

INCAPACITATED

How a Lack of State Capacity Doomed the U.S. Pandemic Response

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Indroduction

he COVID-19 pandemic is not over. During August 2022 – more than 18 months since the first U.S. case was reported on Jan. 20, 2020 – nearly 500 Americans died every day from the disease, while the number of people hospitalized on a given day exceeded 30,000. Worldwide, the confirmed daily death count remained in the thousands.

Despite these grim statistics, it is fair to say that – barring the emergence of some new and deadly variant – the crisis stage of the pandemic has passed. Here in the United States, most restrictions relating to closings, mask wearing, and social distancing have been lifted, and the emergency fiscal responses have played out. Globally, the situation is similar – although China, an outlier, continues to persevere with its "zero COVID" policy of rolling lockdowns. Here and in most places, however, we have transitioned from an extraordinary public health emergency to a grim "new normal" in which a viral killer considerably more lethal than the flu has now been added to life's ongoing risks.

Looking back at the U.S. pandemic response across two administrations and three Congresses, we see a record of crisis management that includes some significant accomplishments and breathtaking successes – and a long, dismal string of missteps and failures. In this essay, I try to identify the fundamental flaws in American state capacity that led to those missteps and failures – and that could lead to much greater death and suffering in future pandemics if we fail to learn from our mistakes.

Let's start with the good news. At the top of the list is the development and mass production of effective vaccines in well under a year – a feat that most experts at the outset of the pandemic would have considered impossible. U.S. companies Pfizer and Moderna were at the forefront of that effort with their pathbreaking mRNA vaccines, and the U.S. government's Operation Warp Speed played a vital role in accelerating drug testing and approval and coordinating the supply chains upon which the rapid scale-up of production depended. It's been estimated that <u>vaccines saved over 1 million American lives</u> during 2021 alone. Globally, the estimated number of lives saved by vaccines during their first year stands at <u>20 million</u>.

Meanwhile, notwithstanding all the different ways public health authorities botched things, they did succeed in leading the country through a mass mobilization whose intensity and duration have no counterpart in the American experience outside of wartime. This time, instead of being mobilized to produce war materiel and fight battles, Americans were mobilized to avoid infecting each other – through staying at home when they could and, when they did go out, through masking and keeping their distance from others. Although this all-of-society effort was badly misdirected at times, and over time was considerably weakened by growing resistance, backlash, and simple exhaustion, nonetheless it stands as one of the most astonishing feats of concerted mass behavior modification in history. The effort was greatly aided by the advanced digitization of economic life, which allowed many people to work from home, schooling (albeit in diminished form) to continue on a remote basis, and online delivery services to substitute for in-person shopping and dining. Since studies now confirm that masking and social distancing were effective in reducing infection rates – by approximately 50 percent and 25 percent, respectively – this mobilization campaign, for all its flaws and excesses and loopholes, saved large numbers of lives by preventing

health care systems from being overrun and keeping people safe until vaccines and better treatments were developed.

Finally, in the face of the massive economic shock caused primarily by fear of the virus and then exacerbated by public health restrictions, Congress overcame a toxically polarized political climate to shovel out trillions of dollars in emergency relief spending. Again, there is much to criticize in the details of those spending packages and in how the emergency programs were implemented; in particular, the inflation we are now experiencing was doubtless made worse by all that largesse. Yet when we look at how well household incomes held up during the crisis, and at how rapidly employment has bounced back, the fairest conclusion is that Congress' fiscal activism prevented a terrible situation from getting much, much, much worse.

Having acknowledged the silver linings, it's time to face the black cloud: The overall U.S. pandemic response must be judged a shocking and dispiriting failure. In May 2022, 16 months into the pandemic, the U.S. confirmed death toll passed 1 million, and six-figure annual death tolls now look likely going forward for the foreseeable future. The U.S. cumulative COVID mortality rate as of Aug. 31, 2022 – 310 deaths per 100,000 people – was the highest of any advanced democracy. By way of comparison, the cumulative mortality rate in the United Kingdom was 305 per 100,000; in Italy, 296; in France, 229; in Sweden, 189; in Germany, 177; in Norway, 74; and in Japan, 32.

Anatomy of a megadeath

Many millions of words have already been written about America's fumbling response to the pandemic. I've read lots of them. And I've <u>interviewed</u> a number of experts for in-depth discussions of various aspects of the story. No doubt more details will come to light over time as official inquires are conducted and definitive histories are written, but the broad outlines of what went wrong – and what occasionally went right – are now abundantly clear.

