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## Failing Grade: The Pandemic Legacy of HHS

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**O**n January 27, 2022, the Government Accountability Office (GAO) issued its ninth report on the efforts of the federal government to respond to and recover from the coronavirus disease 2019 (COVID-19) pandemic.<sup>1</sup> The GAO report reaches as far back as January 2020 to encompass both the Trump and Biden Administrations. Turning its attention to HHS (home to agencies such as the Food and Drug Administration and the Centers for Disease Control and Prevention [CDC]), the GAO found persistent deficiencies in the preparedness and response efforts in several areas. The HHS pandemic record was deemed especially wanting in “establishing clear roles and responsibilities, collecting and analyzing complete and consistent data, providing clear, consistent communication, establishing transparency and accountability, and understanding key partners’ capabilities and limitations.” These and previously reported shortcomings led the GAO to designate the “HHS’s leadership and coordination of a range of public health emergencies as high risk.” In so doing, the GAO sought to drive transformation as well as assure “sustained executive branch and congressional attention so the nation is prepared for future emergencies.”<sup>1</sup> This article reviews the findings of the GAO and discusses the significance and implications thereof.

Leading the GAO report were observations related to the inability of HHS to establish clear roles and responsibilities for a wide range of its key partners.<sup>1</sup> Special mention was made of the apparent inability of HHS to effectively lead the Biodefense Steering Committee and the Biodefense Coordination Team in formulating and implementing a National Biodefense Strategy.<sup>2</sup> A note was also made of ill-coordinated HHS efforts in connection with the repatriation of U.S. citizens during the COVID-19 pandemic. Equally important concerns were raised as to the ability of HHS to manage the ongoing shortages of medical countermeasures such as vaccines, drugs, diagnostics, and related supplies.

Apart and distinct from the foregoing, the GAO found HHS wanting in “collecting and analyzing complete and consistent data to inform decision-making and future preparedness.”<sup>1</sup> It was the conclusion of the GAO that

the “data HHS has relied on during the COVID-19 pandemic have been, and remain, incomplete and inconsistent.” At the outset of the pandemic, data on the spread of COVID-19 were deemed to have been compromised by a flawed diagnostic test, which was developed by CDC. Subsequent data collection was found lacking not only with respect to the case counts but also in terms of the race and ethnicity composition thereof. Data collection of “COVID-19 cases, hospitalizations, and deaths” were deemed similarly compromised. More of the same held for “nursing home data for COVID-19 cases and deaths.”

Another key deficiency highlighted by the GAO revolved around the “clear, consistent communication to key partners and the public.”<sup>1</sup> One example cited made note of the reality that “states often did not have information critical to COVID-19 vaccine distribution at the local level, such as how many doses they would receive and when.” Similar concerns were raised by the “inconsistent communication to healthcare providers about the use of certain personal protective equipment.” The absence of a “publicly available and comprehensive national COVID-19 testing strategy” was cited as well as the proximate cause for the absence of “an informed and coordinated testing response.”

The importance of establishing transparency and accountability with program integrity and public trust in mind was also a subject of significant GAO attention.<sup>1</sup> Notable concerns were raised as to the ability of the Office of the Assistant Secretary for Preparedness and Response (ASPR) to ensure that state, local, territorial, and tribal governments received “correct and undamaged” materials from the Strategic National Stockpile. Significant attention was also paid to the communication

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of the multiple changes to the national testing guidelines in the absence of a clearly articulated scientific rationale. The resultant confusion among providers and public health stakeholder groups whose role it is to implement the testing guidelines was all but predictable.

The GAO also made significant note of persistent deficiencies in the ability of ASPR to possess a complete “understanding of key partners’ capabilities and limitations.”<sup>1</sup> Most of these concerns revolved around the inability of ASPR to “fully execute its preparedness and response activities, especially as ASPR’s responsibilities have increased.” Areas affected by these realities included but were not limited to vaccine responsibilities, domestic manufacturing of medical products, medical supply acquisition, and the emergency responder workforce.

