national-level work being done out of the SNS," including its "important role in supply chain discussions to improve the SNS." Further, you explained that as a direct reporting component, the IBMSC "will help the ASPR to sustain and continue to build permanent domestic industrial base capabilities, inclusive of global supply chain situational awareness, market capabilities, and rapid acquisition execution."

The reorganization at ASPR comes after the COVID-19 pandemic, which tested the limits of our nation's public health and medical preparedness and response framework. Given that ASPR "leads the nation's medical and public health preparedness for, response to, and recovery from disasters and other public health emergencies," it is critical to ensure that the reorganization is fully informed by lessons learned during the pandemic and that it addresses past challenges associated with the coordination of federal response operations. At the same time, ASPR must remain focused on addressing future threats to Americans' safety and security rather than taking on duties beyond its mission.

Finally, in light of ASPR's recent reorganization and the culture change within the agency, it is critical that employees are reporting for in-person work. If the agency is to accomplish its stated goal "to mobilize a coordinated national response more effectively and efficiently during future disasters and emergencies in close collaboration with its sister agencies," ASPR employees must be showing up in person to improve the agency's operations.

As Ranking Member of the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP), it is my responsibility to ensure that ASPR is in the best position to effectively

⁶ Letter from Xavier Becerra, *supra* note 3, at 2.

⁷ *Id.*; *see* DEP'T OF HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE (ASPR), https://aspr.hhs.gov/AboutASPR/ProgramOffices/Documents/ASPR%20-%20Organizational-Chart.pdf (last accessed July6, 2023).

⁸ Letter from Xavier Becerra, *supra* note 3, at 2.

⁹ *Id*

¹⁰ ASPR Organization, ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE, https://aspr.hhs.gov/AboutASPR/ProgramOffices/Pages/ProgramOffice.aspx (last accessed July 6, 2023).

¹¹ See, e.g., Eli Y. Adashi et al., Should the Administration for Strategic Preparedness and Response Lead the National Response to a Public Health Emergency?, JAMA HEALTH F. (Jan. 6, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2800136; Reforming and Strengthening ASPR: Ensuring Specialized Capabilities, Sufficient Capacity, and Specific Authorities to Meet 21st Century Public Health Threat, U.S. Senate Comm. on Health, Educ., Lab., & Pensions (June 24, 2021),

https://www.help.senate.gov/ranking/newsroom/press/burr-releases-new-report-on-asprs-role-in-federal-pandemic-response-key-recommendations; U.S. Gov't Accountability Off., GAO-21-334, COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens During a Pandemic (Apr. 19, 2021), https://www.gao.gov/products/gao-21-334.

¹² HHS Strengthens Country's Preparedness for Health Emergencies, Announces Administration for Strategic Preparedness and Response (ASPR), supra note 1.

prepare for and respond to future public health emergencies. To that end, I ask that you please answer the following questions, on a question-by-question basis, no later than **July 21, 2023**.

- 1. Please produce a complete graphical organization chart of the new ASPR structure. In addition, for each component within this structure, please provide:
 - a. Where applicable, the number of employees and full-time equivalents (FTEs) associated with the component prior to the reorganization;
 - b. The number of employees and FTEs associated with the component following the reorganization;
 - c. The current number of vacancies for the component following the reorganization;
 - d. The number of existing ASPR employees who have been transferred to the component from other ASPR components, and a list of the specific components from which those employees were transferred.

2. Regarding the reorganization of ASPR:

- a. Please explain what HHS expected to accomplish as a result of the reorganization. Also, please provide a detailed list of objectives that ASPR expects to accomplish.
- b. What specific metrics will HHS and ASPR use to assess whether the reorganization is achieving its objectives and otherwise improving ASPR operations?
- c. How will HHS and ASPR ensure that ASPR remains focused on its mission to prepare for and respond to public health emergencies, rather than becoming involved in other crises?
- 3. Regarding the elevation of ASPR to an operating division:
 - a. What are the specific objectives that ASPR is working to accomplish as a result of its elevation to an operating division? Please explain in detail.
 - b. What specific metrics is ASPR using to assess whether the elevation is achieving its objectives and otherwise improving the agency's operations?
 - c. Please explain in detail how ASPR's elevation is affecting its ability to coordinate with other HHS components and other government agencies, as well as its ability to execute its mission.
 - d. What responsibilities, if any, have been shifted to ASPR from other HHS agencies or staff divisions? Are there any activities that have been shifted from ASPR to another HHS agency or staff division? Please explain in detail.

- e. How has ASPR's relationship with the Office of the Secretary evolved as a result of its elevation?
- 4. Regarding the establishment of H-CORE:
 - a. Please explain in detail the responsibilities of the Office of Supply, Production, and Distribution (OSPD) and the Office of Vaccine Development Coordination (OVDC) within H-CORE. How are the responsibilities of those offices distinct from those of the Biomedical Advanced Research and Development Authority (BARDA) and SNS? Please also explain in detail how ASPR plans to address and minimize duplication among these offices.
 - b. Please explain H-CORE's purpose and function in the absence of an active public health emergency. How has H-CORE's purpose and function changed now that the COVID-19 public health emergency declaration has expired?
- 5. Please explain how the responsibilities of the IBMSC are distinct from those of BARDA and SNS. What specific supply chain and industrial base policy and programmatic activities will BARDA and SNS continue to carry out, if any? Please explain in detail how HHS plans to address and minimize duplication among these offices.
- 6. Regarding ASPR's physical office space:

Ranking Member

- a. Where do ASPR employees report for in-person work? Please identify all office locations and the number of employees who work at those locations. Please also identify where each office within ASPR is located. Finally, please identify the number of ASPR employees, if any, who work exclusively remotely.
- b. Where does the Assistant Secretary for Preparedness and Response report for in-person work? Does the Assistant Secretary keep more than one office? If so, how does she allocate her time between those offices? How many days per week does she report for in-person work? Has she changed where she regularly reports for work since ASPR's elevation as an operating division? Please explain in detail.

Thank you for your attention to t	his matter.	
Sincerely,		
Bill Cassidy, M.D.		