There are two major reasons why COVID-19 was so much deadlier in the United States than in most peer countries. First, from before the first confirmed U.S. infection until it was too late to matter (i.e., until the emergence of the highly transmissible omicron variant), American authorities proved incapable of standing up and executing testing at sufficient scale – that is, to enable effective public health screening along with follow-up contact tracing and coordination and support for isolation of the sick and exposed. Accordingly, it was never possible to identify and locate outbreaks early enough to drive down transmission rates and suppress the virus. As a result, until vaccines became available, authorities were forced to rely on the blunderbuss tool of indiscriminate closings and social distancing mandates to keep infections and deaths down. The failures with testing, tracing, and supported isolation account for the vast majority of the nearly 350,000 confirmed deaths in 2020.¹ By comparison, well-managed countries kept fatalities in check during the pre-vaccine, pre-variant phase of the pandemic. Australia and South Korea saw just over 900 confirmed deaths; Japan, fewer than 3,500. Taiwan registered only seven confirmed COVID deaths that year.

^{1.} See my interview with Glen Wey/ for an in-depth discussion of these failures and their consequences.

The second reason is that, despite developing the two most effective vaccines and getting a big jump on most of the world in vaccine distribution, the United States ended up achieving considerably lower vaccination rates than other advanced countries. As of Aug. 31, 2022, <u>68 percent of the U.S. population</u> was fully vaccinated, compared to 75 percent in the United Kingdom, 76 percent in Germany, 79 percent in France, 82 percent in Japan, and 84 percent in Australia. The United States has also lagged badly in booster shots, important for controlling the severity of illness for the more transmissible delta and omicron variants. In the U.S. as of Aug. 24, 2022, <u>39 booster</u>

doses have been administered per 100 people, compared to 55 in Australia, 60 in the United Kingdom, 63 in France, 70 in Germany, and 85 in Japan.

How do we apportion blame for these signal failures? I nominate three leading candidates: (1) failures of political leadership; (2) lack of relevant state capacity; and (3) problems in the underlying political culture, and culture more broadly, that make state capacity hard to amass and wield. All three bear some measure of responsibility, but the purpose of this essay is to make the case for the importance of (2). As I will discuss, the lack of relevant state capacity – that is, the absence of appropriate governing structures, organization, capabilities, and focus – played a critical role in undermining the U.S. pandemic response, and the task of building up that missing capacity should be our top priority in seeking to prevent a similar catastrophe in the future.

The absence of appropriate governing structures, organization, capabilities, and focus played a critical role in undermining the U.S. pandemic response. Building up that missing state capacity should be a top priority.

But first, let's look at the other candidates. As to political leadership, the obvious question arises: Was this all Trump's fault? To be sure, it was singularly unfortunate that the gravest public health crisis in a century occurred during the presidency of the most spectacularly unfit individual to ever hold the office. By May 2020, he had essentially abdicated any federal role in testing, tracing, and isolation, and then spoke out repeatedly against widespread testing because it made the COVID case numbers look bad. He refused to wear masks, encouraged backlash against public health restrictions, and peddled quack cures. It's hard to even imagine a more irresponsible leader.

Despite all this, it's by no means clear that things would have gone much better had Hillary Clinton been president instead. The Centers for Disease Control and Prevention's disastrous misfires on testing would likely have occurred all the same, and the political polarization that sowed the seeds of resistance and backlash against restrictions preceded the 2016 election and most assuredly would not have been pacified by a Clinton victory. And in spite of all Trump's personal clownishness, his administration did conceive and execute Operation Warp Speed. We have no reason to assume, and some reason to doubt, that a Clinton administration would have done as good a job on vaccine development.²

Meanwhile, the return to normalcy under Joe Biden hasn't sufficed to turns things around. As I'll discuss later, the Biden administration's record on all things pandemic-related has been, to put it

^{2.} My interview with Alex Tabarrok addresses this point. See the discussion beginning at approximately 41:45.

kindly, less than stellar. In short, the problems that led to America's failed pandemic response go deeper than Trump: They preceded him and have persisted after his departure.

America's highly polarized political culture, meanwhile, clearly played a role in driving up fatalities during the pandemic. Organized backlash against public health mandates and restrictions doubtless reduced compliance and thereby increased chances for the virus to spread. For a variety of reasons, though, it is difficult to connect variation in compliance with nonpharmaceutical interventions (NPIs) with variations in infections, hospitalizations, and deaths. With vaccinations, meanwhile, impacts are easier to trace – and the variation in vaccination rates on either side of the partisan divide is stark. According to a <u>July 2022 survey</u>, 83 percent of Democrats reported that they were already vaccinated, compared to 63 percent of Republicans. Out of the 17 percent of Democrats not yet vaccinated, just over half said they were unwilling to get the shots; meanwhile, of the 38 percent of unvaccinated Republicans, more than three-quarters said they were unwilling to get vaccinated. The effect of the relatively low U.S. vaccination rate on fatalities has been significant: A study by the Brown University School of Public Health estimates that <u>over 300,000</u> of the million-plus U.S. COVID deaths could have been avoided with vaccinations.

