

SPECIAL REPORT

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CENTER FOR HEALTH AND WELFARE POLICY

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# Forging a Post-Pandemic Policy Agenda: A Road Map for Covid-19 Congressional Oversight

*Robert E. Moffit, PhD, and Doug Badger*

**A**fter three years of COVID-19, it is time for a comprehensive assessment of our response to the pandemic. At the state level, some succeeded while others failed to strike a prudent balance between pressing public health needs and the social and economic lives of their citizens. The federal response has also been mixed. Federal lawmakers must learn from this experience and adopt a broad agenda of public health reform to prepare for the next national health emergency. Congress has a duty to reform government agencies and hold them accountable with a view to restoring public trust in America's public health agencies.

"For 75 years, CDC and public health have been preparing for COVID-19, and in our big moment, our performance did not reliably meet expectations."

Dr. Rochelle Walensky, Director, Centers for Disease Control and Prevention,  
August 17, 2022<sup>1</sup>

## Introduction

The American people have suffered a great deal because of the COVID-19 pandemic. As of December 19, 2022, the nation had experienced an estimated 99.95 million confirmed COVID cases<sup>2</sup> and nearly 1.1 million deaths<sup>3</sup> associated with the disease.

Since the surge of the Omicron variant of the coronavirus began to subside in early 2022, so have previously high rates of hospitalizations and deaths. Meanwhile, Washington's pattern of mixed messages persists.

- On September 18, 2022, President Joe Biden declared that the “pandemic is over.”<sup>4</sup>
- On October 13, 2022, the Biden Administration extended the national public health emergency declaration for another 90 days.<sup>5</sup> On January 11, 2022, the Administration extended it again.
- On November 15, 2022, despite the threat of a presidential veto, the United States Senate passed a resolution to end the national medical emergency by a vote of 62 to 36.<sup>6</sup> (The House of Representatives has taken no action.)

When the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) hit American shores, the disease caused by the virus (COVID-19) was novel, highly contagious, and poorly understood, but it soon became clear that severe illness, hospitalization, and death followed a persistent, highly predictable pattern. Those most at risk were immunocompromised people aged 65 and older with certain comorbidities, particularly heart disease and respiratory conditions, diabetes, and obesity. Because obesity rates in the United States are among the highest in the world, Americans have been especially vulnerable; internationally, by 2021, approximately 90 percent of deaths occurred in nations with a “high level” of obesity.<sup>7</sup>

Younger and healthier people, particularly below the age of 50, have faced relatively low risk, and healthy children 17 years of age and younger have faced hardly any risk at all.<sup>8</sup>

**Social and Economic Costs.** Beyond illness and death, Americans sustained a great deal of social, economic, political, and psychological damage. In April 2020, unemployment exceeded 14 percent, the highest level since the Great Depression of the 1930s, and gross domestic product (GDP) fell 19.2 percent.<sup>9</sup> Yet many public officials in several large states like New York and California insisted on maintaining severe social and economic restrictions. While the nation’s overall employment recovered, many small businesses never recovered, and labor force participation has not yet reached pre-pandemic levels. In response to the pandemic, a combination of massive congressional spending and additional debt imposed a burden on federal taxpayers amounting to \$6.5 trillion through May 2022.<sup>10</sup>

With school closures, children suffered. Remote learning contributed to a widening of racial and economic gaps. A Harvard University research team found that the greatest student losses were in “high poverty” school districts where students experienced a 40 percent loss of a year of learning: “While we

have nothing to add regarding the public health benefits, it seems that the shift to remote or hybrid instruction during 2020–21 had profound consequences for student achievement.”<sup>11</sup> The National Assessment of Educational Progress (NAEP), administered by the U.S. Department of Education, likewise found major declines in math and reading proficiency among American students between 2019 and 2022. For example, in every state, academic proficiency declined; an average 40 percent of 8th graders in public schools were performing below the NAEP’s “basic” level in math; and among 4th graders, 39 percent of public-school students were performing below the basic reading level.<sup>12</sup>

As attorney Mark Pulliam has observed:

After two years, the extraordinary government measures—federal, state, and local—taken in response to the COVID pandemic, some of which were supposed to be temporary, have finally begun to abate, along with the fear and panic that inspired them. In hindsight, many Americans are now questioning the wisdom and necessity of school closings, business shutdowns, bans on public activities (including religious worship), mask and vaccine mandates, and similar edicts, which caused incalculable harm to the economy, our children’s education, and development, and to the fabric of a free society.<sup>13</sup>

**Politicization of public health policy, along with a loss of public trust, was another ugly feature of the coronavirus. Federal and state policies were viewed through partisan lenses, highlighting divisions between blue and red states but also filtering down into social and personal relationships. In a 2022 Morning Consult survey, 49 percent of Americans surveyed said that it was difficult to have conversations about COVID-19 with people who have different views.**<sup>14</sup>

Almost three years after the pandemic was declared, there is a need to reassess calmly and carefully the performance of both federal *and* state governments in responding to the COVID-19 crisis. As David Hyman, professor of law and health policy at Georgetown University, and Charles Silver, professor of law at the University of Texas, have observed:

When patients arrived at hospitals, overworked medical professionals did the best they could with available resources. Accountability rests squarely with federal, state, and local governments, which neither prepared for the pandemic sufficiently nor deployed a sensible strategy for getting through it. The primary lesson to be drawn from America’s experience with COVID-19 is that putting the federal government in charge of the health care system would saddle it with administrative responsibilities that it could not possibly handle.<sup>15</sup>

Though it may be difficult to conduct a successful after-action review considering that the disease, as well as the polarizing partisanship that has accompanied it, is still with us, it is nonetheless necessary to outline the basic facts to hold public health officials accountable and to restore trust in public institutions that have been severely damaged, especially agencies of the federal government. As Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky has acknowledged, “To be frank, we are responsible for some pretty dramatic, pretty public mistakes, from testing to data to communications.”<sup>16</sup>

Both federal and state officials need to examine and assess what went right, what went wrong, and how to respond more effectively to the next inevitable pandemic.<sup>17</sup>

**Congressional Duty.** At the federal level, it is essential that congressional committees fulfill their oversight responsibilities and inquire into a considerable number of structural and functional problems that have undercut the capacity of the federal government to provide appropriate and timely assistance to the states and thus to the people of the United States. These inquiries would include but not necessarily be limited to:

- The origin of the COVID-19 pandemic and any role federal funding played in aiding gain-of-function research in China;
- The lack of effective coordination and communication within the executive branch in responding to the pandemic;
- The problems encountered by state public health officials in securing information from the CDC;
- The reasons behind the initial failure to develop and later rapidly deploy diagnostic testing for the coronavirus;
- The CDC’s persistent failure to upgrade and modernize its data collection and dissemination; and
- The decision of federal officials to try to suppress scientific dissent on a variety of vital issues ranging from the efficacy of lockdowns to the strength of natural immunity to the coronavirus as validated in the professional literature.

## The Federal Government's Response to the Pandemic: An Overview

Though states have the primary constitutional authority to exercise powers to protect public health, the federal government's role is crucial in a national emergency, and its overarching responsibilities to protect the entire nation are multifaceted.

The Secretary of the U.S. Department of Health and Human Services (HHS) reports directly to the President of the United States. HHS is the lead agency with responsibility for responding to public health emergencies. The Centers for Disease Control and Prevention, a subunit within HHS, is responsible for tracking the progress of the pandemic and providing the best scientific and medical information to state and local public health authorities. CDC is also responsible for making medical supplies from the Strategic National Stockpile (SNS), including drugs, medical equipment, and devices, available to state and local public health authorities. The National Institutes of Health (NIH) is the HHS subagency that is charged with medical research. Its activities include making grants to private entities to support the development of vaccines and therapeutics. The Food and Drug Administration (FDA) is charged with approving or granting emergency use authorizations (EUA) for vaccines, diagnostics, and therapeutics based on a finding that they are safe and effective or, in the case of an EUA, that the benefits of the product outweigh its risks.

Other federal agencies also have a role. For example, the Public Health Service (PHS) can deploy medical officers to the states to help local authorities cope with the pandemic and also can work cooperatively with public health authorities in nations overseas. The jurisdiction of the Department of Homeland Security (DHS) includes screening visitors to the United States and enforcing travel bans, as well as supporting state and local responses to the public health emergency through the Federal Emergency Management Agency (FEMA). The Department of State communicates with foreign governments in coordinating international responses to any emerging pandemic.<sup>18</sup>

In the end, however, the President bears ultimate responsibility for assuring that the federal government's response is efficient and effective.

### The Federal Response: 2020

In early January 2020, the World Health Organization (WHO) reported the emergence of a novel coronavirus in China, but the WHO's initial messaging was misleading: On January 14, it declared that the virus was not



transmissible from human to human.<sup>19</sup> On January 20, the United States recorded its first confirmed COVID-19 case, and on January 29, the White House established its Coronavirus Task Force, headed initially by HHS Secretary Alex Azar and later by Vice President Mike Pence. On January 31, citing his authority under the Public Health Service Act, Azar declared a public health emergency.<sup>20</sup> That same day, President Donald Trump suspended the entry of foreign nationals from China.<sup>21</sup>

**Travel Bans.** When the President blocked travel from China, critics in and out of Congress, including then-future President Joe Biden, labelled Trump’s action “xenophobic” (and worse).<sup>22</sup> Nonetheless, over the next two months, Trump extended travel bans to Iran, European nations, and Ireland and the United Kingdom in an effort to stop the spread of the coronavirus.<sup>23</sup>

Despite the criticism, Trump’s prompt action was consistent with those of other governments. By April 1, 2020, a comprehensive study of the responses of 50 countries around the world found that 38 (76 percent) of their governments had initiated “complete” border closures to reduce viral transmission and that 10 of them (20 percent) had imposed partial border closures.<sup>24</sup>

**Emergency Declaration.** On February 29, 2020, the United States reported the first death associated with a confirmed case of COVID-19. On March 13, 2020, President Trump declared a national emergency and issued major disaster declarations for all 50 states and U.S. territories.<sup>25</sup> This was the first such expansive declaration in American history.<sup>26</sup>

On March 16, the President Trump announced a strict set of guidelines intended to “slow the spread” of the disease.<sup>27</sup> The guidelines, which were to be in effect for a 15-day period, called on individuals to “avoid social gatherings in groups of more than 10 people” and “eating or drinking in bars, restaurants and food courts.” It also urged states with confirmed cases to close “bars, restaurants, food courts, gyms, and other indoor and outdoor venues where groups of people congregate.” States quickly applied the CDC guidance on closures as legally enforceable mandates.

Despite suggesting that he might withdraw the guidelines sooner, Trump extended them until the end of April on the advice of federal medical experts.<sup>28</sup>

**Legislative Relief.** Working with Congress, between March and June of 2020, Trump signed into law several COVID relief measures that totaled \$2.7 trillion (about \$8,300 per person in the U.S.) in new federal spending.<sup>29</sup> In March alone, Trump signed into law three major bills that were heavily focused on Medicare beneficiaries, the most vulnerable cohort of the population.<sup>30</sup>

- The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, (Public Law 116-123)<sup>31</sup> codified the authority of the Secretary of HHS to waive or modify certain Medicare rules governing telehealth, expanding telehealth services beyond rural areas, allowing beneficiaries to get telehealth services in their homes, and expanding the number of services that can be delivered through telehealth.
- The Families First Coronavirus Response Act (Public Law 116-127)<sup>32</sup> eliminated Medicare beneficiary cost-sharing for diagnostic tests for COVID under both traditional Medicare and Medicare Advantage plans and further expanded telehealth services for Medicare beneficiaries.
- The Coronavirus Aid, Relief and Economic Security (CARES) Act (Public Law 116-136)<sup>33</sup> was the most ambitious and far-reaching of the three. Among its key provisions, Congress expanded the Accelerated and Advance Payments (AAP) Program for Medicare hospital reimbursements during the national medical emergency while significantly increasing the payment amounts and extending the deadline for hospitals and other medical facilities to repay the government. The law further expanded telehealth and the scope of practice for non-physician practitioners, including nurse practitioners, physician assistants, and clinical nurse specialists, in treating Medicare patients; increased Medicare hospital payment by 20 percent for patients diagnosed with COVID-19; allowed beneficiaries to get a 90-day supply for prescription refills; and required Medicare and Medicare Advantage to cover anticipated COVID-19 vaccines with no beneficiary cost-sharing.

Aside from these initial legislative actions, Trump and Congress enacted measures that would broadly affect employers and employees and bolster public health efforts. In April 2020, Congress enacted the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139),<sup>34</sup> which provided an additional \$493 billion for small business loans, health care providers, and COVID-19 testing. In December 2020, Congress enacted the Consolidated Appropriations Act of 2021 (P.L. 116-260),<sup>35</sup> which provided \$868 billion in additional funding for small businesses, aid to state and local governments, and COVID-19 vaccinations.<sup>36</sup>

**Administrative Measures.** In addition to signing bills to spend trillions in federal money, Trump and his Administration undertook several consequential administrative and regulatory actions.

*First*, the federal agencies reviewed, revised, or suspended many regulatory restrictions that inhibited the flexibility of medical professionals in treating the virus. This resulted in numerous innovations in health care delivery that were beneficial to doctors and patients alike, such as the rapid expansion of telehealth. By July 2020, the Centers for Medicare and Medicaid Services (CMS) had issued more than 200 waivers from federal rules and regulations.<sup>37</sup>

Pursuant to the national emergency declarations, HHS Secretary Alex Azar invoked waiver authority for Medicaid programs under Section 1135 of the Social Security Act, granting medical professionals blanket regulatory flexibilities to cope with the crisis. Florida became the first state to take advantage of these regulatory flexibilities, and by April 16, 2020, every state had submitted a request for the special 1135 waiver.<sup>38</sup> HHS also announced that it would not enforce HIPAA regulations<sup>39</sup> that would have prevented the use of FaceTime, Skype, and Zoom for telemedicine visits.

*Second*, to quell the rising threat of infections in America's nursing homes where mortality was particularly high, the CMS stepped up its oversight and enforcement of nursing home safety standards. Between February 6 and June 1, 2020, the CMS toughened its enforcement of infection control standards and took 13 administrative actions, including detailed guidance, to secure infection control in the nation's skilled nursing facilities.<sup>40</sup> Even with the CMS's new enforcement agenda, however, COVID-19 mortality remained disproportionately high among nursing home residents.

*Third*, in March 2020, President Trump invoked the Defense Production Act of 1950 to compensate for the deficiencies of medical supplies in the Strategic National Stockpile. This was the first time a President had invoked that authority in response to a public health crisis. Under the act, President Trump assumed the emergency power to require corporations to contract with the United States for essential services and provide materials that were needed to respond to the pandemic. The law also gave the President the power to "create incentives" to produce and supply necessary goods and services.<sup>41</sup>

By April 2020, Trump had ordered Ford and General Motors to manufacture ventilators. Trump also ordered Hill-Rom Corporation to manufacture hospital beds and medical equipment. Following Trump's order, Res Med and Medtronic, a biomedical engineering company, also accelerated ventilator production. Royal Philips and Vaire Medical increased their production of medical equipment and supplies, including respirators, oxygen supplies, and face masks, and the 3M Company also increased its production of face masks.<sup>42</sup> In combination with implementation of this

first-of-its-kind, public-private vaccine development program, Trump's initiatives amounted to the greatest single mobilization of private industry to meet a national crisis since World War II.

The HHS Office for Civil Rights acted to prevent utilitarian rationing of ventilators in ways that discriminate on the basis of age and disability. It also required hospitals to allow reasonable clergy access for inpatients who were effectively locked down during the pandemic.

