

# Are U.S. Health Agencies Prepared for the Next Pandemic? It's Entirely Unclear

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## Introduction

The end of the death, disease, and disruption caused by the Covid-19 pandemic provides a good opportunity to consider how best to prepare for the next pandemic. Congress, unfortunately, allowed the Pandemic and All-Hazards Preparedness Act (PAHPA),<sup>1</sup> the cornerstone of federal pandemic preparedness authorities, to expire on September 30, 2023, a date once seen as a “must-pass”<sup>2</sup> deadline. Given the importance of pandemic preparedness revealed by the Covid-19 pandemic, Congress should reauthorize PAHPA and fund federal preparedness, while also insisting on meaningful accountability measures that ensure that federal spending provides cost-effective reductions in pandemic risks.

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The federal response to Covid-19 has been mixed, at best. Operation Warp Speed—the 2020 initiative that developed, tested, authorized, and delivered safe and effective Covid-19 vaccines to Americans in record-breaking time—has been widely and justifiably praised.<sup>3</sup> The vaccines authorized and then approved by the Food and Drug Administration (FDA) are very good compared with those approved abroad, although assessing the relative effectiveness and safety of vaccines is complicated because of differences in populations being studied, differences in the disease (i.e., its new variants), and differences in the type and duration of evaluation methods. The FDA-approved vaccines made by Pfizer-BioNTech and Moderna are better in terms of safety and efficacy than Chinese and Indian vaccines that had received emergency-use authorization from the World Health Organization.<sup>4</sup> The data used for the initial authorization of Russia's Sputnik Covid vaccine have been criticized by some researchers as “very unlikely to occur in



genuinely experimental data,”<sup>5</sup> although observational data from vaccination campaigns point to significant reductions in morbidity and mortality.<sup>6</sup> Despite the success of Operation Warp Speed, the performance of some other federal anti-Covid measures was dismal.

The Centers for Disease Control and Prevention issued disappointing recommendations for how to reduce the risk of contracting Covid-19.<sup>7</sup> They often lacked a credible scientific basis and were generally issued officiously, without regard to public comments. This led to flawed or outright wrong guidance. For example, it took nearly a year and a half for CDC to recognize that the new coronavirus’s primary route of transmission was through the air, rather than on surfaces.<sup>8</sup> (It took the World Health Organization two years to quietly update its guidance. WHO had confidently, but incorrectly, posted on social media early in the pandemic “FACT: #COVID19 is NOT airborne.”)<sup>9</sup> CDC’s recommendations to close schools contributed to significant and lasting deficits in educational attainment, especially among younger disadvantaged students.<sup>10</sup> The inspector general of the Department of Health and Human Services (HHS) reported in October 2023 that the Strategic National Stockpile of medical countermeasures—managed by the Administration for Strategic Preparedness and Response (ASPR), within the Department of Health and Human Services (HHS)—was inadequate and ineffective.<sup>11</sup> The congressional Government Accountability Office (GAO) found that pre-Covid efforts by the Biomedical Advanced Research and Development Authority (BARDA) to create surge capacity for medical countermeasures (including drugs and vaccines) basically failed to accelerate production of Covid-19 vaccines during the pandemic.<sup>12</sup> FDA’s program to identify and manage shortages of medical products—both Covid-related and routine—also needs substantial reform.<sup>13</sup> Despite the early access to remarkably safe and effective vaccines, the total number of U.S. Covid-related deaths exceeds 1.17 million,<sup>14</sup> a toll per 100,000 residents much higher<sup>15</sup> than in most other industrialized democracies.

This issue brief will discuss the measures that U.S. federal health agencies are taking—or, more accurately, not taking—to prepare for the next pandemic, and evaluate whether the funds reserved for pandemic preparedness are being effectively used. It is in the national interest to reauthorize PAHPA, but Congress must demand that federal agencies adopt and implement quantifiable measures of preparedness.

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## Pandemic Preparedness Just One Priority Among Too Many

The height of the Covid-19 pandemic led to a massive federal response involving big increases in federal spending, debt, and federal interest payments. Six Covid-19 relief laws enacted in 2020–21 provided about \$4.6 trillion of additional federal spending, of which \$4.5 trillion was obligated by January 1, 2023, according to GAO.<sup>16</sup> The total U.S. public debt reached 132% of gross domestic product (GDP) in the second quarter of 2022, an all-time high. We are still experiencing historically elevated public debt-to-GDP ratios, according to the St. Louis Federal Reserve.<sup>17</sup> The jump in this ratio from the first quarter of 2020 to the first quarter of 2023—prior to more recent increases—is about 10 percentage points.