Yet if the U.S. pandemic response had been run according to global best practices from the outset, there would have been much more limited scope for political polarization to drive events. With appropriate testing and tracing programs in place, the initial outbreaks of the virus could have been isolated and suppressed, and there would have been no need for mass restrictions of indefinite duration – and no backlash against them. By the time vaccines were available, the contrast between a largely disease-free United States and large-scale suffering elsewhere in the world would likely have bolstered trust in public health authorities and reduced resistance to vaccination.

My conclusion, then, is that governance failures – the inability of American public health authorities to do the job that they were widely considered to be the best in the world at doing – are the primary reason for the country's poor record in dealing with the pandemic. The overwhelming majority of the nearly 350,000 fatalities during 2020 (i.e., before vaccines) could have been avoided, and that accomplishment could have saved many of the 300,000-plus avoidable deaths caused by vaccine resistance.

A failure of imagination

The specific nature of the breakdown in state capacity at fault is made clear by the battle lines of polarization over the pandemic. The country split, with increasing bitterness and rancor, over mandates and restrictions. In the early days, the poles of the split were reversed: People on the right talked up strict limits on international travel, while people on the left minimized the threat and denounced travel restrictions as veiled racism. Relatively quickly, though, the opposing sides switched places and then dug in. On the right, the severity of the virus was minimized, and closures, social distancing requirements, and mask mandates were denounced as tyrannical overkill. The left, meanwhile, took the virus seriously, and taking it seriously meant embracing restrictions and maintaining them indefinitely. Even after vaccines were developed, both sides stuck to their positions: People on the right tended to discount the vaccine's safety and efficacy, while people on the

left tended to minimize the relevance of vaccine availability to the case for maintaining restrictions.³

In other words, Americans split over whether to simply surrender to the virus and let it run rampant or to hide from it indefinitely. What never emerged as a widely embraced option in the prevaccine phase of the pandemic, because our public health authorities were never able to provide it, was a third alternative: not to surrender, not to hide forever, but to defeat the virus. The critical absence of state capacity on display during the pandemic was the inability to develop, manage, and communicate a strategy for victory: to use testing, tracing, and isolation to suppress the virus altogether; pending successful suppression, to develop and deploy protective technologies (high-quality masks, improved ventilation and air filtration, <u>far-ultraviolet light</u>) to allow people to function safely in public; and to expedite the development of effective vaccines and treatments so that we could ultimately return to the status quo ante virus. The third component of that strategy was partially implemented, with tens of millions of lives saved around the world as a result. The other two elements, however, never got off the ground.

The failure to formulate and execute a strategy for victory was, at bottom, a failure of imagination: a failure to shake off a *compliance mindset* wedded to following established procedures and adopt instead a *war-fighting mindset* dedicated to achieving desired results. All government agencies rely on established procedures: Lacking the clear market feedback that private businesses receive on a daily basis, the public sector is forced to lean heavily on fidelity to process in ensuring accountability by officials. Hence the notorious vulnerability that gives bureaucracy its bad name: a pronounced tendency to prioritize looking backward at the rulebook over looking forward toward advancing the agency's mission.

But in a crisis – an acute threat to public safety or order – the feedback problem dissipates and both the objective of government action and the metrics for judging its efficacy become gravely clear. The essential question at such junctures is whether the government can recognize the change in circumstances and adapt accordingly. We see this most clearly in military affairs and the stark differences between a peacetime army and a successful wartime army. In peacetime, leaders frequently rise on the basis of skill at playing various political games: ingratiating themselves with superiors, amassing larger budgets, etc. But when war comes, the army risks annihilation unless it can devise a winning strategy and find leaders who can execute that strategy.

The outbreak of an infectious disease is akin to the outbreak of a war: It is an invasion by a deadly foreign adversary that threatens life and public order on a mass scale. Yet the decline – until recently! – of infectious disease as a major threat to the general population in rich countries had lulled public health authorities into complacency. The development of antibiotics and vaccines once promised to end the age-old scourge of infectious disease – a promise upheld most spectacularly with the global eradication of smallpox by 1980. And as communicable disease receded as a clear and present danger, public health authorities steadily shifted their focus to chronic health problems – cancer, heart disease, obesity, drug abuse, and the like.

^{3.} Although the greater harms created by this polarization were caused by those who resisted restrictions, it must be pointed out that over-reliance on restrictions caused significant harms as well. This was especially true in the case of school closings. It became apparent early on that COVID-19 posed a much smaller risk to minors, especially young children; accordingly, with appropriate testing, distancing, and isolation protocols, schools could operate safely with in-person instruction. In many places, however, an overabundance of caution kept children out of schools for far too long.