**Operation Warp Speed.** The most notable of President Trump's contributions was the successful initiation and execution of Operation Warp Speed (OWS), a public-private partnership created to develop and deploy vaccines for emergency use. According to the Committee for Economic Development, "Vaccine development was a signal success of America's pandemic response. It involved strong public-private partnership and pharmaceutical companies' willingness to take major financial and operational risks in the face of unprecedented challenges."<sup>43</sup>

Paul Mango, who served as Deputy Chief of Staff at the Department of Health and Human Services from 2019–2021, helped to create and manage a multidisciplinary team of private-sector and government experts to run the operation, which for the most part functioned outside of the department's bureaucratic channels.<sup>44</sup> The team surveyed efforts among private companies engaged in vaccine research, selected six candidates using three different vaccine technologies as presenting the highest probability of producing a vaccine within a year, and contracted with those firms to purchase their product pending FDA authorization. The OWS team also developed a production and distribution strategy that resulted in immunizations beginning almost immediately after the FDA authorized use of the Pfizer and Moderna mRNA vaccines.

The forging of an effective public-private partnership for the development and deployment of the vaccines within months rather than years that was accomplished under Trump's leadership will stand as an impressive achievement in the annals of modern public health. As President Biden remarked on December 22, 2021, "Let me be clear. Thanks to the prior administration and our scientific community, America was one of the first countries to get the vaccine. Thanks to my administration and the hard work of Americans, we led a roll out, made America among the world leaders in getting shots in arms."<sup>45</sup>

Even so, Washington's communications with state officials in the process of vaccine distribution was still deficient. As Trish Riley, Executive Director of the National Academy for State Health Policy, has written, "State officials expressed frustration with the lack of consistent, reliable, and timely

information about vaccine supplies, noting that the last-minute information about weekly vaccine allocations gives states little time to inform providers, determine how many doses can be administered that week, and inform the public.”<sup>46</sup>

## The Federal Response: 2021

During the 2020 presidential campaign, Vice President Biden promised that he would give Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID) at the NIH, “full access” to the Oval Office and an “uncensored platform” to address the American people.<sup>47</sup> He would also “massively surge” “free” diagnostic testing, “double the number of drive through testing sites,” and create a “national contact tracing workforce” of “at least 100,000 Americans” to assist public health authorities in containing the vital spread. Biden also proposed a massive and coordinated plan to distribute medical supplies, including personal protective equipment and testing supplies, particularly for “hard-hit areas” of the country, and rely more on American manufacturing capacity to ensure that there would no longer be “supply chain disruptions in times of crisis.”<sup>48</sup>

Biden further promised to accelerate the development of vaccines and therapeutics, initiate a nationwide vaccination campaign, and create a “nationwide pandemic dashboard,” an “easy-to-read” Internet program that ordinary Americans could use to monitor viral transmission in their zip codes. For health care workers, Biden promised premium pay, priority access to personal protective equipment, and emergency paid leave.<sup>49</sup>

President Biden also asked for congressional action on another major COVID-19 relief bill. In March 2021, Congress enacted and Biden signed the American Rescue Plan Act of 2021 (P.L. 117-2),<sup>50</sup> which provided a total of \$1.9 trillion in relief for individuals, businesses, and “various” public health measures.<sup>51</sup>

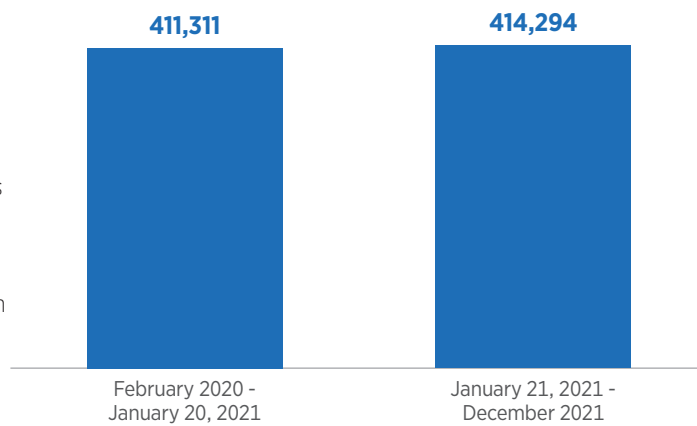
**Rising Mortality.** In October 2020, with cumulative national COVID-related mortality exceeding 220,000, candidate Biden, referencing Trump, declared that “[a]nyone who’s responsible for that many deaths should not remain as president of the United States of America.”<sup>52</sup> In fact, however, pandemic-related mortality over the first 11 months of the Biden presidency was slightly higher than that of the Trump presidency.

- From the first reported COVID-related death in the U.S. (February 29, 2020) through the end of Trump’s term (January 20, 2021), 411,311 deaths were reported.<sup>53</sup>

CHART 1

## Deaths with COVID-19

**SOURCE:** Authors' calculations based on data from Edouard Mathieu et al. "Coronavirus (COVID-10) Deaths," Global Change Data Lab, Our World in Data, <https://ourworldindata.org/covid-deaths> (accessed December 23, 2022).



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- From Biden's inauguration through December 31, 2021—a period of roughly 11 months— there were 414,294 COVID-related deaths in the U.S.<sup>54</sup>

In other words, despite widespread immunizations, rising natural immunity, and new treatments, more people died with COVID-19 during the first 11 months of the Biden presidency than died during the last 11 months of his predecessor's.

Deaths with COVID have continued to mount during 2022, with an additional 219,000 having occurred through the end of August.<sup>55</sup> President Biden's campaign declaration basing fitness for the nation's highest office on the number of people who had died with COVID was ill-conceived, whether or not he considers himself "responsible" for the more than 664,000 deaths with COVID that had been recorded between the time he took office and mid-December 2022.<sup>56</sup>

The emergence of the Delta variant of the coronavirus during the summer of 2021 generated increasing numbers of confirmed cases and COVID-related hospitalizations and deaths. On September 9, 2021, President Biden signed an executive order directing his Administration to impose vaccine mandates on federal workers and contractors, health care workers, and all Americans employed by private companies with 100 or more workers.<sup>57</sup>

While President Trump publicly criticized governors who kept restrictive policies in place,<sup>58</sup> Biden accused governors who failed to adopt aggressive nonpharmaceutical intervention strategies of "undermining life-saving

requirements.”<sup>59</sup> And while the rapid development and deployment of COVID vaccines was a noteworthy exception to the federal government’s lackluster performance in other areas, even the vaccines themselves were quickly politicized.

Before the 2020 presidential election, then-New York Governor Andrew Cuomo joined other Democratic governors in saying that they would delay distribution of an FDA-authorized vaccine until they had the opportunity to review the agency’s work.<sup>60</sup> Cuomo said that he did not “trust the federal government’s opinion” on the vaccine’s safety and efficacy. Once Biden was in office, however, opposition to the vaccine was more common in Republican circles, with Republicans less likely to be vaccinated than Democrats.<sup>61</sup>

The federal government’s response to the pandemic, like the responses of many other highly developed nations’ governments, was characterized more by failure than by success, but there were external contributing factors. The WHO initially accepted representations from the Communist Chinese government that the pathogen did not spread by human contact, allowing the disease to spread silently during the critical early weeks. China’s subsequent noncooperation proved deadly not only for the United States, but also for the global community.

Once they began to appreciate the magnitude of the challenge, federal public health authorities were not prepared to meet it despite billions in federal spending and years of developing pandemic preparedness plans. They quickly cobbled together a set of nonpharmaceutical interventions that they initially announced would last 15 days and then recommended that they should remain in place for extended periods.

Some state governments fully embraced the federal guidelines, and others deviated from them. The public health response moved from chaotic and ineffective to partisan and divisive. As noted, it was a major issue during the 2020 presidential campaign, with Biden saying that COVID-related deaths rendered Trump unfit for the presidency. But despite widespread vaccine availability, confirmed cases and COVID-related deaths during the first months of Biden’s presidency exceeded those of his predecessor.

In the summer and fall of 2022, the disease continued to spread, vaccine administration had long since plateaued, public health policy had been politicized, and the nation continued to experience the aftereffects of nonpharmaceutical interventions like the shuttering of businesses, schools, and churches. Nor has it yet recovered from the extraordinary fiscal and monetary interventions that were designed to mitigate the economic effects of lockdowns. The U.S. and other highly developed countries that trod a similar path in public health policy now face serious inflation and other economic dislocations.<sup>62</sup>

We elaborate on the federal government's pandemic policy blunders not to score political points against one party or the other, but rather to urge policymakers to learn from their errors. Congress has an obligation not only to examine the causes and effects of these errors, but also to recommend policies that will equip Washington to face future public health challenges more competently.

## The Federal Response: Key Weaknesses

During the first two years of the pandemic, it was not uncommon for critics of government policy to charge that America's system of federalism—the division of power between the states and the national government—was at the root of the nation's inability to respond effectively to the national emergency. The tacit assumption, not borne out by the evidence, is that a unitary system of government would have performed much better. A closer examination of the most prominent critiques, however, shows that much of the academic and media criticism is more about President Trump and his Administration than it is about American federalism.<sup>63</sup>

The truth is that several institutional failures in the federal government's response are more deeply rooted than noncareer personnel or partisan control of the White House and predate both the Trump and the Biden Administrations. Among the most significant of these problems was the failure to create and maintain a locus of institutional authority to coordinate federal efforts in responding to a pandemic, inadequate data collection and dissemination, and failure to maintain an adequate level of supplies in the CDC's Strategic National Stockpile.

With the onset of the COVID-19 pandemic, certain problems became acute including

- The failure of federal officials to provide the public with clear and consistent messaging based on the most recent scientific findings,
- The failure to develop and deploy an adequate testing program to monitor the coronavirus,
- The failure to create a clearinghouse of reliable and timely information for medical professionals on best clinical practices, and



- The decision by federal officials to ignore or even try to suppress scientific information that differed from what they had previously published or recommended even after data in peer reviewed journals and other reputable sources indicated a need to reexamine, alter, or modify public health policy.

In view of this record, Congress needs to address at least 13 prominent weaknesses.

### **Weakness No. 1: The Absence of a Center to Coordinate a Proper Federal Response.**

Federal officials have failed to create and maintain a command center to coordinate the national government's pandemic response. There is a need for an experienced and well-staffed command center reporting directly to the President. As the Heritage Foundation's National Coronavirus Recovery Commission observed:

Rapid response to a national emergency, such as a pandemic, requires an effective and efficient centralized point of decision-making authority that is both tasked with making and has the operational ability to execute decisions, while leveraging the critical role of a wide range of actors in state and local government and civil society.<sup>64</sup>

**The absence of such an institutionalized center has been a recurrent problem at least since the 1990s. Writing in *The New England Journal of Medicine*, Dr. Gail Wilensky, former CMS administrator, says:**

Since the early 1990s, such an office has repeatedly been established after a national health scare—and then disbanded by the successor administration. The Biodefense and Health Security Office established during the Clinton administration was closed by President George W. Bush, reopened after the anthrax scare, closed by President Barack Obama, and then reopened after the Ebola and Zika scares, at which point the Directorate for Global Health Security and Biodefense was created. The plan prepared in the wake of the Ebola outbreak might have been helpful in preparing a response for the current COVID pandemic, but like his predecessors, former National Security Advisor John Bolton dissolved the Office in 2018. Once again, some of the Office's personnel were merged into other [National Security Council] units, but the pandemic office itself no longer existed.<sup>65</sup>

President Biden restored the office within the National Security Council and renamed it the White House Office for Global Health Security early in his presidency.<sup>66</sup> Wilensky had recommended that such an office should be reestablished close to the “center of power” in the White House. In the absence of such an office, HHS, a bureaucratic empire with many kingdoms, would be the de facto lead federal agency, and as the Government Accountability Office (GAO) has determined, HHS was plagued by internal managerial problems in coordinating a response.<sup>67</sup>

HHS has manifold responsibilities for the day-to-day operations of the federal government’s huge entitlement programs, such as Medicare, Medicaid, and the federal health insurance exchanges in addition to an enormous number of social services programs. While the department and its agencies are crucial in executing a response to the pandemic, it has not demonstrated superior performance in interdepartmental coordination and collaboration in a national medical emergency. In fact, the GAO reports that the department’s performance in responding to the pandemic has been poor—so poor that the GAO has designated HHS “programs and operations” in this regard as “high-risk,” meaning that they are vulnerable to “fraud, waste, abuse and mismanagement, or...need transformation.”<sup>68</sup> The GAO has made 115 recommendations concerning HHS leadership and operations in coping with public health emergencies since fiscal year (FY) 2007. As of January 2022, however, 72 of these recommendations remained unaddressed.<sup>69</sup> Once again, these recommendations have spanned different presidential Administrations.

With regard to coordination and decision-making, the GAO found that HHS failed to clarify the roles and responsibilities of its agencies within and outside the department to protect America from “potentially catastrophic biological threats.” In the language of the GAO report, “The lack of clear decision-making roles can especially impede the ability of agencies to address gaps or leverage resources that span department or agency boundaries, which is frequently the situation for biodefense, leading us to recommend that HHS document such roles.”<sup>70</sup> As of January 2022, when the report was published, HHS had not fully addressed the GAO’s recommendation.

Once again, this HHS managerial problem had festered. In 2018, GAO had warned about the multiple problems of leadership, coordination, and interagency collaboration that threatened to undercut the nation’s response to a pandemic, and in 2020, the GAO was proven prophetic.<sup>71</sup>

Looking to the future, the Biden Administration is creating a new Administration of Strategic Preparedness and Response (ASPR), in effect elevating

the HHS Office of Assistant Secretary for Preparedness and Response, to respond to national health emergencies. The new agency will be phased in over two years.<sup>72</sup> It will be incumbent upon congressional investigators to maintain close scrutiny of the new agency's performance and how it interacts with the CDC, the NIH, the Public Health Service, and other relevant agencies inside and outside of HHS.