When it comes to public health emergencies, the Secretary of HHS is entrusted with the complex and far-reaching role of leading the federal public health and medical response.<sup>1</sup> Among the multiple GAO recommendations that HHS has yet to implement, a few stand out by dint of their central import. Topping the list is the imperative of clearly defining the roles and responsibilities of the federal agencies that make up the Biodefense Coordination Team. Just as importantly, HHS is to establish the national capacity for the timely and complete collection of public health data, the review and reporting of which is to be overseen by an expert committee. The GAO further recommended that the Food & Drug Administration and CDC work toward the communication of clear and consistent guidance to health-care providers. ASPR, for its part, should see to the development of a “transparent and deliberative process” for the procurement of vaccines, supplies, and other materials for the Strategic National Stockpile. In this context, ASPR will do well to work with key federal response partners to advance an understanding of their capabilities and limitations.

One all-important reality that the GAO report does not touch upon is the division of labor between HHS and the White House Office of the Coronavirus Response Coordinator.<sup>3</sup> In doing so, the GAO report fails to take into account the intense politicization of the COVID-19 pandemic and the significant impact thereof on the very ability of HHS to carry out its proscribed responsibilities. To most observers, it was the White House Coronavirus Response Coordinator who commanded the public stage. In a notable article in the *Harvard Law Review*, the then professor, now Justice Elena Kagan described the phenomenon of the Presidential Administration that emerged during the Clinton era. A note was made of the “use of directive power over regulatory agencies, as well as [President Clinton’s] assertion

of personal ownership over regulatory product,” which reconfigured the administrative state.<sup>4</sup> It is at least possible that the prominence of the White House Coronavirus Response Coordinator was at the heart of the difficulties that HHS has faced and that the GAO report enumerates. The Coordinator was one among a long list of what the press has called czars (with portfolios as diverse as drug control policy, homelessness, climate change, and the like)—appointees who typically do not have the power of any agency but are often followed in interagency coordination because they are presumed to speak for the White House. These czars often have the effect of disempowering agencies in the conversation. A different but related problem, especially in the Trump period of pandemic management, was the changes in the role of CDC. From the displacing of CDC data collection of hospitalization data in favor of funneling it through a private contractor, the installation of individuals without public health backgrounds to monitor CDC officials, or the publishing of testing guidance bypassing CDC scientific review, at several key junctures the White House sidelined and diminished CDC.<sup>5</sup> As the nation plans for the next pandemic, it is worth reflecting on the optimal and all-too-critical balance between the White House on the one hand and HHS on the other.

The GAO report also does not address the ways in which the public’s expectation as to CDC’s role is a mismatch for the authority granted to it by Congress. In the U.S., public health has always been an instance of cooperative federalism, with much of the power residing in individual states’ police powers and, in turn in some instances, further devolved to local governments. Some have suggested that compared with other countries, the U.S.’ poor performance in the early months of the pandemic may be traced to this structure, and question whether more centralization of power in a national public health agency would be desirable.<sup>6</sup>

The posting of the GAO report all but coincided with the release of the discussion draft of the long-awaited PREVENT Pandemic Act by Senator Patty L. Murray (D-WA), Chair of the Senate Health, Education, Labor, and Pensions Committee, and ranking member, Senator Richard M. Burr (R-NC).<sup>7</sup> Potentially, the signature pandemic preparedness bill of the 117th United States Congress, the PREVENT Pandemic Act, has since been passed by the Senate Health, Education, Labor, and Pensions Committee by a wide bipartisan margin.<sup>8</sup> If enacted, the PREVENT Pandemic Act could address several of the shortcomings identified by the GAO in its report.<sup>8</sup> Examples include the improvement of interagency coordination, the strengthening of the medical product supply chain, the crafting of a CDC-wide strategic plan, and the redress of disparities affecting at-risk

populations.<sup>8</sup> Senator Murray said it best when noting that “the pain of this pandemic is unforgettable, and we have the responsibility to make sure its lessons are unforgettable too.”<sup>7</sup>

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