Since the victory over smallpox, however, our ancient adversary has been staging a comeback – thanks to the rise of antibiotic resistance, the ongoing human encroachment onto habitats of disease-carrying wildlife, the spread of factory farming and livestock as disease vectors, and the intensification of domestic and global travel. First came HIV/AIDS, but outside Africa its con-

centration among gay men tragically muted its warning signal. The 21st century has seen outbreaks of bird flu, swine flu, SARS, MERS, Zika, and Ebola, but none made sufficient inroads in rich-country populations to significantly alter perceptions of the threat level. Our luck ran out in late 2019, precisely a century after the end of our last global pandemic.

In Taiwan, a bad experience with SARS helped to banish complacency, and the poor handling of MERS in South Korea had a similar effect there. But in the United States, none of the nearmisses earlier this century sufficed to impress on public health authorities or political leaders that the country was not adequately prepared for a direct hit. And when that direct hit came, it proved impossible for the now deeply entrenched organizational cultures in the public health system to turn on a dime and switch to "war mode."

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Peacetime agencies, wartime challenges

The CDC entered the pandemic with the reputation as the world's leading disease-fighting agency. And in many respects the reputation was deserved: It houses world-class expertise and conducts vitally important research. But whatever the CDC had been in the past (it originated from a World War II military program to control malaria in the southern United States, and it spearheaded hugely successful smallpox eradication efforts in Africa and later globally), it was no longer oriented toward directing action in the field, much less large-scale crisis management. The CDC was a peacetime agency, focused on conducting academic research rather than preparing for invasion. As former Food and Drug Administration commissioner Scott Gottlieb commented, "CDC is a retrospective agency, it's not in the business of gathering real-time info that requires analytical work and providing partial answers."

The CDC notoriously produced a test kit that didn't work, but its whole approach to testing was fatally flawed. There was never any chance of standing up adequate testing capability without the participation of the big private labs; only they were capable of producing and administering tests at sufficient scale. The CDC, however, had no history of working with private labs; it preferred to work alone, or in conjunction with the small network of public labs. During the Zika scare of 2015-16, it became painfully apparent that this approach was insufficient to handle a U.S. outbreak. The CDC fell behind in supplying tests, then developed a new test that didn't work as well as the

^{4.} As Michael Lewis details in his book on the pandemic, the swine flu episode back in 1976 marked a key moment in the CDC's evolution. Faced with the emergence of a potent influenza strain and the threat of a major outbreak in the United States, the CDC launched what was planned to be a massive vaccination drive. But the vaccine produced side effects, the major outbreak never materialized, and the vaccination effort fizzled out as an embarrassing failure. In 1977, the incoming Carter administration fired the CDC director, a career civil servant, and a few years later the Reagan administration made the position of CDC director a political appointee. See Michael Lewis, The Premonition: A Pandemic Story (New York: W.W. Norton & Company, 2021), pp. 281-294.

old one, and then failed to supply a test to commercial labs to ramp up supply.⁵ As a result, there was never adequate testing to track progress of the disease – and Zika, a mosquito-borne illness, spreads far more slowly than the airborne novel coronavirus. Yet despite widespread criticism of the CDC's handling of Zika, nothing changed. The CDC jealously guarded its institutional control over testing rather than adapting in the face of failure.

Beyond its problems with testing, which made it impossible to develop actionable intelligence about the location of the enemy, the CDC also proved incapable of assimilating incoming intelligence about the nature of the virus and applying it successfully to response efforts. Its backward-looking, academic culture, focused on generating publishable research results, was inimical to the kind of intellectual nimbleness and flexibility needed to operate in the fog of war. The most spectacular failure in this regard was the CDC's dogged refusal to recognize that the virus spread through aerosolized airborne transmission as well as through small saliva droplets. From very early on in the pandemic, the pattern of infection in superspreader events – for example, aboard the <u>Diamond Princess</u> cruise ship and at a <u>choir practice</u> in Washington state – suggested strongly that airborne transmission was likely. But it wasn't until <u>October 2020</u>, many months into the crisis, that the CDC made a grudging admission that airborne transmission was possible while still discounting its importance; only in <u>May 2021</u> did the CDC finally issue guidance that properly acknowledged the threat of airborne transmission.

A whole domino effect of missteps ensued from this intelligence failure. The overemphasis on saliva droplets led to a misplaced fear of surface transmission – and enormous amounts of wasted effort on "hygiene theater." Parks were closed and outdoor activities restricted, when spending time outside was the safest thing you could do. In indoor spaces, maintaining 6 feet of distance between people became holy writ while pressing issues of ventilation and air filtration were badly underemphasized.