### **Weakness No. 2: The Failure to Provide Complete and Consistent Data.**

Commenting on the nation's initial COVID response, Dr. Deborah Birx, former coordinator of the White House Coronavirus Task Force, told Congress that "the No. 1 public health issue in the United States today is that there is no comprehensive database or integration of data from laboratories, public health institutions, and clinics."<sup>73</sup>

In rambling and sometimes off-the-cuff remarks, both President Biden and President Trump have made false or inaccurate statements concerning Covid-19. Even more seriously, federal public health officials, particularly at HHS, not only have sent mixed or confusing messages, but also have failed to provide "complete and consistent" data to inform sound decision-making. Sound data are necessary to determine the extent and location of infection, but once again, according to the GAO, "the data HHS has relied on during the COVID-19 pandemic have been, and remain, incomplete and inconsistent, highlighting longstanding concerns we have had with the data HHS relies on to respond to public health emergencies."<sup>74</sup> In addition, with respect to the catastrophic impact of COVID-19 on nursing home residents, "By not requiring nursing homes to submit data from the first 4 months of 2020, HHS limited the usefulness of the data in helping to understand the effects of COVID-19 in nursing homes during the initial stage of the response."<sup>75</sup>

The CDC's data deficiency has been particularly serious. According to Dr. Birx, "Data are in siloed systems across the CDC without a single common data collection system, resulting in vast inefficiencies and significant duplication across diseases."<sup>76</sup>

The CDC is supposed to function as the key transmission belt in supplying vital information to state and local public health authorities, but its record during the pandemic has been troublesome. In March 2022, for example, the CDC had to adjust its mortality statistics, removing 72,277 deaths because they were not in fact attributable to COVID-19.<sup>77</sup> Statistical precision in the case of COVID-19 mortality figures is admittedly a challenge for a variety of reasons, not the least of which is distinguishing death

from COVID-19 from death *with* COVID-19. Whether vaccinated or not, patients with many common comorbidities are particularly vulnerable to the disease. Vaccinated persons—though having a lower risk of severe illness and death from the coronavirus than the unvaccinated—can die either with or from the disease. This is especially true among the immunocompromised or persons with several comorbidities. According to Dr. Walensky, the data show that 77.8 percent of vaccinated persons who died from or with COVID also had “on average” four comorbidities.<sup>78</sup>

For the public, the problem has been the absence of clear and consistent communication. The COVID-19 pandemic, with its rapid and multiple viral mutations and disparate patient impacts, unquestionably presented an enormous challenge to public health officials. The Committee for Economic Development reports that the CDC thus far has issued more than 7,000 pandemic guidance documents. “Despite the challenges,” however, “the CDC’s changing signals led to public confusion and, over time, growing skepticism. The substance of the CDC’s recommendations changed frequently as well (faulty tests, changing guidance on masks just before the Delta variant surge, confusion over the length of time patients should isolate during the Omicron wave).”<sup>79</sup>

The CDC has also had difficulty communicating with state and local public health authorities.<sup>80</sup> While these officials have complained about CDC’s communications with them, CDC also failed to secure vital information from states and localities concerning the conditions on the ground. “In the U.S.,” according to University of Maryland Professor Emeritus Donald F. Kettl, “there simply wasn’t any mechanism for collecting nationally what the states and their cities were learning, and that handicapped the American response. In fact, one of the most profound American breakdowns was the failure even to recognize that this was an essential question in desperate need of a solid answer.”<sup>81</sup>

Far more troublesome is the CDC’s decision to hide crucial data. In February 2022, major media reported that the agency, fearing “misinterpretation,” was withholding crucial data concerning persons getting vaccine booster shots, the effectiveness of the vaccines among certain age groups, and cases of COVID-19 reinfection.<sup>82</sup> In addition, the Biden Administration was enforcing a vaccine mandate on health care workers, federal workers, and military personnel. Such a lack of transparency on a vital set of issues undercuts independent scientific analysis to the detriment of public health. In reporting on the subject, *The New York Times* has explained that with two full years of accumulated data on the pandemic, the CDC had published only a “tiny fraction” of the information.<sup>83</sup>

Unfortunately, the CDC's refusal to be transparent in its data collection has followed a persistent pattern, even extending to stonewalling congressional oversight requests. Senator Ron Johnson (R-WI) reports that from May to December 2021, CDC Director Walensky failed to respond to eight specific inquiries concerning CDC data and information on a variety of vital and sensitive topics, including information on COVID-19 vaccine adverse events, vaccine safety monitoring, CDC data on the effectiveness of natural immunity, and the effectiveness of prompt treatment of the coronavirus. On March 2, 2022, Senator Johnson renewed his request because the CDC had not responded.<sup>84</sup> Aside from undermining the constitutional responsibility of Congress to fashion policy based on official and crucial information, the CDC Director's lack of timely responsiveness amid a national medical emergency demonstrated a flagrant disregard for congressional authority.

Early in the pandemic, The Heritage Foundation identified the CDC's repeated failure to modernize its data collection and dissemination for frontline health care workers as a major weakness in the federal response.<sup>85</sup> Even though Congress statutorily authorized data modernization as far back as 2006, the problem persists today. The House Appropriations Committee, for example, has observed that public health data must "move from siloed and brittle public health data systems to connected, resilient, adaptable, and sustainable systems to achieve real change. Essential to this significant effort are core data standards and support to recruit and retain the data science workforce."<sup>86</sup>

Unless Congress changes course, House and Senate appropriators will continue to entrust the CDC with the task of modernizing data collection and dissemination—a task at which it has proved itself to be persistently incompetent. Evidently believing that money is a panacea, Congress provided CDC with \$175 million in FY 2023 for "Public Health Data Modernization,"<sup>87</sup> which is nearly four times the amount Congress allocated for FY 2020 and FY 2021.<sup>88</sup> In exchange for this largesse, Congress has asked only that the agency "include the use of an established minimal data set and transmission via existing and automated reporting mechanisms to the extent possible."<sup>89</sup>

It seems highly unlikely that unleashing a deluge of money into the CDC with little more than precatory language about employing automated transmission "to the extent possible" will produce the real-time data reporting system that the law has required of CDC since 2006. Money cannot buy competence.

### Weakness No. 3: The Federal Bureaucracy’s Testing Debacle.

Federal officials initially failed to deploy diagnostic testing for surveillance and defense against the coronavirus. During the winter of 2020, at the inception of the pandemic, the CDC tried to develop and distribute its own test, but the test was flawed and had to be recalled.<sup>90</sup> This delayed crucial testing for weeks. The federal testing problem was compounded by the FDA’s preexisting regulatory regime, which blocked the provision of private-sector alternatives, in addition to which CMS regulations governing labs did not permit nonclinical laboratories the flexibility to respond to the emerging crisis. Because of this regulatory morass, the federal government’s performance on initial pandemic testing was abysmal.<sup>91</sup>

The initial testing failure made it impossible for people to secure tests in a timely manner, particularly in the pandemic’s earliest stages. Without effective testing, and thus a clearer idea of the extent of the infection, public officials had no way to target public health resources to contain the spread. Combined with a widespread and perfectly understandable public fear, this contributed to the resultant policy response: the imposition of broad restrictions on state and local populations rather than targeted measures that were proportionate to the public health threat.

To create an effective testing program, federal officials should have issued clear guidelines, including priorities for populations that would benefit the most from testing. It did not happen. In a comprehensive after-action review of federal performance, the GAO stated that:

In November 2020, we reported that COVID-19 testing guidelines had changed several times over the course of the pandemic with little scientific explanation of the rationale behind the changes, thereby confusing providers and public stakeholder groups implementing the guidelines and risking the erosion of trust in the federal government.<sup>92</sup>

The initial diagnostic testing failure was not only a major setback in the early days of the pandemic; it also continued with the FDA’s delay in approving rapid at-home testing. The human cost of that delay during the Trump Administration was compounded by the Biden Administration’s failure to prepare and expeditiously deploy mass at-home testing to cope with an anticipated viral surge. When the Omicron variant surged in December 2021 and January 2022, the tests were still not readily and widely available to the public, and when the promised “free” at-home tests arrived in their mailboxes, the Omicron variant had already infected tens of millions of Americans, including the vaccinated.<sup>93</sup>

#### Weakness No. 4: Neglect of the Strategic National Stockpile.

The SNS is the federal repository of vital medical equipment and supplies. At the onset of COVID-19, supplies were deficient. As Dr. Birx has reported, “The United States ran out of not only protective equipment but almost ra[n] out of essential medication, devices, and diagnostic[s]. This is an emergency and needs to be addressed.”<sup>94</sup>

For years spanning presidential Administrations, the CDC had failed to maintain the SNS properly so that it could cope effectively with a pandemic. For example, in 2015, federal officials estimated that in the event of a pandemic, the country would need between 1 *billion* and 7 *billion* N95 masks, which are the most effective masks. With the onset of COVID-19, the SNS had only 10 *million*.<sup>95</sup>

Persistent problems with the SNS have spanned both Democratic and Republican Administrations. With the outbreak of COVID-19, states and localities were scrambling to secure the necessary supplies to cope with the pandemic, including personal protective equipment (PPE). But state and local public health officials were often confused about how best to go about securing these vital items. “[A]s of January 2022,” according to the GAO, “HHS ha[d] not developed a formal process for engaging with key stakeholders on a supply strategy for pandemic preparedness. These stakeholders, including state, local, tribal, and territorial partners and the private sector, have a shared role for providing supplies during a pandemic.”<sup>96</sup>

As of August 2022, the SNS reported having:<sup>97</sup>

- 424 million N95 respirators;
- 516 million gloves;
- 273 million surgical/face masks;
- 12 million face shields;
- 17 million surgical gowns and coveralls;
- 8 million goggles;
- “A variety of ventilator models to supplement state and local supplies” (the website lists 16 different models of ventilators but does not provide quantities); and

- The capacity to establish federal medical stations capable of treating 50–250 primary and critical care patients along with a three-day supply of pharmaceuticals and medical equipment.

Congress and the executive branch have replenished the stockpile with equipment that was in short supply when it was needed more than two and a half years ago. Whether the existing stockpile will prove to be sufficient for a future public health emergency remains to be seen.

### **Weakness No. 5: Mass Confusion About Mask Mandates.**

A key issue that emerged from the pandemic is the effectiveness of masking and mask mandates. Public health officials at the federal and state levels broadly endorsed mask mandates following the onset of COVID-19, but scientific support for these measures was thin.

The World Health Organization initially denied the value of mask-wearing for healthy persons because the scientific evidence was insufficient and then muddied the issue by offering confusing guidance on the subject.<sup>98</sup> Federal officials also denied, sometimes vehemently, the value of face masks in preventing transmission of the disease. For example, Dr. Anthony Fauci and Dr. Nancy Messonnier of the NIH and U.S. Surgeon General Dr. Jerome Adams all initially insisted that face masks were unnecessary or ineffective.<sup>99</sup> “Seriously, people,” Adams tweeted, “STOP BUYING MASKS! They are NOT effective in preventing general public from catching #Coronavirus.”<sup>100</sup>

Federal officials soon reversed course. In April 2020, the CDC declared that all Americans should wear masks. In a congressional hearing, CDC Director Dr. Robert Redfield even went as far as to declare—incorrectly—that face masks would be even more effective than a vaccine in combating the coronavirus.<sup>101</sup>

The revised federal mask guidance and the state response were decisive. By September 2020, the Trump Administration had distributed 600 million face masks to the public, and 32 states and “numerous municipalities” had implemented mask mandates that sometimes, as in New York City, were accompanied by stiff fines for persons who refused to comply.<sup>102</sup>

In January 2021, the CDC imposed a mask mandate on all travelers over the age of two using public transportation or facilities. The Transportation Safety Administration (TSA) enforced the mandate on all modes of public transportation, including planes, trains, buses, and ride-sharing vehicles. The CDC mandate was framed as an “emergency action” to protect public health and would apply to persons, with few exceptions, regardless of their vaccination or infection status or whether they had previously recovered from COVID-19.<sup>103</sup>



CDC messaging on the topic was convoluted and confusing. In May 2021, while enforcing the interstate transportation mandate, the CDC declared that vaccinated persons “in almost any setting” would *not* have to wear masks.<sup>104</sup> In July 2021, the CDC then reversed course and said that even fully vaccinated persons would *still* have to wear masks when they are indoors.<sup>105</sup> Growing public skepticism was hardly surprising.<sup>106</sup>

Within a year, states and localities started lifting various COVID-related restrictions, and the federal judiciary halted continuation of the CDC’s mask mandate. On April 18, 2022, Judge Kathryn Kimball Mizelle of the U.S. District Court in Florida struck down the CDC mask mandate for travelers on airplanes and other modes of public transportation. In her 59-page summary judgment, Judge Mizelle ruled that the CDC had exceeded its statutory authority, had violated the Administrative Procedure Acts in issuing the regulation without the benefit of public notice and comment, and had issued a mandate that was arbitrary and capricious, thus directly violative of federal law since the agency failed to provide a sufficient explanation for its regulatory action.<sup>107</sup>

Dr. Anthony Fauci, until recently President Biden’s chief medical adviser, criticized the federal courts for preventing the CDC from issuing the mandate without statutory authority: “We are concerned about courts getting involved in things that are unequivocally public health decisions.”<sup>108</sup> He also termed the ruling “unfortunate” because it “superseded the authority of the CDC.”<sup>109</sup>

Fauci’s comments raised another issue that has surfaced because of the pandemic. Public health officials sometimes view their recommendations as authoritative and their policies, as evidenced in this case, as immune from the constraints of the constitutional order. Congress makes laws; the executive branch faithfully executes them. The CDC’s authority derives entirely from congressional enactments. The court found that the agency had no statutory authority to issue a transportation mask mandate. The CDC exceeded its statutory authority. The court did not, as Fauci alleged, “supersede” the CDC’s authority.

**The Case for Masking.** Fauci’s criticism of the court’s ruling is wrong as a matter of law. His defense of the CDC’s “public health decision” to establish a transportation mask mandate was hardly clear-cut. The evidence for the efficacy of masks is hardly conclusive. Nor have U.S. public health authorities conducted a randomized controlled trial to determine whether masks work.

One reason public health officials counseled against wearing masks in the pandemic’s early months is that earlier research had not documented their efficacy against respiratory diseases like the flu. For example, publishing in *Emerging Infectious Diseases*, a team of researchers reported on

their review of 10 random controlled studies in the professional literature concerning the effectiveness of face masks in reducing viral infection. “In pooled analysis,” they concluded, “we found no significant reduction in influenza transmission with the use of face masks.”<sup>110</sup> Focusing specifically on surgical masks, they further observed:

We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility. However, as with hand hygiene, face masks might be able to reduce the transmission of other infections and therefore have value in an influenza pandemic when healthcare resources are stretched.<sup>111</sup>

In a 2021 Cato Institute paper on the evidence for community cloth face masking to limit the spread of SARS-CoV-2, Ian T. Liu, Vinay Prasad, and Jonathan J. Darrow examined numerous studies and meta-analyses on the subject and concluded that:

Evidence of facemask efficacy is based primarily on observational studies that are subject to confounding and on mechanistic studies that rely on surrogate endpoints (such as droplet dispersion) as proxies for disease transmission. The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit in the intent-to-treat populations.<sup>112</sup>

The authors examined the findings of numerous studies, but two are of particular interest. The first was a randomized controlled trial conducted by Danish researchers in 2020. Published in the *Annals of Internal Medicine*, it addressed the specific question of whether wearing a surgical mask outside the home combined with other public health measures would show a statistically significant reduction in viral transmission. In their research, 3,030 participants were assigned masks, and 2,994 were assigned to a control group. COVID-19 infection occurred in 42 masked participants (1.8 percent) and 53 control group participants (2.1 percent): a statistically insignificant difference of only -0.3 percent.<sup>113</sup>

Another randomized clinical trial on mask-wearing discussed in the paper was conducted in Bangladesh. That study found that surgical masks reduced the incidence of symptomatic illness due to COVID-19 but that cloth masks did not offer a statistically significant rate reduction.

Both studies, the authors observed, have limitations. The Danish study, for example, did not ascertain whether people were infected in the home or while wearing masks. The Bangladesh study was conducted in remote villages where natural immunity was low and vaccination largely absent. The study excluded children and schools.

Writing in *The New England Journal of Medicine* in May 2020, a team of researchers offered this assessment:

We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes). The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal. In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic.<sup>114</sup>

In short, the case for the efficacy of cloth masks is weak, and for surgical masks, it is ambivalent. Nevertheless, the CDC continues to recommend masking without informing the public of the weakness of the evidence, especially for cloth masks.<sup>115</sup> Instead, it urges that people “[w]ear a mask with the best fit, protection, and comfort for you.”<sup>116</sup>

As the authors of the Cato Institute review of published research on the efficacy of masking note, “ethical principles require that the strength of the evidence and best estimates of amount of benefit be truthfully communicated to the public.”<sup>117</sup>

The CDC continually failed this test.