A large part of the spending increases linked to Covid would have been unnecessary had federal pandemic preparedness and response been more effective, thorough, and focused. The debt increase contributed to a jump in federal interest costs, which nearly doubled between FY 2020 and FY 2023, when it reached almost \$660 billion (or 2.5% of GDP).<sup>18</sup> Interest payments are now the fourth-largest expense of the federal government, behind only Social Security, Medicare, and national defense.<sup>19</sup> These high debt levels and interest payments strongly suggest that the federal



government might have trouble responding to the next pandemic with spending increases like those used to fight Covid-19. So what are government agencies doing to prepare? Unfortunately, little that they show is productive.

The number and variety of federal agencies and programs with overlapping responsibilities for pandemic preparedness greatly complicate the tracking and evaluation of federal pandemic preparedness and response efforts. ASPR, which is within HHS, has operational responsibilities for the advanced research, development, and stockpiling of medical countermeasures, as well as the coordination of the federal public health and medical response to emergencies and disasters. The office states on its website that it “*leads the nation’s* medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR constantly scans the horizon to prepare for whatever emergency might come next, whether natural or manmade” (emphasis added).<sup>20</sup> But ASPR’s post-Covid, 2022–26 strategic plan lists four separate strategic goals, only two of which directly involve preparedness and response.<sup>21</sup> The stated goals are: (1) preparing for future public health emergencies and disasters; (2) managing the federal response to such emergencies and disasters; (3) improving and leveraging partnerships with health-care and public health stakeholders; and (4) ensuring workforce readiness through development of innovative workplace practices.

The federal CDC, also part of HHS, has four to six major units with pandemic-preparedness capabilities, but none dedicated exclusively to pandemic preparedness and response.<sup>22</sup> Three units within the immediate office of the CDC director are potentially involved with preparedness—the offices of: (1) Readiness and Response; (2) Public Health Data, Surveillance and Technology; and (3) the Center for Forecasting and Outbreak Analytics. In addition, capabilities to help prepare for and respond to pandemics exist at the CDC’s National Center for Immunization and Respiratory Diseases, the National Center for Emerging and Zoonotic Infectious Diseases, and the Global Health Center.

The “2022–2027 CDC Strategic Plan” states that it “advances science and health equity and affirms the agency’s commitment to one unified vision—equitably protecting health, safety, and security,” but it does little to highlight strengthening of pandemic preparedness and response.<sup>23</sup> Neither CDC’s website nor its strategic plan prominently cites the National Biodefense Strategy issued by the White House in October 2022 (a post-Covid update to the 2018 iteration of the biodefense strategy) to promote pandemic preparedness.<sup>24</sup> To highlight the lack of focus on pandemics generally at CDC, note that nine of the first 10 responses to a recent Google search for “CDC pandemic preparedness” involved only pandemic influenza. Just one, focused on “global preparedness,” extended to pandemics caused by pathogens more generally, such as new coronaviruses.<sup>25</sup>

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## Pandemic-Fighting Budgets Not Connected to Meaningful Milestones

Federal budgeting echoes the confusing overlaps in responsibilities and strategies among federal agencies. The FY 2024 President’s Budget discretionary request for ASPR is \$4.27 billion, an increase of nearly 19% above the funding enacted for FY 2023.<sup>26</sup> But the FY 2024 President’s Budget request also includes \$20 billion in mandatory funding for the Public Health and Social Services Emergency Fund (PHSSEF) as part of a department-wide plan to prepare for future pandemics and other biological threats.<sup>27</sup> The administration’s budget request would allow allocation of this preparedness funding over five years across ASPR, CDC, FDA, and the National Institutes of Health (NIH).

Economists generally recommend judging the merit of federal preparedness programs by comparing their cost with the incremental reductions in pandemic damages, i.e., the benefits expected from such programs. While there are no estimates of the benefits of the current federal programs to promote

pandemic preparedness, there is a high probability of observing pandemics similar to Covid (38% in one's lifetime) and this risk may double in coming decades.<sup>28</sup> These risks are big enough that policymakers must address how to ensure the effectiveness of preparedness in reducing expected damages and the cost-effectiveness of federal pandemic preparedness.