Another major intelligence blunder, involving not just the CDC but other elements of the national and global public health establishment as well, concerned the use of face masks. Early on, public health authorities discouraged the use of masks by the general public – in part because of a misreading of evidence concerning their utility, in part as an underhanded effort to reserve dwindling supplies for health care workers. This flip-flopping at the outset of the crisis gave clear evidence that the experts in charge weren't just fallible, they were untrustworthy – helping to set the stage for resistance and backlash to come.

The other federal agency with a leading role in managing the pandemic was the Food and Drug Administration, which is in charge of approving new diagnostics, vaccines, and treatments. Like the CDC, the FDA came to the pandemic with a deeply entrenched institutional culture that was inimical to effective crisis management. Dating all the way back to the <u>thalidomide disaster</u> of the late 1950s, the FDA has prioritized keeping unsafe drugs off the market over expediting the approval of new safe and effective drugs. The politics of this asymmetry are understandable: A drug approval that backfired would create known victims, causing a public firestorm and grievously compromising the FDA's reputation, while the identities of the people who might die

^{5.} See my interview with Scott Gottlieb (starting around 9:30); see also Scott Gottlieb, Uncontrolled Spread: Why COVID-19 Crushed Us and How We Can Defeat the Next Pandemic (New York: Harper, 2021), pp. 93-106.

as a result of delays in the approval of a new drug would generally never be known. The economist Alex Tabarrok refers to these hidden victims of delay as the FDA's "invisible graveyard." But in an outbreak of communicable disease, the victims are visible – and they pile up rapidly.

Yet the FDA carried its "peacetime" institutional caution into the pandemic. Early on, it contributed to the testing debacle by improperly asserting jurisdiction over the approval of lab-developed tests before backing off. To be fair, participation in Operation Warp Speed did rouse the agency from its usual torpor, at least temporarily, as the FDA showed unaccustomed flexibility in expediting clinical trials for the new vaccines. But old habits quickly reasserted themselves. After Pfizer submitted its Emergency Use Authorization for its mRNA vaccine on

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Nov. 20, 2020, the FDA waited until Dec. 10 to schedule a meeting to consider the application (during which time it basically closed for four days during the Thanksgiving holiday); nearly 40,000 Americans died during this interim. The FDA never approved the AstraZeneca vaccine despite its successful use around the world; also, it (along with the CDC) imposed a misguided temporary pause on use of the Johnson & Johnson vaccine, dealing a serious blow to public confidence in the drug. And it dragged its feet on approval of at-home COVID test kits, which were readily available in Europe months before here.

As my colleague <u>Matthew Yglesias</u> noted on his "Slow Boring" blog, public health authorities asked and expected the American public to show incredible flexibility, upending their lives for the common good – working from home, masking and distancing, supervising kids' remote education, missing weddings and funerals. Yet what they asked of us, they proved unable to do themselves. Faced with an unprecedented crisis in which rapid action on the basis of incomplete information was the only path to victory, again and again they chose to stick with established rules and procedures over the adaptation and improvisation that were called for. "We've changed a lot to cope with the pandemic," Yglesias wrote, "but the institutions charged with protecting us have stayed rigid."

That rigidity has proved depressingly durable. As revealed by the recent course of the global monkeypox outbreak, the nation's public health authorities remain stuck in bureaucratized amber. The first U.S. monkeypox infection was confirmed on May 19, 2022; by Aug. 22, the U.S. had over 15,000 confirmed cases, out of a world total of just under 43,000. The virus was able to spread so rapidly because, once again, we failed to do adequate testing and contact tracing. The CDC reprised its role as bottleneck, insisting at the beginning that all tests be run through its network of public labs and also be sent to the agency for confirmation. Furthermore, doctors were required to get state health department authorization for every test, slowing things down further. The CDC did not expand testing to include commercial labs until late June. By the end of June, only around 2,000 tests had been completed.

Fortunately, this time we already have vaccines and treatments, created for the similar but far deadlier smallpox virus. But although we have known for years that the disease was endemic in Africa and could jump to our shores on the next plane flight, we allowed our stockpile of the new,

state-of-the-art vaccine to dwindle to 2,400 doses (enough to vaccinate 1,200 people). Millions of doses were warehoused in unmixed, freeze-dried form in the Netherlands, and another 1.4 million doses were filled and ready for shipment. After the first U.S. case, the Biden administration ordered 372,000 vaccine doses to be shipped to the United States. The other million-plus doses couldn't be shipped yet, because the FDA had not gotten around to inspecting the drug maker's new "fill-finish" facility. That inspection did not occur until the end of June – more than a month after the first case – and thus vaccine distribution fell badly behind demand. (When asked about the delays in getting doses to the U.S., one government spokesperson said the delays were less severe if counted in "business days.") The administration has ordered millions of more doses to be made from the bulk supply, but that will take months.