**Masking Children.** During the past two years, the imposition of mask mandates on children has emerged as a particularly sensitive issue, especially since children are demonstrably at low risk for serious illness or death. According to the American Academy of Pediatrics, the U.S. data show that children’s risk of being hospitalized with the coronavirus ranges between 0.1 percent and 1.5 percent of cases and that their risk of death is even lower: from 0.00 percent–0.02 percent.<sup>118</sup>

The CDC’s recommendation that children as young as two years old wear masks, still extant as of September 2022,<sup>119</sup> is out of step with other national and global public health organizations. In its March 2022 guidance, the World Health Organization writes: “Children aged 5 years and under do not need to wear a mask because in this age group, they may not be able to properly wear a mask without help or supervision.”<sup>120</sup> The European Center for Disease Control and Prevention goes further, recommending *against* masking children under 12:

In primary schools, the use of face masks is recommended for teachers and other adults when physical distancing cannot be guaranteed, but it is not recommended for students.

In secondary schools, the use of face masks is recommended for both students and adults (i.e. masks for children older than 12 years) living in areas with community transmission of SARS-CoV-2.<sup>121</sup>

The CDC's guidelines are also poorly grounded in science. There is little empirical evidence to establish that masking children reduces COVID-19 transmission and much evidence—including the CDC's own data—demonstrating that they do not.

In a devastating *Lancet* preprint published in June 2022, Ambarish Chandra and Tracy Beth Hoeg examined the CDC's own data on cases in U.S. counties with and without school mask mandates from July–October 2021.<sup>122</sup> The authors note the lack of randomized clinical trials and refer to “numerous additional US and international observational studies finding no significant effect of school mask mandates on pediatric cases.” They then look at a highly cited CDC study that purports to show that school mask mandates do in fact reduce pediatric COVID-19 cases. That study looked at a select group of comparison counties over a short period of time. Chandra and Hoeg extended the study, using CDC data from a larger sample of districts over a longer time interval, and found “no significant relationship between mask mandates and case rates.”<sup>123</sup>

In a mild chastening of the CDC, which arrived at a conclusion that supported its school mask recommendations by making selective use of data, Chandra and Hoeg write that their study “demonstrates that observational studies of interventions with small to moderate effect sizes are prone to bias caused by selection and omitted variables.”<sup>124</sup> It would be uncharitable to say that the CDC cherry-picked its data to support its preferred policies, but the agency continues to post the flawed study on its *Morbidity and Mortality Weekly Report* website<sup>125</sup> without telling readers that it has been soundly refuted. Nor had the CDC modified its recommendations as of October 2022.

While persisting in this policy recommendation, the CDC also neglected contrary evidence from other studies and ignored the recommendations of other medical professionals. For example, Spanish data from 2021 showed that mask mandates on schoolchildren were not associated either with a reduced rate of COVID-19 cases or with a lower rate of transmission. Writing on the experience of face masks for schoolchildren in Catalonia, Spain, the researchers concluded that “FCM (face covering masks) mandates in

schools were not associated with lower SARS-CoV-2 incidence or transmission, suggesting that this intervention was not effective.”<sup>126</sup>

According to Dr. Nicole Saphier, an assistant professor at New York’s Memorial Sloan Kettering Cancer Center:

[By] summer 2021 enough data emerged demonstrating cloth masks predominantly had no perceptible benefit, and the low risk of severe COVID in children became apparent. Yet, no updates were made by CDC regarding mask-wearing in schools. In fact, despite vaccines being readily available for everyone five years and older, it doubled down on its school masking recommendations as the less severe Omicron variant became dominant.<sup>127</sup>

Some state officials, such as Governor Glenn Youngkin of Virginia, followed a new and different path, making school masking of children a voluntary parental decision.

As Dr. Martin Makary of Johns Hopkins Medical School has suggested, “[t]he NIH could have funded researchers to properly study each mask type in the first 10 days of the pandemic, but they failed to pivot funding to do so. Current data suggests that covering the faces of children for two years with a cloth mask had zero benefit and some harm.”<sup>128</sup> The NIH did not authorize a similar study of the effectiveness of mask types for travel—a worthwhile scientific investigation in view of the CDC’s attempt to impose a comprehensive transportation mask mandate.

### **Weakness No. 6: Costly School Closures.**

The CDC’s school masking policies, though poorly supported by scientific evidence and to some extent at variance with the policies of other prominent public health agencies, represented a softening in the agency’s position. Beginning in March 2020, the CDC called on state and local authorities to close schools and keep them closed. The CDC recommended masking of students and teachers, distancing (at first keeping desks six feet apart, later revised to three), and other measures as preconditions for reopening them.

As with student masking, the CDC’s recommendations lacked strong scientific support. A study of the efficacy of extended school closures published by the British Royal Society concluded that “the lower susceptibility of school children substantially limited the effectiveness of school closure in reducing COVID-19 transmissibility.”<sup>129</sup> A United Nations study noted that the costs of school closures “stand to be tremendous in terms of learning losses, health and well-being and drop-out.”<sup>130</sup>

Drs. Sandro Galea and Michael Stein, professors of public health at Boston University, have warned policymakers to be cautious when invoking science to inform decisions about “complex systems” and that in the case of school closures, many decisions did not reflect the scientific evidence: “The science showed relatively quickly that children were at low risk from the virus, and did not much influence transmission of COVID-19 in the general populations.”<sup>131</sup> By the summer of 2020, the data showed that children were “less likely” to contract the coronavirus, and when they did become infected, the symptoms were “mild” and their capacity for transmission of COVID-19 was low.<sup>132</sup>

Unfortunately, in many states and localities, the data made little or no difference. Conducting an econometric analysis of the impact of school closures on children and their future earnings in April 2020, Brookings Institution scholars estimated that with just four months of “lost education,” the cost to their future earnings would amount to \$2.5 trillion:

And with well over half the country’s states deciding to keep schools and universities closed until the fall at the earliest, much of this loss may well materialize. Extrapolating to the global level, on the basis that the U.S. economy represents about one-quarter of global output, these data suggest that the world could lose as much as \$10 trillion over the coming generation as a result of school closures today.<sup>133</sup>

Also examining the global impact of the school closures, researchers writing for the Organisation for Economic Co-operation and Development (OECD) in September 2020 warned that:

While the precise learning losses are not yet known, existing research suggests that the students in grades 1-12 affected by the closures might expect some 3 percent lower income over their entire lifetimes. For nations, the lower long-term growth related to such losses might yield an average of 1.5 percent lower annual GDP for the remainder of the century.<sup>134</sup>

It should also be noted that in imposing massive school closures, the United States was an outlier in the international community. As summarized by Derek Thompson, a staff writer for *The Atlantic*:

Schools remained open in France, the United Kingdom, Germany, and Italy in late 2020 and early 2021. (Some European schools were later closed briefly during the height of the Omicron wave.) Compared with their counterparts in the U.S.,

European policy makers seemed to place more faith in reports that schoolchildren did not play a major role in community transmission, and in evidence from Ireland, Singapore, Norway, Israel, South Korea, and North Carolina that young children were less likely than adults to get severely sick from COVID.<sup>135</sup>

The CDC's policy recommendations with respect to COVID and children will have lasting consequences. They have never been well-grounded in science. COVID-associated severe illness and death among children are extremely rare both in the U.S. and throughout the world. Deaths among otherwise healthy children are rarer still. A June 2022 study of children in England found that most of those who died with COVID between March 2020 and December 2021 had serious underlying medical conditions.<sup>136</sup> The researchers identified 81 COVID-related deaths among those who were under 20. Of those, 61 had an underlying condition with severe neurodisability and immunocompromised conditions the most prevalent.

The CDC had not undertaken a similar analysis, although it did acknowledge in March 2022 that it had overestimated deaths among children.<sup>137</sup> It never had good data on the efficacy of school closures, but its recommendations prompted many school districts to extend closures for months. The agency then shifted to counseling mask mandates, a recommendation that also lacked a firm basis in science.

Teachers' unions have also apparently had strong (and often undue) influence on public health decisions, both local and federal. For example:

- Researchers writing in *Health Affairs* found that “[i]n the absence of a statewide mask mandate, school districts in Iowa with higher teachers’ unionization rates were more likely to adopt mask mandates, which the CDC strongly recommended.”<sup>138</sup>
- Last year’s CDC guidance on school reopenings raised significant questions among Members of Congress. On February 12, 2021, the agency issued its guidance on reopening schools, but it had previously shared its draft guidance with the American Federation of Teachers (AFT), one of the nation’s two major teachers’ unions. Such guidance is normally confidential. In breaking with past practice, the CDC permitted AFT officials to insert language into the guidance before its final release that would have the effect of extending the time that K–12 schools would remain closed. An Administration lawyer instructed a CDC official not to answer a question as to why the draft guidance was shared with the AFT.<sup>139</sup>

Given the accumulated evidence that children were overwhelmingly free of severe illness or mortal danger from the pandemic, along with accumulating evidence of the costs imposed by lost in-person learning, particularly among low-income and minority children, it is remarkable that so many public officials refused to resume normal K–12 schooling in many parts of the country.

Congressional investigators should inquire into the rationale behind CDC school guidance decisions and the extent to which those decisions were influenced by factors, political or otherwise, that were external to scientific justification.

### **Weakness No. 7: The CDC Eviction Moratorium.**

State and local officials imposed school closures and masking requirements pursuant to CDC guidelines, but the CDC's imposition of a nationwide moratorium on evictions exceeded its statutory authority.<sup>140</sup>

Congress instituted a 120-day ban on evicting tenants during the public health emergency in March 2020.<sup>141</sup> When the moratorium expired in July, President Trump issued an executive order directing HHS Secretary Alex Azar to consider whether extending it was “reasonably necessary.”<sup>142</sup> The CDC issued a temporary eviction moratorium on September 4.<sup>143</sup> When a subsequent extension of the moratorium lapsed early in 2021, the CDC under the Biden Administration both reinstated and periodically extended it.

The CDC's actions under both the Trump and Biden Administrations relied on an imaginative reading of a 1944 statute that authorized the CDC. As Paul J. Larkin Jr. of The Heritage Foundation has aptly summarized, the government's extravagant view of the CDC's authority is that “[t]he Public Health Service Act authorizes CDC Director Walensky to issue whatever rules she deems medically necessary to prevent the interstate transmission of the SARS-CoV-2 virus.”<sup>144</sup> The CDC was laying claim to “the power to draft private parties into the quarantine business by ordering them to admit onto their land or into their homes people potentially or actually suffering from a highly contagious and potentially fatal disease—in other words, potentially everyone—who cannot meet their rental obligations.”<sup>145</sup>

The agency suffered a series of defeats in the courts, although the Supreme Court of the United States did not at first vacate the order. On June 29, 2021, in *Alabama Association of Realtors v. Department of Health and Human Services*, Justice Brett Kavanaugh agreed that the agency “exceeded its existing statutory authority by issuing a nationwide eviction moratorium”



but, citing the CDC’s pledge to “end the moratorium in only a few weeks,” sided with Chief Justice John Roberts and Associate Justices Samuel Alito, Clarence Thomas, and Amy Coney Barrett and let the order stand.<sup>146</sup>

In early August, the Administration reversed course and reinstated the eviction moratorium that had expired just a few days earlier. This time, the Court struck down the moratorium. “If a federally imposed eviction moratorium is to continue,” its August 26, 2021, *per curiam* opinion stated, “Congress must specifically authorize it.”<sup>147</sup>

### **Weakness No. 8: Flawed Vaccine Policy.**

**Vaccine Mandates.** Following his victory in the 2020 presidential election, while promising to “crush” the virus, President-elect Biden also declared that he would not impose a mandate on Americans to get a COVID-19 vaccine. Dr. Anthony Fauci, senior medical advisor to both Trump and Biden, also expressed the view that a vaccine mandate was inappropriate. In August 2020, Fauci said, “You don’t want to...try and force someone to take the vaccine.... [W]e’ve never done that for the general population.”<sup>148</sup>

Despite these previous promises and disclaimers, on September 9, 2021, President Biden announced that he had asked his Administration to impose multiple vaccine mandates.<sup>149</sup> One applied to health care workers in hospitals and other facilities that received Medicare and Medicaid funding. Another required all executive branch employees to be vaccinated. A third applied that requirement to federal contractors. The fourth required employers to terminate the employment of unvaccinated workers who refused to submit to a mandatory testing and masking regime. These mandates were in addition to a mandate on military personnel imposed by the Secretary of Defense.

On November 4, 2021, at Biden’s direction, the U.S. Department of Labor’s Occupational Safety and Health Administration (OSHA) issued an “Emergency Temporary Standard” to be applied to all American workers employed by businesses with 100 or more employees—an unprecedented mandate affecting an estimated 80 million persons in the private sector. Workers were to secure a vaccination or get a weekly test, and employers who violated the OSHA rule would be subject to a fine starting at \$13,653 for each violation, up to a total fine of \$136,532 annually. The OSHA rule was drafted to preempt any state requirements that differed from the federal rule, including state or local rules that ban such vaccine mandates. The OSHA rule was also to be enforced by employers, who would also assume the cost of administering it.<sup>150</sup>

The OSHA vaccine mandate was immediately challenged in the federal courts. OSHA claimed that its statutory authority to issue “emergency standards” justified the unprecedented mandate.<sup>151</sup> The Supreme Court disagreed, enjoining the mandate in January 2022.

It is telling that OSHA, in its half-century of existence, has never adopted a broad public health regulation of this kind: one addressing a threat that is untethered in any causal sense from the workplace. This lack of historical precedent, coupled with the breadth of authority that the Secretary now claims, is a telling indication that the mandate extends beyond the agency’s legitimate reach.<sup>152</sup>

The Court let stand a separate vaccine mandate on health care workers in facilities that receive Medicare funds, ruling that the CMS’s statutory authority to impose conditions that advance patient safety on the receipt of Medicare funds justified its mandate that medical workers be vaccinated.<sup>153</sup> The mandate on federal workers has remained mired in litigation as does a similar requirement on federal contractors.<sup>154</sup>

On December 23, 2022, President Biden signed the FY 2023 National Defense Authorization Act, which removes the requirement that military personnel receive the COVID-19 vaccine.<sup>155</sup> By that point, thousands of military personnel had been discharged for their refusal to be vaccinated.<sup>156</sup> It is unclear whether statutory rescission of the mandate will render them eligible to return to the uniform.<sup>157</sup>

There also is ongoing litigation involving those who have applied for religious exemptions from the mandate. Congressional action may affect these cases, in which plaintiffs have argued that the military has given only perfunctory consideration of their religious scruples, an allegation reportedly corroborated by an internal memorandum written by the Pentagon’s Inspector General.<sup>158</sup> The government’s attitude more generally toward religious objections to the vaccines has at times been cavalier. “God wants you to be vaccinated,” New York Governor Kathy Hochul proclaimed at a Brooklyn church.<sup>159</sup>

**Vaccine Hesitancy.** In September 2022, FDA authorized the latest “variant-specific” booster, but fewer than 40 million Americans had received the updated shot as of November 30.<sup>160</sup> Nor is this poor showing atypical. As of December 7, 2022, vaccination rates remained lowest among children (fewer than one-third of children aged 5–11 had completed their series, and fewer than 7 percent had been boosted) and highest among the elderly (94 percent had completed the series, 68 percent had received one booster, and 39 percent had received two).<sup>161</sup>

Despite ample supply, vaccines being authorized for more age groups, and recommendations that most adults receive multiple boosters, fewer

shots are being administered. Through June 28, there had been just 76 million jabs in 2022.<sup>162</sup> That compares with 302 million over the first six months of 2021 and 519 million throughout all of 2021.