The Government Performance and Results Act (GPRA), enacted in 1993 and updated in 2010, requires agencies to engage in systematic data-driven strategic planning.<sup>29</sup> It directs federal agencies to identify their strategic goals and establish milestones to measure progress toward those goals and also to link funding and requests for additional funding to specific progress toward those milestones. Specifically, Section 1115(a) of GPRA directs the White House Office of Management and Budget to develop a federal performance plan that “shall establish:

- Performance goals to define the level of performance to be achieved;
- Common Federal Government performance indicators with quarterly targets to be used in measuring or assessing [overall progress and the individual contribution of each agency or program]; and
- Clearly defined quarterly milestones.”<sup>30</sup>

In addition, under Section 1115(b) of GPRA, the performance plan “shall express such [performance] goals in an objective, quantifiable, and measurable form,” unless another form is duly authorized by the Office of Management and Budget.<sup>31</sup>

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## Box-Checking and Underwhelming “Measures of Progress”

Unfortunately, the milestones and goals used by HHS to justify the president's FY24 budget request for pandemic preparedness fall well short of the standards set forth in GPRA. In fact, they appear to be an exercise in box-checking rather than the result of a reasoned, risk-based, and data-driven process that might help ensure that federal resources are well-placed to ensure maximum preparedness for the next pandemic. Thus, the milestones and goals are very limited in providing a reasoned basis for evaluating or supporting the proposed budget.

The HHS strategic plan for FY 2022–FY 2026 includes five strategic goals, but only Strategic Goal 2—Safeguard and Improve National and Global Health Conditions and Outcomes—is related to pandemic preparedness.<sup>32</sup> Two strategic objectives involving pandemic preparedness support goal 2.<sup>33</sup> The goal of one of these, strategic objective 2.1, is to improve capabilities to predict, prevent, prepare for, respond to, and recover from disasters, public health and medical emergencies, and threats across the nation and globe. Working to achieve this objective are 15 separate operating divisions and staff divisions within HHS, a number sufficient to prevent anyone from ever attributing either exceptional or unsatisfactory performance in implementing objective 2.1 to a specific division or agency of HHS.<sup>34</sup>

### **Strategic Objective 2.1**

In describing its strategic objective 2.1, HHS notes: “The HHS Annual Performance Plan provides information on the Department's measures of progress towards achieving the goals and objectives described in the HHS Strategic Plan for FY 2022–2026.”<sup>35</sup> The Annual Performance Plan, however,

offers “measures of progress” that are, at best, partial and incomplete.<sup>36</sup> These measures provide little credible basis to claim that the proposed improvements in performance from FY23 to FY24 might amount to significant reductions in the expected harm from future pandemics.

For example, one of the department’s measures of progress is “the number of new licensed medical countermeasures across BARDA programs,” to be achieved by ASPR as the lead agency.<sup>37</sup> The target for this measure was three such countermeasures (vaccines, drugs, therapeutics, diagnostic tools, etc.) for each of FY 2017 to FY 2023, and four for FY 2024. But the average of the actual number of newly licensed countermeasures for FY 2017–FY 2022 was 5.5, strongly suggesting that the “target” of four for FY 2024 was deliberately set at a level that ASPR expects to achieve easily. In addition, this measure is entirely silent on how innovative such “new licensed” countermeasures might be. If they are pharmaceuticals requiring FDA authorization or approval, for example, they might involve new molecules or active pharmaceutical ingredients, new dosage forms, or new strengths. FDA would treat all such drugs or biologic products as requiring new approvals, authorizations, or licensing to be legally marketed, but products with new molecules that are first in their class, or even new molecules generally, are widely seen as more innovative than products that are new only because they have a new dosage form or a new strength (e.g., a pill of 10 mg. rather than 5 mg.).

The HHS measure of progress for CDC consists of the number of graduates from its Field Epidemiology Training Program (FETP), which trains public health workers in other countries.<sup>38</sup> The HHS plan provides no information about the relationship between the number of FETP graduates and, say, reductions in morbidity and mortality from infectious disease. The targets, moreover, are not the number of new graduates in a given year, but rather the cumulative number of graduates since the program began. Therefore, whether the target was met in a given year cannot be interpreted as a measure of performance in that year, but rather the cumulative performance since the program was launched.