Inadequate testing, CDC control-freakery, leisurely FDA approval schedules – sound familiar? And the déjà vu moments keep coming. Messaging to the public has been a mess. Although monkeypox cases outside Africa have been heavily concentrated among gay men, the CDC and other health authorities have buried that fact in their public pronouncements for fear of creating stigma. Meanwhile, improvisations that could make the best of a bad situation have been officially discouraged rather than promoted. Despite strong evidence that a single dose of monkeypox vaccine confers good protection, the CDC and FDA have warned against adopting a "first doses first" vaccination strategy to stretch limited supplies of the drug. Fortunately, the New York City health department has ignored the federal warnings and proceeded to maximize the availability of first doses.

One glimmer of hopeful news: On Aug. 17, 2022, CDC Director Rochelle Walensky announced plans to reorganize the agency after publicly admitting to major failures during the pandemic. "To be frank, we are responsible for some pretty dramatic, pretty public mistakes, from testing to data to communications," Walensky said. Her reform plans focus on shifting the CDC's focus away from academic research and toward more rapidly sharing data and translating research into practically useful intelligence and guidance.

Although the overall outlines of the reorganization initiative look sound, there are limits to what purely internal reforms can accomplish. As Walensky has noted, some of her plans will <u>depend on congressional action</u>, including requiring state and local authorities to share data with the CDC and providing additional funding. Beyond that, it is doubtful that the deep cultural change that is needed can be accomplished without a more thoroughgoing shake-up of the agency and resetting of its priorities by Congress.

The path partially taken

The one area where the U.S. pandemic response not only met but exceeded expectations was in vaccine development – thanks in particular to the Trump administration's Operation Warp Speed initiative. OWS, a partnership between the Department of Health and Human Services and the Department of Defense, sought to accelerate the development and distribution of vaccines through a variety of mechanisms. It selected six vaccine candidates on three different "platforms" (i.e., different types of vaccines); this diversified portfolio maximized chances for finding a winner early. It entered advance purchase contracts with the drug makers, agreeing to purchase large volumes at attractive prices if a firm came through with an approved drug. It provided billions in

financial support to expedite vaccine development, clinical trials, and ramp-up of manufacturing capacity (Pfizer did not accept funds under OWS, but its partner BioNTech received hundreds of millions of dollars of support from the German government). It allowed companies to run different phases of clinical trials concurrently to accelerate the approval process. It worked with participants to expand manufacturing capacity even before approval so distribution could begin as soon as possible. And it worked with producers and suppliers to identify and resolve supply chain problems so that competing firms did not work at cross-purposes in ramping up production.

The result was a spectacular and historic success – one that deserves to be mentioned in the same breath with the Manhattan Project, the Berlin airlift, and Project Apollo. It was a return to glory of what Alex Tabarrok calls the "American model" of innovation: "getting the visible hand and the invisible hand to work together" by "combining the spending power of the federal government with the innovativeness and the speed of America's incredibly sophisticated private companies."

Operation Warp Speed succeeded because it shifted innovation policy from "peacetime" to "wartime" mode. Under normal, "peacetime" conditions, the government has a general interest in encouraging innovation but is unable to predict where the most promising avenues for commercially viable technological progress might lie. Accordingly, rather than trying to aim private efforts at particular projects, the government offers a general incentive in the form of patents: If you come up with something new, nonobvious, and useful, and you find a market for it, you can enjoy temporary market exclusivity to ensure you recoup your investment and earn a healthy return. But under the "wartime" conditions of the pandemic, the situation is very different. The government now knows exactly what kind of technological progress is urgently needed: diagnostics, vaccines, and treatments for a particular pathogen. In these situations, upfront R&D support and advance purchase agreements that guarantee a healthy return for development of the desired product offer the focused, targeted incentives that are necessary. There is no need to defer to private companies to figure out which innovations can be commercialized, because here the government is the purchaser and can tell the companies what it wants. And the government needs to be the relevant purchaser because we don't want access to vaccines to be contingent upon ability to pay.

Operation Warp Speed's one tragic flaw was that its model was not applied much more widely. Most obviously, after the initial stumble on testing, an OWS for test kits – not only the more sensitive PCR tests, but also the cheaper, faster antigen tests – could have blanketed the country in ubiquitous testing capacity. Even after the pandemic was in full swing, it would have been possible to set up testing and isolation protocols to allow essential businesses and activities to continue operating safely. The NFL did it, completing a full season of a contact sport without resort to a self-isolated "bubble"; a number of universities used regular testing to stay open. With ubiquitous, cheap tests available, these outlier success stories could have been the norm.

The OWS model could also have been extended to encompass personal protective equipment. Here again, we could have had massive quantities of face masks – not just surgical masks, but N95 masks that afford much better protection. We could have gone further and developed next-generation PPE: masks or headgear that are easy to wear, comfortable for longer use, and safe.