Exactly why this rate has stalled is unclear, but there appear to be several reasons.

*First*, people over 65, most of whom completed their primary courses over the first half of 2021, have not been as eager to get boosters. As noted, only 39 percent—just a fraction of those who completed the original series—had received four shots as of December 2022.

*Second*, while the FDA has authorized COVID vaccines for infants as young as six months, a tiny percentage of children are vaccinated. The FDA first authorized shots for children aged 5–11 in November 2021. By December 2022, as noted, fewer than one-third were vaccinated, and fewer than 7 percent were boosted. Since then, that rate has slowed to a trickle. Only 72,000 children in that age group got shots during the week ending December 7, 2022, compared with a peak of 1.6 million for the week ending November 24, 2021. This is more remarkable given efforts by the American Academy of Pediatrics to promote the COVID vaccine. It is unclear, however, whether pediatricians are less enthusiastic about the vaccine than are leaders of their professional association or parents who are spurning their advice.

In either case, there are legitimate questions about the wisdom of vaccinating young children. That is why Representative Bill Posey (R–FL) and Senator Ted Cruz (R–TX), along with 16 other Members of the House and Senate, posed 19 specific questions to FDA Commissioner Robert M. Califf about the rationale for vaccinating children under five, especially since 68 percent of children between one and four years of age, according to CDC data, had already been infected with COVID 19:

The broad approach of the CDC and FDA to date has been a one-size fits all policy—get the vaccine regardless of age, risk factors, the underlying health of the individual, or previous infection. Yet, to date there remain many unanswered questions about these EUA-approved COVID-19 vaccines and only a small percentage of the safety data about these vaccines that are in the possession of the FDA and the manufacturers has been released for review.<sup>163</sup>

*Third*, the vaccines have not ended the pandemic. The rationale behind nonpharmaceutical interventions is that they would slow the spread of the virus until a vaccine became available. Once a sizable portion of the population was vaccinated, the thinking goes, COVID would essentially be

eradicated.<sup>164</sup> But the largest waves of new infections in the U.S. and other highly developed nations occurred *after* large percentages of their populations were vaccinated. Ironically, even as the Biden Administration was pressing for vaccine mandates on the theory that the shots would prevent transmission, confirmed cases of COVID-19 were reaching unprecedented heights. Vaccines still appear to reduce the risk of severe illness, but they did not prevent the Omicron wave.

*Fourth*, there is growing evidence that vaccine efficacy fades with time. A May 2022 study published in the *Journal of the American Medical Association* found that Omicron-specific neutralizing antibody levels dropped in a matter of weeks after a second or third dose of the Pfizer vaccine.<sup>165</sup> This rapid waning of efficacy may well affect people's decisions about whether or not to get boosters. Two years ago, the FDA concluded that two doses of the original mRNA vaccines were more than 90 percent effective against symptomatic illness. Those results did not measure how long that protection lasted. Since then, millions of vaccinated and boosted people have acquired symptomatic cases. Moreover, vaccination does not provide an ironclad protection against Covid-related mortality. As *The Washington Post* has reported, 58 percent of deaths related to Covid-19 recorded in August 2022 were among vaccinated or boosted persons.<sup>166</sup> Knowing that the efficacy, as measured by antibody levels, wanes within weeks of a third or fourth shot might dissuade some from getting boosted.

*Fifth*, while the benefits of the vaccine appear to be less than originally advertised, their risks have become a matter of increasing concern. The accumulating data from the federal government's Vaccine Adverse Event Reporting System (VAERS) show that adverse reactions to the Covid vaccines, such as serious cardiovascular consequences including strange blood-clotting, dwarf those of all other vaccines. Yet federal officials imposing vaccine mandates have not appeared to be as alarmed as one would reasonably expect them to be.

They should consult the emerging research. A June 2022 preprint study co-authored by Joseph Fraiman and five colleagues examined safety and efficacy data in the Phase III trials of the Pfizer and Moderna mRNA vaccines.<sup>167</sup> It found that both vaccines were associated with an increased risk of serious adverse events when compared against the placebo group. Moreover, it found that this excess risk of serious adverse events surpassed the risk reduction for COVID-19 hospitalization relative to the placebo group.

The authors suggested two reasons why the FDA had not flagged this when it reviewed the Phase III data before approving both the Pfizer and Moderna products.

- Fraiman and his colleagues looked at people who had received two doses over a longer period of time (two months or more). The FDA’s analysis included thousands of additional individuals, most of whom had received just one dose, with very little follow-up.
- The FDA compared the number of trial participants that had experienced serious adverse events, but the study’s authors counted the number of such events. This is important because the study found that twice as many individuals in the vaccine group experienced multiple adverse events as experienced them in the placebo group. The FDA review of the safety and efficacy data did not account for that.

Fraiman and his colleagues call for a “more formal harm-benefit analyses especially in individuals at low risk of COVID-19 hospitalization and death.”<sup>168</sup> They also point to the work of Alison Krug, Josh Stevenson, and Tracy Beth Hoeg, who examined the federal database that tracks adverse events associated with the COVID-19 vaccines.<sup>169</sup> Specifically, Krug, Stevenson, and Hoeg examined data from the Vaccine Adverse Event Reporting System (VAERS) to look at the post-vaccination risk of myocarditis and pericarditis among adolescents aged 12–15 and 16–17. Previous studies had documented that boys in these age groups were more likely to develop heart conditions after receiving the Pfizer vaccine than were those in other groups. Krug and her colleagues found that the benefits of the Pfizer vaccine in this age group outweighed the risks only for nonimmune girls with a comorbidity. In boys with prior infection and no comorbidities, even one dose carried more risk than benefit, the authors found.

In a recent risk/benefit analysis of university vaccine mandates, a team of 11 academic researchers with affiliations ranging from Harvard and Johns Hopkins to Oxford and the University of California concluded that:

Based on public data provided by the CDC, we estimate that approximately 22,000 to 30,000 previous *uninfected* young adults ages 18–29 years must be boosted with an mRNA vaccine to prevent one Covid-19 hospitalization. Given the fact that this estimate does not take into account the protection conferred by prior infection nor a risk-adjustment for comorbidity status, this should be considered a conservative and optimistic assessment of benefit. Our estimate shows that university Covid-19 vaccine mandates are likely to cause net expected harms to healthy young adults—between 18 and 29 serious adverse events requiring hospitalization and 1373 to 3234 disruptions of daily activities—that is not outweighed by a proportionate public health benefit. Serious

Covid-19 vaccine-associated harms are not adequately compensated for by current US vaccine injury systems. As such, these severe infringements of individual liberty are ethically unjustifiable.<sup>170</sup>

This is not to suggest that the vaccines are inherently unsafe. Rather, it suggests that policymakers must account for the fact that the risks and benefits of the vaccine relative to those of the disease vary by age and health status. The risk of COVID-associated severe illness and death is highly age-stratified. Older adults are highly vulnerable, young adults are much less so, and the risk to children without underlying comorbidities is infinitesimal. Thus, the risk of the vaccine relative to its benefit is much different for an 18-year-old male than for an 82-year-old.

Some vaccine hesitancy may also be attributable to legislation that granted vaccine manufacturers immunity against lawsuits filed by people who have experienced adverse events. Instead, HHS administers the Countermeasures Injury Compensation Program (CICP), which provides compensation for people seriously injured by a covered countermeasure, including COVID vaccines.<sup>171</sup> Under this program, people who believe a vaccine or treatment for COVID-19 has injured them during the public health emergency may file a claim for compensation from the CICP. They can recover losses due to death or an injury severe enough to require hospitalization or cause a significant loss of function or disability.<sup>172</sup>

In the CICP, as in the Vaccine Injury Compensation Program, awards are capped, and plaintiffs cannot recover punitive or exemplary damages. Unlike the Vaccine Injury Compensation Program, however, the CICP also prohibits recoveries for attorneys' fees and pain-and-suffering damages. Death benefits are capped at \$370,376, and the fund limits recovery of lost employment income to \$50,000 annually, up to a \$379,000 lifetime cap.<sup>173</sup>

As of November 2022, the CICP had received 7,624 claims alleging injury or death from COVID vaccines.<sup>174</sup> The agency had determined that nine of these claims, eight of which concerned myocarditis, were eligible for compensation.<sup>175</sup>

Some may be reluctant to be vaccinated because they consider this limit on liability a tacit acknowledgment that recoveries for adverse events would be ruinously large for the manufacturer absent government liability limits. It is the case, however, that vaccines more generally have long had liability protections, in part to encourage their development and dissemination. Had the vaccines held the possibility of eradicating the virus, there would be an argument (though by no means dispositive) that people at very low risk of severe COVID-related outcomes should be vaccinated for the good

of society. It is now clear, however, that this is not the case. Vaccines reduce the risk of severe COVID-related illness, but they also carry very real risks of their own. One-size-fits-all vaccine policies ignore this.

On July 21, 2021, President Biden incorrectly told a CNN audience that vaccinated Americans could not be infected by COVID-19. In July 2022, after being fully vaccinated and *twice* boosted, the President himself contracted the coronavirus. In a remarkable comment on the efficacy of the vaccines, Dr. Birx said, “I knew these vaccines were not going to protect against infection. And I think we overplayed the vaccines, and it made people then worry that it’s not going to protect against severe disease and hospitalization.”<sup>176</sup>

By urging virtually everyone—from infants to nonagenarians—to get vaxxed and boosted, public health authorities may well have helped to dampen vaccination rates. Laypeople can be forgiven for sometimes inaccurately assessing the risks and benefits of vaccines. Public health officials cannot.

### **Weakness No. 9: Ignoring and Downplaying Natural Immunity.**

An elemental principle of biology is that a bacterial or viral infection will normally stimulate an immune response to protect the body and prevent or reduce the impact of a future infection. Childhood viral maladies such as measles, mumps, and chicken pox all provide natural immunity, and such immunity is not seriously questioned. With the rise of COVID-19 and the imposition of vaccine mandates, natural immunity suddenly became a controversial topic.

One of the more remarkable features of public health officials’ responses to the pandemic has been to downplay or simply ignore scientific evidence relating to COVID-19. As Dr. Martin Makary, professor of medicine at Johns Hopkins University, has noted, the NIH has responded to the issue of natural immunity by dismissing it, declaring that its duration is unknown, and then “failing to conduct studies to answer the question.”<sup>177</sup>

In fact, there is robust scientific evidence for natural immunity among those who have contracted the coronavirus. At least 150 research studies validate its effectiveness.<sup>178</sup> For example:

- Writing in the April 2021 edition of *The Lancet*, the prestigious British medical journal, a team of researchers reported on their massive study of 30,625 participants. They concluded that previous COVID-19 infection was “associated with an 84% lower risk of infection, with median

protective effect observed 7 months following primary infection” and that “previous infection...induces effective immunity to future infections in most individuals.”<sup>179</sup> The CDC simply ignored this major *Lancet* study.<sup>180</sup>

- Writing in the June 2022 edition of *The Lancet Child & Adolescent Health*, a team of British medical researchers found that COVID-19 reinfection is “uncommon” in adults but even more uncommon in children. The researchers found that in England between January 2020 and July 2021, there were 688,419 primary infections in children 16 years or younger and just 2,343 reinfections. Of the 109 children hospitalized with the reinfection, 78 (72 percent) had comorbidities. Of the entire cohort, there were 44 deaths among children testing positive for the coronavirus. All childhood deaths occurred among children with a primary infection; none occurred after reinfection. And of the four children admitted to an intensive care unit (ICU) following a COVID-19 reinfection, all four “had multiple and severe multisystem comorbidities and, despite detailed case note review, ascertaining the contribution of SARS-CoV-2 infection to the illness that eventually led to the intensive care admission was not possible.”<sup>181</sup>
- In March 2021, a team of Israeli researchers who had conducted a large study of people that had recovered from COVID in order to determine their level of reinfection reported that “[o]ut of 149,735 individuals with a documented positive PCR [polymerase chain reaction] test between March 2020 and January 2021, 154 had two positive tests at least 10 days apart, reflecting a reinfection proportion of 1 per 1000.”<sup>182</sup>
- With the emergence of the Delta variant of COVID-19, another team of Israeli researchers examined the comparative strengths of vaccine-induced immunity and natural immunity in an exceptionally large population study. They concluded that natural immunity was much stronger:

This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Individuals who were both previously infected with SARS-CoV-2 and given a single dose of the vaccine gained additional protection against the Delta variant.<sup>183</sup>



- **In January 2022, the CDC released its own study on the comparative strength of natural and vaccine immunity based on case data from 2021 in California and New York. The CDC researchers concluded that:**

During May–November 2021, case and hospitalization rates were highest among persons who were unvaccinated without a previous diagnosis. Before Delta became the predominant variant in June, case rates were higher among persons who survived a previous infection than persons who were vaccinated alone. By early October, persons who survived a previous infection had lower case rates than persons who were vaccinated alone.<sup>184</sup>

**It was the first time that the CDC conceded that natural immunity *alone* scored higher than vaccination *alone* in reducing cases, although the researchers emphasized that vaccination remains the “safest and primary” strategy to prevent infection.<sup>185</sup> Commenting on the CDC findings, Dr. Makary noted that:**

[T]he CDC spun the report to fit its narrative, banner[ing] the conclusion ‘vaccination remains the safest strategy.’ It based this conclusion on the finding that hybrid immunity—the combination of prior infection and vaccination—was associated with a slightly lower risk of testing positive for Covid. But those with hybrid immunity had a similarly low rate of hospitalization (3 per 10,000) to those with natural immunity alone. In other words, vaccinating people who had already had Covid didn’t significantly reduce the risk of hospitalization.<sup>186</sup>

- **In another large 2022 Israeli study of unvaccinated persons five to 18 years of age, researchers concluded that:**

Overall, children and adolescents who were previously infected acquired durable protection against reinfection (symptomatic or not) with SARS-CoV-2 for at least 18 months. Importantly, no COVID-19 related deaths were recorded in either the SARS-CoV-2 naïve group or the previously infected group. Effectiveness of naturally acquired immunity against a recurrent infection reached 89.2 (95% CI: 84.7%–92.4%) three to six months after first infection, mildly declining to 82.5% (95%CI, 79.1%–85.3%) nine months after infection, then remaining rather steady for children and adolescents for up to 18 months, with a slight non-significant waning trend.<sup>187</sup>

Natural immunity obviously has direct relevance for vaccine policy, particularly the imposition and enforcement of government or private-sector mandates. Dr. Paul Offit, a professor of pediatric medicine at Children’s Hospital of Philadelphia and an FDA advisor, has said that “natural infection” should count as “two” vaccine doses and that the CDC guidance that all Americans over the age of 12 should get three shots is not only a waste of vaccine, but also a recommendation that incurs “unnecessary” health risks.<sup>188</sup>

Congressional investigators should inquire into the reasons why Administration officials pursuing vaccination mandates ignored, downplayed, or refused to acknowledge the professional literature on the effectiveness of natural immunity from COVID-19 infection.

### **Weakness No. 10: Imposing Lockdowns.**

One of the most remarkable developments of the pandemic was the overwhelming degree to which Americans—particularly those gripped by fear—tolerated and supported the draconian public health measures that government officials imposed on them. With the passage of time, however, it became clear that the comprehensive lockdowns, restrictions on personal mobility, personal isolation, imposition of mask mandates, and other restrictive measures were exacting multiple social and economic costs as well as collateral damage to public health.