The HHS measure of progress for NIH is to establish by 2026 “a formalized funding pathway for the development, validation, and regulatory review of diagnostic technologies to enhance surveillance and pandemic preparedness.” The milestone for FY 24 is for NIH to “receive FDA authorization or approval (including updated authorization or approval) for at least two home, point-of-care, or lab-based diagnostics, at least one of which is fully accessible to people with disabilities.”<sup>39</sup> But this commitment seems quite underwhelming because in FY 22, NIH supported the development of technologies that led to two at-home Covid-19 tests, five point-of-care Covid-19 tests, and two lab-based Covid-19 tests. Moreover, all nine tests received an FDA emergency-use authorization.

## **Strategic Objective 2.2**

The second HHS strategic objective involved in pandemic preparedness lacks meaningful quantitative performance measures for pandemic preparedness. Strategic objective 2.2 is “to protect individuals, families, and communities from infectious disease and non-communicable disease through equitable access to effective, innovative, readily available diagnostics, treatments, therapeutics, medical devices, and vaccines.”<sup>40</sup> Perhaps most pertinent for pandemic preparedness is a performance measure for ASPR’s BARDA. This performance measure is that BARDA “continue advanced research and development initiatives for more effective influenza vaccines manufactured using modern, flexible, agile technologies, and the development of influenza therapeutics for use in outpatient and hospital settings, including pediatric patients.”<sup>41</sup> The target level for FY 24 (as well as for FY 23) is “3 programs”; but unfortunately, the minimum characteristics of a successful program are not identified. So there is simply no basis to judge how much better pandemic preparedness might be if BARDA developed four “programs” instead of three.

The HHS strategic plan thus presents performance measures that are not in an “objective, quantifiable, and measurable form,” as prescribed by GPRA. It indicates that HHS has no vision on how best to use federal funds to ensure that our nation is better prepared for the next pandemic than it

was for Covid-19. It also indicates that Congress must, through the reauthorization of PAHPA, require HHS to develop and implement a reasoned, risk-based, and data-driven process to deploy federal resources in a way that ensures the greatest possible pandemic preparedness.

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## Conclusion and Recommendations

What improved performance standards should Congress demand as part of PAHPA reauthorization? It should require that HHS adopt standards that allow a fair and full evaluation of the expected effectiveness and cost-effectiveness of federal pandemic preparedness. This means expressing the performance of federal preparedness programs in terms of reductions in expected pandemic-driven damages, i.e., disease, death, and economic disruption.

HHS will need to develop new models of pandemic-driven disease and damages more broadly. In general, an estimate of the probability distribution of an epidemic of given intensity is necessary to assess global losses of lives and economic damages and to motivate global coordination and resource mobilization.<sup>42</sup> The difficulty of such modeling should not, however, be seen as a reason not to attempt it. In the absence of such models, there is little reason to believe that the billions spent on pandemic preparedness are effective or cost-effective at improving preparedness. HHS thus needs to develop models about how expected damages from pandemics might be reduced by specific actions to improve preparedness, such as improved stockpiling of medical countermeasures, or successful development of universal vaccines. Finally, HHS should state by how much specific increases in federal funding to ASPR and CDC could reduce expected damages from pandemics.

In the short run, HHS could use prediction markets and periodic expert elicitation to develop estimates of the odds of another Covid-level pandemic by a given date. Such predictions have already been made in other contexts. A 2016 Taiwanese study created a prediction market system (like a futures market, which combines information from different sources to predict the outcomes of certain events in the future) to predict infectious diseases during a 31-week period. It considered five disease indicators: confirmed cases of dengue, severe and complicated influenza, the rate of influenza-like illnesses, confirmed cases of severe and complicated enterovirus infection, and the rate of enterovirus infections. The study found that markets predicted the trends of three out of five disease indicators more accurately than the preexisting system.<sup>43</sup> Markets that allowed more participants and persisted for longer periods might lead to more precise estimates. In an expert elicitation study from 2006, experts assessed pandemic influenza risks from the bird flu H5N1. The study concluded that there was a 15% chance of efficient human-to-human transmission in the next three years.<sup>44</sup> Such explicit and easy-to-interpret estimates are not found in reports on pandemic preparedness by federal or international public health agencies. They certainly should be.

Pandemic preparedness requires congressional action now to ensure that federal preparedness activities are effective and cost-effective. The key to improving pandemic preparedness in the U.S. is not simply additional funding but also better management of federal resources. The HHS justification for the FY 24 budget request does not provide the objective quantifiable measurable performance metrics called for by GPRA. Congress needs to demand the use of such metrics in reauthorizing PAHPA and funding federal pandemic preparedness.

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## Endnotes

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