^{6.} Interview with Alex Tabarrok, starting around 41:05.

Even with vaccines, Operation Warp Speed remained partially stuck in "peacetime" mode. After being incentivized appropriately with advance purchase agreements and government research support, drug makers were also allowed to retain patent rights. In the case of Moderna, the National Institutes of Health actually held patents on key elements of the vaccine; for the other firms, the government could have bought out their patent rights or asserted licensing authority under laws ("march-in rights" under the Bayh-Dole Act, or Section 1498) that allow the government to use intellectual property with just compensation. In this way the government could have dramatically accelerated global vaccine distribution by directing one or more OWS participants to share technology and manufacturing know-how with capable producers in less-developed countries.

The only chance to truly suppress this virus and keep it from becoming endemic was to achieve high rates of highly effective vaccination around the world. As of late August 2022, the global vaccination rate stands at only <u>63 percent</u>; in the <u>world's poorest countries</u>, less than 20 percent

of people have been fully vaccinated. And the vaccines are no longer highly effective; new variants of the virus emerged that can transmit fairly easily notwithstanding vaccination, although inoculation continues to offer strong protection against severe illness and death. The bottom line: The horses are now long out of the stable, and the novel coronavirus will be with us for many years to come.

Meanwhile, Operation Warp Speed was discontinued by the Biden administration, and no equivalent effort to fund and expedite next-generation vaccines was instituted. We continue to use vaccines that were designed for the original novel coronavirus. On the bright side, Pfizer and Moderna have both developed "bivalent" boosters that target both the original virus and the currently dominant B.A.5 omicron subvariant

Operation Warp Speed was a spectacular and historic success — one that deserves to be mentioned in the same breath with the Manhattan Project, the Berlin airlift, and Project Apollo. Its one tragic flaw was that its model was not applied much more widely.

(actually, they were designed for the now-superseded <u>B.A.1 subvariant</u>, and are substantially less effective against B.A.5); the FDA granted an emergency use authorization for both boosters on Aug. 31, 2022. But other, <u>more promising vaccines</u> remain in development, including nasal vaccines that more effectively block transmission as well as so-called pan-variant vaccines. Alas, on current schedules these new vaccines are unlikely to be available before 2024. If Operation Warp Speed or its equivalent were still in place, we could have had these important weapons in our antipandemic arsenal available much sooner.

Please look up

One might have expected that the failures of the pandemic response would produce a sufficient shock to the system to catalyze major change. And as mentioned above, the CDC, to its credit, has conducted an internal review and is planning some important reforms. But the sweeping organizational changes and significant funding increases needed to create world-class pandemic-fighting state capacity cannot occur without new legislation. And thus far, at least, there is virtually no appetite in either Congress or the Biden administration for taking on this challenge.

The only pandemic-related reform legislation to make any headway to date is the PREVENT Pandemics Act, co-sponsored by Senators Patty Murray and Richard Burr. This rather modest bill does a few potentially useful things, including establishing a permanent White House office for pandemic preparedness, authorizing a national task force to conduct an extensive postmortem on the country's pandemic response, and mandating better information sharing between the CDC and state and local health authorities. But it is a far cry from the comprehensive changes that are called for – and its prospects for passage are far from bright. The bill was advanced out of the Senate Health, Education, Labor, and Pensions Committee back on March 22 but has not yet found its way to the Senate floor; meanwhile, there is as of yet no companion bill in the House.

The Biden administration, for its part, in September 2021 proposed a 10-year, \$65 billion <u>spending</u> <u>package</u> to upgrade the country's pandemic preparedness. The proposal, based on the recommendations of a <u>Bipartisan Commission on Biodefense</u> co-chaired by Joe Lieberman and Tom Ridge, called for creating vaccines for a variety of pathogens; using genomic sequencing and clinical data to establish an early warning system for outbreaks; developing next-generation PPE; replenishing key stockpiles; and more. What the proposal did not include was any plan to overhaul and reorganize

the public health agencies so that they could spend these new monies effectively. Nonetheless, it represented a clear step in the right direction – and a step not taken, as the proposal went nowhere.

It is instructive to compare this inaction to the response to the 9/11 terrorist attack. By Nov. 12, 2001 – two months and a day after 3,000 Americans had perished – Congress had passed the PATRIOT Act and the U.S. military had invaded Afghanistan and captured Kabul. We can debate the wisdom of these actions and their ultimate effects, but there's no doubt that American leadership recognized a serious threat and moved quickly to respond. But today, over two-and-a-half years after the first U.S. COVID cases and with a death toll over 300 times greater than that of 9/11, there has still been no movement to upgrade our biodefense capability.