State government responses, in particular, were unprecedented. Following federal guidance first issued in March 2020, states and localities initiated comprehensive lockdowns, closures of schools and businesses, social distancing, and enforced masking. Even with the 1918 flu, the United States did not resort to such comprehensive lockdowns.

Beginning in March 2020, however, pursuant to federal recommendations and guidelines, states and localities adopted massive social and economic restrictions on healthy populations. The evidence supporting such a broad rather than targeted pandemic strategy was thin, particularly regarding the reduction in COVID-19 death. For example:

- In July 2020, a group of researchers writing in *eClinicalMedicine* reported the results of a massive study of government responses in 50 countries that they had conducted to determine the extent to which common public health measures, including border closures, social distancing, lockdowns, and widespread testing, reduced transmission or mortality: “Our country-level model demonstrated that travel restrictions and containment measures put in place up till 01 May

2020 may have an impact on the total number of COVID-19 cases in a given country, but there was no observed association between public health policies and the number of critical cases or mortality.” With respect to the impact of lockdowns and testing, they found that “that more restrictive public health practices may indeed be associated with less transmission and better outcomes. However, in our analysis, full lockdowns and widespread COVID-19 testing were not associated with reductions in the number of critical cases or overall mortality.”<sup>189</sup>

- With the benefit of two years of empirical data, an international research team writing in *Studies in Applied Economics* published a systemic review of the professional literature on the effectiveness of government mandates, including lockdowns, shelter-in-place orders (SIPOs), and various nonpharmaceutical interventions (NPIs). Focusing on 24 studies that specifically addressed the topic of government lockdowns, the authors concluded:

An analysis of each of these three groups support[s] the conclusion that lockdowns have had little to no effect on COVID-19 mortality. More specifically, stringency index studies find that lockdowns in Europe and the United States only reduced COVID-19 mortality by 0.2% on average. SIPOs were also ineffective, only reducing COVID mortality by 2.9% on average. Specific NPI studies also find no broad-based evidence of noticeable effects on COVID-19 mortality.

While this meta-analysis concludes that lockdowns have had little to no public health effects, they have imposed enormous economic and social costs where they have been adopted. In consequence, lockdown policies are ill-founded and should be rejected as a pandemic policy instrument.<sup>190</sup>

- A comparison of the different approaches taken by countries in response to the pandemic found that strict lockdowns did not result in better outcomes than did more targeted measures such as isolation of the sick, mass testing, and contact tracing.<sup>191</sup>

**Impact on the Free Exercise of Religion.** Some states and jurisdictions applied different prohibitions to religious institutions than they did to commercial enterprises. The Supreme Court rejected early challenges to these disparate lockdown policies brought by churches but eventually shifted its stance, holding that such policies could not treat comparable secular activities more favorably than they treated religious activities.<sup>192</sup>

- In *Roman Catholic Diocese of Brooklyn v. Cuomo*, the Court granted emergency relief from New York State’s restrictions on worship services, holding that those restrictions “violate[d] ‘the ‘minimum requirement of neutrality’ to religion.”<sup>193</sup>
- In *Tandon v. Newsom*, the Court invalidated a California restriction on religious gatherings because it “treat[ed] some comparable secular activities more favorably than at-home religious exercise, permitting hair salons, retail stores, personal care services, movie theaters, private suites at sporting events and concerts, and indoor restaurants to bring together more than three households at a time.”<sup>194</sup>

**Economic Impact.** By Spring 2020, the economic impact was devastating. The closure of hundreds of thousands of businesses, particularly small and minority owned businesses, had disastrous effects: By April of 2020, millions of jobs were lost, the labor force had dropped to 60.2 percent, and unemployment soared to 14.8 percent, the highest level since the Great Depression of the 1930s.<sup>195</sup>

**Worsening Health Outcomes.** To cope with the pandemic, hospitals and other medical facilities restricted routine treatment for many conditions and postponed testing and treatment for many medical conditions. The results were predictable: worsening health and higher mortality. Writing in *The Lancet*, Dr. Santiago Garcia and Dr. Timothy Henry observed that:

COVID-19 has dramatically impacted healthcare delivery around the world. As hospital systems prepared for the actual or perceived onslaught of COVID-19 patients, “measures were implemented that effectively discouraged or restricted patient access to outpatient care, and diagnostic and therapeutic cardiac procedures deemed elective.”<sup>196</sup>

Beyond the delays and denials of hospital care that resulted in worsening health outcomes, hospitals and other medical facilities also restricted or denied visits by families, friends, or relatives to dying patients. “The barbaric policy of banning loved ones from holding the hand of their dying loved one and saying goodbye was a human rights violation that spanned much of the pandemic,” writes Dr. Makary. “All the so-called experts and the medical establishment were complicit, allowing this cruel policy to be instituted while abandoning their duty to respect the dignity of human life.”<sup>197</sup>

Mental health suffered, along with increased abuse of alcohol and substance abuse, and the hardest hit communities were lower-income and minority communities. According to Drs. Galea and Stein:

As those with resources were able to shift rapidly to working from home, they had lower risk of acquiring Covid-19, and subsequent lower burden of infection and death from the pandemic. Yet as Covid-19 progressed, prolonged social isolation became associated with harmful behaviors including use of substances, leading to a surge of poor health we will be dealing with long after the worst days of Covid-19 have passed.<sup>198</sup>

Writing in the journal *Frontiers in Public Health*, Dr. Ari Joffe, a clinical professor in the Division of Pediatric Critical Care in the University of Alberta's Department of Pediatrics, has aptly summarized the initial year-long impact of the lockdowns:

The lockdowns implemented in the name of public health entailed trade-offs that were not adequately considered. Lockdowns may prevent some COVID-19 deaths by flattening the curve of cases and preventing stress on hospitals. At the same time, lockdowns cause severe adverse effects for many millions of people, disproportionately for those already disadvantaged among us. The collateral damage included severe losses to current and future wellbeing from unemployment, poverty, food insecurity, interrupted preventive, diagnostic, and therapeutic healthcare, interrupted education, loneliness and deterioration of mental health, and intimate partner violence. The economic recession has been framed as the economy vs. saving lives from COVID-19, but this is a false dichotomy.<sup>199</sup>

### **Weakness No. 11: Ignoring or Overlooking Frontline Clinical Experience.**

A key weakness of the federal response to the pandemic has been the lack of a regular forum for physicians and other frontline medical professionals to communicate weekly or biweekly and share vital clinical observations on disease progression and treatment. Despite recommendations to provide such a forum,<sup>200</sup> the CDC failed to do so and missed the opportunity to establish a clearinghouse for best clinical practices to help medical professionals combat the coronavirus. The absence of such a clearinghouse as a problem became acute in the spring of 2020 during the earliest stages of the pandemic.

For example, in April 2020, Dr. Thomas Yadegar, medical director of the ICU at the Providence Cedars Sinai Medical Center in Tarzana, California, reported that the COVID-19 virus would express itself as an infectious disease that resembles many other infectious diseases like the flu but also triggers not only pneumonia, but also a severe autoimmune response, a “cytokine storm” in which the immune system attacks the virus *and* the patient’s own vital organs. In other cases, the patients may have a hypercoagulation response with widespread blood clotting that is sometimes unresponsive to anticoagulant medications. Patients end up on ventilators, and their deteriorating conditions often end in death. As Dr. Yadegar and other physicians quickly discovered, this autoimmune response to COVID-19 can manifest itself in different ways because patients’ immune systems are unique. His response in these cases was to administer strong immunosuppressive medications to quell the autoimmune response as quickly as possible, keep patients off the ventilators, and save their lives.<sup>201</sup>

Dr. Yadegar discussed his clinical experience with a representative of the NIH, but the agency official wanted him to submit studies for randomized trial. For a clinician treating seriously ill patients in danger of death in an ICU, this did not seem practical. In October 2020, however, the NIH did begin a clinical trial of drugs to treat this autoimmune response in COVID patients,<sup>202</sup> and in June 2021, the FDA issued an EUA for Acemtra, a medication to treat Covid-induced inflammation.<sup>203</sup> The problem was that federal officials did not quickly share vital information on clinical experience and treatment of the deadly disease broadly with other clinicians in a timely fashion. This was hardly the kind of lightning-fast response that is appropriate during a national medical emergency.<sup>204</sup>

Federal public health officials need to collect frontline information on the clinical trajectory and treatment of any novel virus early and often, and they also need to create a national forum, scheduled routinely, for sharing this vital information with other medical professionals.

## **Weakness No. 12: Suppressing Scientific Dissent.**

At the outset of the pandemic, a key public health issue was the proper identification of persons who were most vulnerable to the virus: those most in danger of severe illness, hospitalization, and death. Based on their examination of the accumulating data, three prominent medical scientists—Dr. Jay Bhattacharya, professor of epidemiology at Stanford University; Dr. Martin Kulldorff, professor of medicine at Harvard University; and Dr.

Sunetra Gupta, professor of theoretical epidemiology at Oxford University—prescribed an approach vastly different from the one recommended and enforced by federal and state public health officials. They outlined their position in the Great Barrington Declaration, arguing that the appropriate strategy was a strong, targeted response designed to safeguard the most vulnerable populations, particularly older persons and persons with comorbidities, while avoiding mass lockdowns and forced isolation of younger and healthier individuals, who are at far less risk, thereby sparing them the inevitable social, economic, and health costs.

The authors of the Great Barrington Declaration also warned of the danger and damage sustained from resorting to comprehensive social and economic lockdowns:

Current lockdown policies are producing devastating effects on short[-term] and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health—leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden. Keeping students out of school is a grave injustice.<sup>205</sup>

**The authors of the Declaration outlined a balanced response to the pandemic that would focus protection on the vulnerable while allowing younger and healthier persons to resume a normal social and economic life:**

As immunity builds in the population, the risk of infection to all—including the vulnerable—falls. We know that all populations will eventually reach herd immunity—i.e. the point at which the rate of new infections is stable—and this can be assisted by (but is not dependent upon) a vaccine. Our goal should therefore be to minimize mortality and social harm until we reach herd immunity.

The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at higher risk. We call this Focused Protection.

Adopting measures to protect the vulnerable should be the central aim of public health responses to COVID-19....<sup>206</sup>

Responding to the October 4, 2020, publication of the Great Barrington Declaration, NIH Director Dr. Francis Collins in an email called for a “quick and devastating published takedown of [the Declaration’s] premises.”<sup>207</sup> Dr. Fauci likened the outside academic response as akin to “AIDS denialism,” and Dr. Collins dismissed the three prominent scientists as “fringe epidemiologists.”

The alternative strategy of social and economic lockdowns, embraced by equally prominent leaders in the public health community including Dr. Rochelle Walensky, was embodied in an alternative declaration, the John Snow Memorandum. The memorandum’s authors noted that:

Although lockdowns have been disruptive, substantially affecting mental and physical health, and harming the economy, these effects have often been worse in countries that were not able to use the time during and after lockdown to establish effective pandemic control systems. In the absence of adequate provisions to manage the pandemic and its societal impacts, these countries have faced continuing restrictions.<sup>208</sup>

**Addressing the Great Barrington Declaration’s case for “herd immunity,” the John Snow authors declared:**

The arrival of a second wave and the realization of the challenges ahead has led to renewed interest in a so-called herd immunity approach, which suggests allowing a large uncontrolled outbreak in the low-risk population while protecting the vulnerable. Proponents suggest this would lead to the development of infection-acquired population immunity in the low-risk population, which will eventually protect the vulnerable. This is a dangerous fallacy unsupported by the scientific evidence.<sup>209</sup>

This proved to be a legitimate scientific debate. On the face of it, Collins’s charge that the authors of the Great Barrington Declaration were “fringe epidemiologists” was baseless. The authors of both the Great Barrington Declaration (GBD) and the John Snow Memorandum (JSM) were equally prominent members of the scientific community. Writing in the *British Medical Journal Open*, Dr. John P. Ioannidis, a professor in the Department of Medicine at Stanford University, examined the professional publications as well as social media communications of the original signers of the Declaration and found that:



Among the 47 original key signatories of GBD, 20, 19 and 21, respectively, were among the top-cited authors for their career impact, their recent single-year (2019) impact or either. Among the 34 original key signatories of JSM, 11, 14 and 15, respectively, were among the top-cited authors for their career impact, their recent single year (2019) or either. The percentage of top cited scientists is modestly higher for GBD than for JSM, but the difference is not beyond chance ( $p > 0.10$  for all three definitions).<sup>210</sup>

Dr. Fauci's charge that the scientists denied COVID-19 was equally baseless. Dr. Bhattacharya emphasized, "In no way have I or any of the signers of the Great Barrington Declaration denied COVID. COVID is a deadly disease. It's killed millions. It in particular is a danger to older populations." Dr. Kulldorff emphasized that the "focused protection" of the Declaration was based on the fact that "there needed to be much better protection for older, high-risk people," but "we protected the younger members of the laptop class who were terrified of the COVID when they should not have been because the risk was very, very small."<sup>211</sup>

Professors Galea and Stein of the Boston University School of Public Health cite the non-debate over the Great Barrington Declaration as a highlight of the growing "intolerance of disagreement" in the field of public health: "The Declaration, while patently flawed, embedded ideas that were contrary to mainstream views and could have been grounds for discussion and debate had there been space in our collective scientific conversation."<sup>212</sup> The scientific enterprise is an ongoing process of testing and verifying hypotheses based on empirical evidence; whether a set of propositions is "patently flawed" is not settled by robotic repetition of the transient tenets of an ideologically fashionable faith.<sup>213</sup>

The American public health response was unprecedented. Never have healthy populations been subjected to a comparable level of lockdowns, not even during the horrific 1918 Spanish Flu pandemic that killed 675,000 Americans.<sup>214</sup>

Isolation and various limitations on social interaction have had manifold social, economic, and health consequences. For example, there has been a dramatic increase in alcohol and substance abuse. In 2020 alone, according to public health experts, there were 91,799 drug overdose deaths: "Almost all states experienced increased rates of fatal drug overdose from 2019 to 2020, with 26 states experiencing increases upwards of 30%. West Virginia saw the largest relative increase in drug overdose deaths from 2019 to 2020 at 54%."<sup>215</sup>

Soon, Americans should see a return to normalcy. Dr. Fauci has said that he does not expect a return to tough lockdowns, but he has also emphasized that public officials must be flexible. Meanwhile, joined by the States of Louisiana and Missouri, Dr. Bhattacharya, Dr. Kulldorff, and Dr. Aaron Kheriaty have filed suit in federal court against President Biden, Dr. Fauci, Carol Crawford of the CDC, and other federal officials for colluding with major social media platforms to censor and suppress scientific dissent.<sup>216</sup>

### **Weakness No. 13: Veiling the Origin of COVID-19.**

In the early days of the pandemic, there were contradictory public assessments of its transmissibility and lethality, notably from the World Health Organization, which declared on January 14, 2020, that humans could not transmit the newly discovered coronavirus to other humans.<sup>217</sup> For its part, Communist China refused to cooperate in sharing accurate and reliable information. The consequences proved disastrous for the United States and other countries worldwide: It is estimated that 6.7 million people had died with the disease as of December 2022.<sup>218</sup>

It is believed that COVID-19 first emerged in China's Wuhan Province sometime late in 2019. In January 2020, China reported a death from the virus and locked down Wuhan Province. At the time, the reigning explanation for the origin of the coronavirus was that it originated from nature, presumably from an animal sold in a "wet market" in Wuhan Province. Communist Chinese officials continuously insisted on this "natural" explanation. The alternative theory—that it was a pathogen that either escaped or somehow leaked from the Wuhan Lab—was then largely dismissed as an unfounded or debunked "conspiracy theory" by America's leading public health officials as well as *The New York Times* and *The Washington Post*.<sup>219</sup>

Major American media seemed remarkably incurious. Doubtless contributing to the general media dismissal of the lab leak theory was the fact that it had been endorsed by former President Donald Trump. Writing in the *Bulletin of the Atomic Scientists*, Nicholas Wade, a prominent science writer, argued that:

Because President Trump said the virus had escaped from a Wuhan lab, editors gave the idea little credence. They joined the virologists in regarding lab escape as a dismissible conspiracy theory. During the Trump administration, they had no trouble in rejecting the position of the intelligence services that lab escape could not be ruled out. But when Avril Haines, President Biden's director of national intelligence, said the same thing, she too was largely ignored.<sup>220</sup>

The facts do not—and did not—justify any such dismissal. Communist China steadfastly refused to cooperate or share information with Western officials. Nonetheless, in April 2020, NIH Director Collins told NIAID Director Fauci that they should find some way to “put down this very destructive conspiracy.”<sup>221</sup> Collins further advised Fauci that “science and international harmony” could be damaged if the lab leak explanation gained currency.

Subsequently, a group of scientists attempted to debunk the lab leak theory in two prestigious medical journals, *The Lancet* and *Nature Medicine*.<sup>222</sup> In the case of *The Lancet*, the response was framed in the form of correspondence to the journal, not a peer-reviewed article. Note the sequence of events:

- Peter Daszak, president of the EcoHealth Alliance of New York, “organized and drafted” and signed the letter that appeared in the March 7, 2020, issue of *The Lancet*, declaring that he had no conflict of interest even though his organization had received substantial NIH funding for coronavirus research at the Wuhan Institute of Virology.<sup>223</sup>
- Dr. Kristian Anderson of the Scripps Research Institute and five virologists published a peer-reviewed paper in the March 17, 2020, issue of *Nature Medicine* in which they declared definitively that the novel coronavirus was not a “laboratory construct.”<sup>224</sup>
- Then, on March 26, 2020, Collins followed up these two publications with an NIH blog hammering home the same point: “Some folks are even making outrageous claims that the new coronavirus causing the pandemic was engineered in a lab and deliberately released to make people sick. A new study debunks such claims by providing scientific evidence that this novel coronavirus arose naturally.”<sup>225</sup>

Note that since January 2020, Communist China had forbade the sharing of *any* COVID-19 information without government approval. As Wade observes, based on the information then available, it was impossible for any of these scientists to know with any degree of certainty that the virus was not the product of a Chinese laboratory.<sup>226</sup>

Remarkably, other NIH-funded scientists told Fauci that in their view, the strange coronavirus had been “engineered.”<sup>227</sup> Specifically, in a February 2, 2020, email to Collins, Fauci, and NIH Principal Deputy Director Lawrence Tabak, prominent British scientist Dr. Jeremy Farrar of Wellcome Trust conveyed the initial skepticism of his colleagues as to whether the

novel coronavirus had developed *outside* of a lab. For example, microbiologist Robert Garry of Tulane Medical School, a coauthor of the *Nature Medicine* article, initially said that there was “no plausible” scenario that the virus had developed the way it did in nature.<sup>228</sup>

By 2021, rather than being dismissed as a baseless conspiracy theory or a product of former President Trump’s undisguised hostility to Red China’s dictatorship, the lab leak theory had become progressively respectable. In February 2021, the WHO organized a commission to visit the Wuhan Institute of Virology. Chinese Communist authorities restricted commission access, and the trip proved unproductive.

Meanwhile, President Biden ordered American intelligence agencies to collaborate and investigate that possibility and provide a report within 90 days. The final August 2021 report declared that the virus was not the product of a biological weapons program. It was, however, inconclusive as to whether the virus had a “natural” origin or was the result of a laboratory incident:

The IC [Intelligence Community] judges they will be unable to provide a more definitive explanation for the origin of COVID-19 unless new information allows them to determine the specific pathway for initial natural contact with an animal or to determine that a laboratory in Wuhan was handling SARS-CoV-2 or a close progenitor virus before COVID-19 emerged.<sup>229</sup>

Given the gravity of the issue, there was a curious absence of interdepartmental communication on the pandemic’s origins. While NIH officials were working to discount the validity of the lab leak theory, one or more State Department officials concluded long before Nicholas Wade that COVID-19 more than likely did indeed originate in the Wuhan Institute of Virology in China. According to a remarkable April 2020 State Department memo, “There is no direct, smoking gun evidence to prove that a leak from Wuhan labs caused the pandemic, but there is circumstantial evidence to suggest such is the case.”<sup>230</sup> The author(s) of the department’s five-page memo further claimed that:

- “The Wuhan labs remained the most likely yet least probed. All other possible places of [the] virus’s origin have been proven false.”
- The “first known patient who was diagnosed 12/01[ ]2019 was not related to the Wet Market.”

- “The most logical place to investigate the virus origin has been completely sealed off from outside inquiry by the CCP [Chinese Communist Party]. A gag order to both places was issued on 1/01/2020, and a Major General from the PLA [Peoples’ Liberation Army] took over the WIV [Wuhan Institute of Virology] since early Jan. Of the five possible theories, the WCDC and WIV are most likely yet least investigated. All other proposed theories are likely to be a decoy to prevent inquiry to WCDC and WIV.”
- “WIV has failed to convince the world of the whereabouts of its former employee Huang Yanlin, rumored to be Patient Zero. Huang worked at WIV but she is the only WIV employee who[se] bio, profile and picture have been deleted by WIV, fueling speculation of foul-play. WIV issued vigorous denial about Huang being infected claiming she has left WIV to another unnamed province to work and is currently healthy and fine. But Huang herself has never appeared in public and she has since ‘disappeared.’”<sup>231</sup>

Based on the preponderance of circumstantial evidence, Nicholas Wade (among others) has concluded that the virus had indeed originated in a lab, specifically the Wuhan lab, rather than nature and is a product of genetic engineering:

It’s documented that researchers at the Wuhan Institute of Virology were doing gain-of-function experiments designed to make coronaviruses infect human cells and humanized mice. This is exactly the kind of experiment from which a SARS2-like virus could have emerged. The researchers were not vaccinated against the viruses under study, and they were working in the minimal safety conditions of a BSL2 laboratory. So, escape of a virus would not be at all surprising. In all of China, the pandemic broke out on the doorstep of the Wuhan Institute. The virus was already well adapted to humans, as expected for a virus grown in humanized mice.<sup>232</sup>

The scientific debate over the pathogen’s origins continues.<sup>233</sup> A study published in the July 2022 issue of *Science*, a peer-reviewed journal, concluded that its “emergence likely resulted from multiple zoonotic events.”<sup>234</sup> A September 2021 critical review of COVID-19 origins also concluded that “the most parsimonious explanation for the origin of SARS-CoV-2 is a zoonotic event.”<sup>235</sup> Comparing the likelihood of zoonotic origins with that of a lab leak, the authors wrote:

We contend that although the animal reservoir for SARS-CoV-2 has not been identified and the key species may not have been tested, in contrast to other scenarios there is substantial body of scientific evidence supporting a zoonotic origin. Although the possibility of a laboratory accident cannot be entirely dismissed, and may be near impossible to falsify, this conduit for emergence is highly unlikely relative to the numerous and repeated human–animal contacts that occur routinely in the wildlife trade.<sup>236</sup>

**More recently, another team of scientists came to a very different conclusion. In an October 2022 preprint study, the authors concluded “that the SARS-CoV-2 is an anomaly, more likely a product of synthetic genome assembly than natural evolution.”<sup>237</sup> According to their analysis:**

To construct synthetic variants of natural coronaviruses in the lab, researchers often use a method called *in vitro* genome assembly. This method uses special enzymes called restriction enzymes to generate DNA building blocks that then can be “stitched” together in the correct order of the viral genome. To make a virus in the lab, researchers usually engineer the viral genome to add and remove stitching sites, called restriction sites. The ways researchers modify these sites can serve as fingerprints of *in vitro* genome assembly.

We found that SARS-CoV-2 has the restriction site fingerprint that is typical for synthetic viruses. The synthetic fingerprint of SARS-CoV-2 is anomalous in wild coronaviruses, and common in lab-assembled viruses. The type of mutations (synonymous or silent mutations) that differentiate the restriction sites in SARS-CoV-2 are characteristic of engineering, and the concentration of these silent mutations in the restriction sites is extremely unlikely to have arisen by random evolution. Both the restriction site fingerprint and the pattern of mutations generating them are extremely unlikely in wild coronaviruses and nearly universal in synthetic viruses. Our finding strongly suggest a synthetic origin of SARS-CoV-2.

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**In October 2022, the Minority Oversight Staff of the U.S. Senate Committee on Health Education, Labor and Pensions released a measured and impressively detailed report on the subject. The authors concluded that:**

While precedent of previous outbreaks of human infections from contact with animals favors the hypothesis that a natural zoonotic spillover is responsible for the origin of SARS-CoV-2, the emergence of SARS-CoV-2 that resulted in the pandemic was most likely the result of a research-related incident. This

conclusion is not intended to be dispositive.<sup>239</sup>

**The report, however, further observes that:**

If the Covid-19 pandemic is the result of the zoonotic spillover of SARS-CoV-2 in Wuhan from an intermediate host species, there should be evidence of SARS-CoV-2 circulating in animals before it spilled over into humans. Instead, there is no evidence that any animal was infected with SARS-CoV-2 prior to the first human cases.<sup>240</sup>

The scientific debate over COVID's origins is hardly settled. Efforts by senior Administration officials and federally funded research scientists to suppress and marginalize the lab leak theory did not advance science and did a great disservice to scientific inquiry and the advancement of public knowledge. Congress therefore must not let the matter drop. As President Biden has rightly declared, "We must have a full and transparent accounting of this global tragedy. Nothing less is acceptable."<sup>241</sup>

**Viral Gain of Function.** There is evidence that Chinese scientists were working to enhance the ability of certain viruses to replicate, improve their transmissibility, and make them more virulent. According to the State Department memo, the lead coronavirus scientist at the Wuhan Institute of Virology was Shi Zhengli, the "Bat Woman of China"<sup>242</sup> who "conducted genetic engineering of bat virus to make it easily transmissible to humans."<sup>243</sup> In addition:

On 1/31/2020, a group of Indian scientists published a bombshell article claiming the Wuhan virus was very likely genetically engineered in a lab. The only lab that capable of doing such [a] deed in all of China would be WIV. China immediately launched a fierce rebuttal forcing the Indian medical journal to withdraw the article from its website, but the Indians refused to say their analysis and conclusions are wrong. The abstract of the article is still on its website and the original article in its entirety has been reprinted by other research publications.<sup>244</sup>

The crucial question is: How, why, and to what degree did federal public health officials contribute to China's gain-of-function coronavirus lab research, regardless of whether SARS-CoV-2 originated there? In June 2014, the National Institute of Allergy and Infectious Diseases awarded a \$3.7 million grant to EcoHealth Alliance, a research firm headed by British virologist Peter Daszak,<sup>245</sup> so that EcoHealth Alliance could study bat coronaviruses

in China and lay the groundwork for “a sort of pandemic early-warning system.”<sup>246</sup> Daszak’s organization was also funding coronavirus research at the Wuhan Institute of Virology. From 2014 until 2017, there was a moratorium on such funding for gain-of-function research, but there was an exception to the ban if the NIH or NIAID deemed such funding “urgently necessary to protect the public health or national security.”<sup>247</sup>

The Wuhan Institute of Virology appeared to have conducted gain-of-function research between June 2018 and May 2019, and in an October 20, 2021, letter to Representative James Comer (R-KY), the NIH’s Dr. Lawrence Tabak acknowledged that EcoHealth Alliance was engaged in a “limited” coronavirus experiment to see whether the spike proteins from bat coronaviruses were “capable of binding to the human ACE2 receptor in a mouse model.” The experimental mice got “sicker” than other mice used in this project, but Tabak emphasized that genetic differences meant that the bat coronaviruses could not become SARS-CoV-2 and that the experimental work in question did not fit the definition of “research involving enhanced pathogens of pandemic potential (EPPP).”<sup>248</sup> Curiously, following Tabak’s letter to Representative Comer, NIH officials removed the definition of gain-of-function research, which they then defined as “a type of research that modifies a biological agent so that it confers new or enhanced activity to that agent.”<sup>249</sup>

Regardless of how or why the NIH defined (or redefined) gain-of-function research, however, certain facts are indisputable. It is a fact that Dr. Shi Zhengli worked to genetically engineer coronaviruses. It is a fact that Shi collaborated on NIH-approved research with Dr. Ralph Baric of the University of North Carolina, as well as other scientists, on the potential of bat coronaviruses to infect humans.<sup>250</sup> It is also a fact that she functioned as a subcontractor of EcoHealth Alliance, the firm funded by the NIAID grant.

In assessing the evidence that was available as of May 2021, Nicholas Wade, observed that:

Whether or not SARS2 is the product of that research, it seems a questionable policy to farm out high-risk research to unsafe foreign labs using minimal safety precautions. And if the SARS2 virus did indeed escape from the Wuhan Institute, then the NIH will find itself in the terrible position of having funded a disastrous experiment that led to the death of more than 3 million worldwide, including more than half a million of its own citizens.<sup>251</sup>

As noted previously, as of December 2022, the number of people who had died with COVID globally was approaching 6.7 million, including nearly 1.1 million in the U.S.



In sworn testimony on July 20, 2021, during a contentious Senate hearing, Dr. Anthony Fauci emphatically denied that the NIH had supported gain-of-function research in China.<sup>252</sup> In an August 2022 hearing—the first congressional inquiry of its kind—the Senate Homeland Security and Governmental Affairs Subcommittee on Emerging Threats and Spending Oversight focused its attention on the potential dangers of gain-of-function research. Dr. Steven Quay, CEO of Atossa Therapeutics and a key witness, declared that “[t]here is no dispositive evidence that the pandemic began as a spillover of a natural virus in a market. All evidence is consistent with a laboratory-acquired infection.”<sup>253</sup>

To the best of their ability, congressional investigators need to determine exactly *how* COVID-19 originated, whether it was genetically engineered through gain-of-function research, and to what degree American officials, inadvertently or not, contributed taxpayer funding for such research. In assessing the evidence, they will require the assistance of highly accomplished scientists who specialize in evolutionary virology. Moreover, they should not be satisfied by the Intelligence Community’s August 2021 assessment that the virus was not “developed as a biological weapon.”<sup>254</sup> Relying on the most recent intelligence, including the sworn testimony of well-vetted Chinese defectors or others who might have relevant knowledge, congressional investigators must also determine whether the coronavirus research was related in any way to any biological warfare program of the People’s Liberation Army.

## **An Oversight Agenda for Lawmakers: Getting the Answers to Key Questions**

One of Congress’s most vital roles is oversight of executive branch agencies. Carefully examining the federal government’s poor response to the pandemic should be high on the agenda of the 118th Congress. The purpose would not be merely to find out what went wrong but to formulate policies that will enable federal agencies to get things right during future crises.

Agencies are creatures of statute, and those statutes must provide at least some clarity and direction in times of crisis. During the pandemic, the CDC emerged as a troubled agency. But though the CDC is responsible for its failures, Congress is not blameless. For example, in multiple bills dating back to 2006, Congress directed the agency to implement a system to collect and disseminate public health data in real time. Congress knew for years that the CDC had not done any such thing. In examining the executive branch’s failures, Congress should not lose sight of its own culpability. More important, it should take care to minimize the risk of a future failure.

By no means an exhaustive list, Congress should focus on these crucial questions:

- **How should the federal government best coordinate responses to public health crises?** Congress has established several loci of authority during public health crises, including the HHS Office of Preparedness and Response, the CDC, FEMA, and various White House offices, including the National Security Council and the Domestic Policy Council. Lines of authority were confused, impairing the federal government's response. Congress should examine these failures in detail and consider stipulating in legislation which agency should coordinate these responses.
- **Why has the CDC failed to provide for the collection and dissemination of real-time public health data?** The CDC's failure to collect and disseminate data necessary for effective response is discussed at some length in this paper. Instead of holding the CDC directly accountable for its deficiencies in responding to the pandemic, in December 2022, Congress enacted and the President signed the Consolidated Appropriations Act, 2023, and provided the agency with a hefty infusion of new cash, allocating \$9.2 billion for FY 2023, amounting to an increase of 42 percent since 2019.<sup>255</sup> As noted previously, that includes \$175 million for public health data modernization. Given the importance of these efforts and the agency's chronic inertia, Congress should conduct aggressive oversight of the agency's handling of these additional resources to ensure that this time, the CDC is spending it efficiently and effectively.
- **How can the testing debacle that marred Washington's initial response to the pandemic be avoided in the future?** As discussed earlier, the federal government's blunders in making accurate and timely COVID-19 tests available contributed to the pathogen's silent spread during the pandemic's critical early weeks and months. Congress should closely examine what went wrong and consider enacting legislation directing the FDA, CDC, and CMS to establish procedures to ensure rapid development, production, and distribution of tests during future public health crises.
- **What is the proper role of the Strategic National Stockpile, and is it prepared for the next crisis?** As noted previously, front-line medical workers confronted a shortage of personal protective

equipment and other medical supplies during the time of greatest stress on the medical system. The government's failure to stockpile necessary supplies and subsequent supply-chain disruptions threatened clinicians and patients. Congress should conduct a detailed inquiry into these failures, assess the adequacy of the current stockpile, and set provide clear direction to federal agencies so that they can be better prepared for the next public health crisis.

- **What does science tell us about mask efficacy, and how did the CDC formulate its recommendations?** Between February and April 2020, federal officials reversed policy. Thereafter, the CDC recommended masking without firm scientific support for its efficacy. Previous scientific research was apparently ignored. Studies published in the CDC's *Morbidity and Mortality Weekly Reports* that support masking have proven to be both tendentious and flawed. While some have argued that the CDC's emphasis on scientific inquiry and peer review hampered its response to the pandemic, much of the scientific literature it produced in support of its recommendations did not attain the highest standards of scholarship. Congress should closely examine how the CDC came to publish studies with dubious findings that supported its public health recommendations and determine the extent to which the agency rushed these studies to print in response to political and bureaucratic pressure.
- **What was the scientific basis, particularly in peer-reviewed studies, for recommending mask mandates on school children?** Among the flawed studies published by the CDC were several that the CDC used to support its recommendation to mask schoolchildren. As noted, the CDC remains the only national or international public health agency that recommends masking two-year-old children. Congress should demand a detailed account of why the CDC published and promoted the results of these substandard studies and learn the extent to which political and bureaucratic pressures may have contributed to a rushed and inadequate peer review process.
- **How has federal policy, particularly on school closures and masking, affected children, and how can the CDC best avoid similar policy blunders in the future?** Although it was clear from the pandemic's earliest days that COVID-related hospitalizations and deaths were exceedingly rare among children, the CDC promoted

policies that caused children demonstrable harm. Academic research suggests that the extent of the cognitive, developmental, and social damage will extend years into the future. Assessing this harm should be a critical concern for lawmakers and could lead to more general reform of the CDC and the education system.

- **Why did the federal government impose vaccine mandates when the science did not establish that vaccines prevented infection and transmission of the disease?** Vaccine mandates were premised on the view that the government could require people to be immunized not to protect themselves against the disease but to protect others. President Biden, for example, said that the OSHA vaccine mandate was necessary to “protect the vaccinated” against infection from their unvaccinated coworkers.<sup>256</sup> Unvaccinated workers risked termination of employment unless they tested frequently and wore masks in the workplace. But the clinical trials on which the FDA relied to authorize the COVID-19 vaccines were not designed to determine whether they prevented transmission. In its December 2020 announcement of the emergency use authorization for the Pfizer mRNA vaccine, the FDA wrote that the trials had not adduced “evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person.”<sup>257</sup> The mandates thus rested on a false premise, as did the government’s refusal to distinguish between unvaccinated people who had never contracted the disease and those who had acquired natural immunity by recovering from it.
- **What are the risks and benefits of coronavirus vaccines relative to age and medical condition, and should the CDC modify its recommendations with respect to COVID vaccines?** Early development, production, distribution, and administration of COVID-19 vaccines during a national medical emergency were among the government’s most significant pandemic policy successes, but the value of those vaccines, like the risk of COVID-related mortality and severe morbidity, is highly dependent on age and medical condition. Even after it became apparent that the vaccines did not prevent the transmission of the disease, the CDC continued to require that children and young adults be vaccinated. Congress should require the CDC to explain how it derived its risk/benefit analysis for vaccination schedules and why it has not revised those recommendations despite changing science.

- **Why did the CDC take so long to acknowledge the value of natural immunity when the supporting science is so clear?** The value of natural immunity is well-established in science. Public health authorities in other developed countries acknowledged its importance early on. For example, Italy issued vaccine passports to people who had received shots and those who had recovered from COVID-19 over the previous six months. The CDC should explain why it was an outlier in not conceding the efficacy of natural immunity until nearly two years after the pandemic began. This is critical because it goes to the heart of the CDC's credibility, which is crucial during public health emergencies. If the CDC refused to acknowledge the value of natural immunity because it thought doing so would conflict with its promotion of vaccines, then public health officials deliberately misled Americans about their risk of contracting the disease.
- **Why should the CDC administer the Vaccine Adverse Event Reporting System (VAERS) when the FDA is responsible for monitoring adverse effects associated with every other drug and all medical devices?** In addition to determining whether drugs and devices are safe and effective, the FDA has lead responsibility for monitoring adverse events once a product enters the market. The agency's surveillance system is well-established, and clinicians are well acquainted with reporting procedures. Federal law, however, makes the CDC the lead agency in monitoring the safety and efficacy of vaccines. The VAERS system, based on self-reporting, has proven to be deeply inadequate throughout the pandemic, depriving doctors and patients alike of accurate, age-related information about the risks and benefits of vaccines. Congress should examine these failures in detail and consider shifting lead responsibility for assessing vaccine safety to the FDA. Congress must improve the nation's system of vaccine surveillance to ensure public safety.
- **What were the lockdowns' measurable effects on population health, including mental health? What were the social and economic impact of the federally recommended lockdowns? What were their positive effects?** The value of government-imposed nonpharmaceutical interventions, especially lockdowns, is a matter that requires further inquiry. Whether and to what extent they slowed the spread of disease is a matter that requires additional attention. In addition to gathering evidence on the public health benefits of lockdowns,

Congress should look into their economic, social, and psychological harms. Such a risk/benefit analysis will be essential for policymakers in deciding how best to respond to future public health crises.

- **How and why did federal agencies fail frontline clinicians, and what reforms are necessary to serve them more effectively during future crises?** During the early stages of the pandemic, the CDC recommended aggressive use of ventilators on patients who manifested respiratory symptoms linked to COVID-19. Its recommendation proved to be disastrous, but the agency was slow to adapt. In particular, it failed to convene physicians—something eminently feasible in an age when remote meetings have become commonplace—to share their clinical experiences with other clinicians. This was crucial during the early months of the pandemic when overburdened doctors and nurses sought more effective interventions for their severely ill patients. Congress should examine this failure in detail and consider legislation requiring the CDC or some other federal entity to establish a strategy for facilitating real-time communication with and between clinicians during public health emergencies.
- **Why did the federal government repeatedly garble its messaging?** CDC and other public health officials have sometimes acknowledged that their messaging has been inconsistent and confusing. This failure significantly diminished the credibility of public health officials to the detriment of the public. What remains unclear is why these repeated messaging failures occurred. Did officials make pronouncements without adequately establishing their scientific basis? Did political or bureaucratic pressures prompt mistaken declarations or prevent the agency from withdrawing or modifying erroneous guidance? Understanding the reasons for these failures is crucial to assuring that the federal public health bureaucracy is better prepared for future public health emergencies.
- **What can Congress do to prevent NIH and other federal officials from suppressing legitimate dissent, particularly in the scientific community?** It is important that federal officials protect the integrity of scientific research. Open and civil debate is essential to scientific inquiry, but NIH officials tried to discredit dissenting views among members of the scientific community who argued that the coronavirus likely emerged from a Chinese lab. They also tried to discredit prominent medical scientists who subscribed to a targeted

protection strategy for COVID-19—a conventional public health approach to dealing with contagious disease. Congress should determine whether and to what extent federal officials pressured private social media companies to censor scientific dissent.

The peer review process is essential to scientific inquiry. Professional journals insist on transparency in research and publish studies only after they have passed through a rigorous peer review process. There is abundant evidence, as discussed earlier, that this process was sometimes disregarded during the pandemic by those who attempted to ignore research that led to findings that deviated from the prevailing views of favored academics and government officials. These breaches of scientific integrity rise to the level of government concern when they influence public health policy. They are of particular concern in government-published peer-reviewed journals such as the CDC's *Morbidity and Mortality Weekly Reports*. Congress should look closely into the role of public officials in dismissing or attempting to suppress scientific dissent, especially when that dissent reflects findings published in peer-reviewed journals, and consider legislation to prohibit such inappropriate actions.

- **Did NIH officials inappropriately seek to suppress inconvenient hypotheses about the origins of COVID-19?** The origins of SARS-CoV-2 remain shrouded in uncertainty and (given the Chinese Communist Party's suppression of evidence) may well remain so. NIH officials especially sought to marginalize the hypothesis that the pathogen may have originated in a Wuhan laboratory. Congress should determine why certain government officials tried very hard to dismiss the possibility of a lab-engineered coronavirus during the early stages of a national medical emergency. If it finds evidence that these officials testified falsely under oath during congressional hearings, it should consider making criminal referrals to the Department of Justice. Only vigorous prosecution of unlawful behavior will deter it in the future.
- **What controls should Congress impose on NIH funding for biomedical research that poses a potentially grave danger to public health? Should government stop funding gain-of-function research overseas?** Whether or not SARS-CoV-2 escaped from a laboratory conducting gain-of-function research, the global

pandemic clearly indicates how dangerous that research is. To the extent that the NIH funds such research, Congress should undertake a rigorous risk/benefit analysis to determine whether continued funding is appropriate. It also should look carefully into the safety requirements on laboratories where such research is conducted and consider requiring such facilities to increase their security. Finally, it should consider whether the NIH or any other federal agency should fund such research either directly or indirectly through grantees or international agencies in overseas laboratories that are not subject to U.S. government oversight.

## Restoring Public Trust

America most likely has weathered the worst of COVID-19. On August 11, 2022, the CDC published revised guidance in its *Morbidity and Mortality Weekly Report* that appears to reflect that fact:

As SARS-Cov-2, the virus that causes COVID-19, continues to circulate globally, high levels of vaccine- and infection-induced immunity and the availability of effective treatments and prevention tools have substantially reduced the risk for medically significant COVID-19 illness (severe acute illness and post-COVID-19 conditions) and associated hospitalization and death. These circumstances now allow public health efforts to minimize the individual and societal health impacts of COVID-19 by focusing on sustainable measures to further reduce medically significant illness as well as to minimize strain on the health care system, while reducing barriers to social, educational and economic activity.<sup>258</sup>

Greta Massetti, the lead author of the CDC report, said that an estimated 95 percent of the American population has acquired antibodies from vaccination or previous infection.<sup>259</sup>

It is time for a comprehensive assessment. Under the U.S. Constitution, public health is primarily a state responsibility, and states retain broad police powers to protect their citizens. Nonetheless, the federal government has crucial national responsibilities in providing the best scientific information and the best guidance, strong border protection and any necessary travel restrictions, and the financial and material support necessary to contain a pandemic. Some states succeeded, and others failed to strike a prudent balance by taking into consideration the pressing needs of public health, the social and economic life of their citizens, and the need to protect their lives and the livelihoods.



For federal lawmakers, the range of inquiry is unavoidably broad. Following two internal reviews, Dr. Walensky conceded that the CDC had failed to respond adequately to the pandemic and acknowledged the need for more rapid release of scientific information, greater clarity in public communication, and more effective cooperation with other federal agencies and state public health authorities. But the CDC should not be left to “heal” itself.

After three years of hard experience with COVID-19, federal lawmakers must also adopt a broad agenda of public health reform and plan and prepare for the next national health emergency. To accomplish that task, they must pursue aggressive and vigorous oversight, securing detailed information as to how and why federal officials acted as they did in responding to the greatest public health emergency since the 1918 flu. As Cato Institute scholars Charles Silver and David Hyman have written:

Even though the federal government has dealt with epidemics and pandemics for more than a century, it was not ready for COVID-19. The first lesson the pandemic teaches is that when the federal government mishandles a core responsibility, it should not be saddled with additional administrative burdens. Instead, reform should focus on improving the performance of the federal agencies that were responsible for the country’s fragmented and ineffective response to COVID-19.<sup>260</sup>

The record is mixed. The federal government succeeded in several crucial areas, such as the unprecedented production and distribution of an emergency vaccine during a national health emergency, the rapid mobilization of private-sector companies to provide medical equipment and supplies, and the relaxation of federal rules and regulations to give health care professionals the flexibility to respond quickly to the pandemic. But federal agencies also failed the people and their states on several fronts by:

- Failing to establish and maintain an experienced and well-staffed “center of command,” with clear authority and reporting directly to the President, to coordinate the federal government’s response;
- Failing to improve and modernize the CDC’s data collection and dissemination;
- Failing to develop and deploy diagnostic testing expeditiously for surveillance and defense against COVID;

- Failing to approve and quickly deploy rapid at-home testing;
- Failing to maintain and upgrade the Strategic National Stockpile of vital medical equipment and supplies;
- Failing to provide the public health authorities and the public with clear and consistent messaging on key measures to combat the coronavirus; and
- Failing to create a forum for continuous professional communication and a clearinghouse to track the progress of the disease (including its deadly autoimmune reaction) and share information on the best clinical practices for frontline physicians and nurses.

Certain high-ranking federal officials have routinely requested other Americans to respect their judgments, but too often they have failed to respect scientific disagreement even if expressed or reflected in peer-reviewed scientific journals. They have done so without any obvious or compelling scientific justification. Worse, certain federal officials have attempted to discredit or suppress scientific dissent and have been less than forthcoming about what they have known or should have known about the safety and efficacy of vaccines and the still mysterious origins of COVID-19 and the Chinese gain-of-function research that facilitated the lethal transmissibility of the virus.

The American people have paid a steep price—and none more so than America’s children. As Michael Brendan Dougherty has aptly summarized in *National Review*:

Scores of millions of parents figured out that their children weren’t at serious risk and by the summer of 2020 could read credible science showing their kids at school did not pose serious risks to others. These millions of people have reasons privately to feel vindicated. But they deserve to have someone in public life affirm the fact that they weren’t crazy, that in fact public health did mislead them, shaded the truth, and occasionally abused the trust placed in them.<sup>261</sup>

Congress has a duty to reform government agencies and hold them accountable with a view to restoring public trust in America’s public health agencies.

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