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What are we to make of the absence of any serious attempt to

bolster American state capacity to fight pandemics in the aftermath of the COVID disaster? At this point the other two contributors to that disaster besides lack of relevant state capacity – namely, inadequate political leadership and a dysfunctional political culture – must come to the fore. To build the requisite state capacity, we need political leadership – and also a political culture that, if it doesn't push leaders in the right direction, at least doesn't block them.

Let's start with political culture. There is no reason to expect that public opinion will pressure politicians to do the right thing here. The problem goes deeper than our toxic polarization: Even in well-functioning polities, recognizing and addressing low-probability/high-impact risks are not tasks that the *demos* can be counted upon to perform well. On the bright side, upgrading the nation's pandemic preparedness is a very different job from managing an actual crisis in the here and now;

it is quiet, boring work unlikely to rouse great public controversy and activate polarized responses. If public opinion is not where the answer lies, neither does it make an answer impossible. It is with the nation's political leadership that responsibility for preventing the next crisis inescapably resides. And as the contrast of the current apathy with the immediate response to 9/11 reveals, what is missing in our leadership at present is the proper mindset – namely, seeing the risk of pandemics as a key national security threat.⁷

The risks to life and treasure posed by pandemics make them among the gravest threats we face. Since the eradication of smallpox fostered the complacent assumption that infectious disease is no longer a pressing problem, the world has experienced two global pandemics: first, HIV/AIDS, which over four decades has killed some 40 million people worldwide and 700,000 Americans; and now, COVID-19, which according to best estimates had killed more than 18 million people worldwide by the end of 2021, with the confirmed U.S. death count passing the 1 million mark in May 2022. These death tolls are in line with those of the bloodiest wars in human history; the U.S. death count from COVID-19 equals the country's total losses in the Civil War and World War II combined.

Because the last pandemic that indiscriminately threatened the general population occurred a century ago, it is tempting to think of the COVID-19 experience as a terrible one-off that we just want to put behind us and forget about. But there is no ground whatsoever for thinking that way; we may have lost interest in deadly pathogens, but they haven't lost interest in us. Just in the current century, we have already experienced a number of "near misses" – outbreaks of communicable diseases caused by novel pathogens that for whatever reason weren't transmissible enough to set the world on fire. Bird flu, SARS, MERS, and Ebola should have been wake-up calls, and indeed served that function in the more attentive and directly affected parts of the world. And COVID-19, in addition to being a tragedy of historic proportions, also serves as a warning: A pathogen with the same or greater transmissibility, and much greater lethality, could make the jump from animals to humans at any time.

As we lost our age-old fear of infectious disease over recent decades, we were inadvertently creating conditions that are <u>ever-more favorable</u> for the <u>emergence of new pandemics</u>: ongoing <u>impingement on the habitats</u> of disease-carrying wild animals; <u>factory farming</u> that puts humans in close contact with dense populations of disease-carrying livestock; and increasingly densely trafficked domestic and <u>international travel networks</u> to spread infections around the planet. While we've slept, we've allowed the threat posed by our viral and microbial adversaries to escalate precipitously. Unless we rebuild our defenses, it is only a matter of time before disaster strikes.

And if we are somehow incapable of adopting a national security mindset unless the danger to lives and well-being involves a human adversary, we should still put pandemics at or near the top of the list of threats we face. After all, the most terrifying pandemic scenario is that of an artificial pathogen genetically modified to heighten its lethality. And just as the risk of nuclear war extends to accidental launches, the risk of biological warfare likewise extends to accidental releases from laboratories. Of course there is a possibility – in all likelihood never to be definitely confirmed or

^{7.} In my interviews with Scott Gottlieb and Philip Zelikow, both stressed the importance of viewing pandemic preparedness through a national security lens. See <u>Gottlieb interview</u>, starting around 38:09, and <u>Zelikow interview</u>, starting around 50:35. See also Gottlieb, Uncontrolled Spread, pp. 340-380.

denied – that COVID-19 itself originated in a leak from the Wuhan Institute of Virology. Regardless of what actually happened, the mere fact that the lab leak theory is plausible – because leaks of this kind are distressingly routine – ought to convince us that we are dangerously exposed. Although a "Star Wars"-style missile defense system may never be impermeable enough to prevent catastrophe in the event of a nuclear strike, we can construct pathogen defense systems that can do much to protect us from biological weapons.

It is beyond the scope of this essay to lay out in detail the specific reforms needed to provide our public health authorities with the disease-fighting capacity that a national security mindset requires, but here are a few of the obvious steps to take:

- Focus the CDC on infectious diseases. This was the original focus of the agency, but as the threat of infectious disease waned the CDC's mission creeped steadily into management of a variety of chronic diseases and conditions like heart disease, diabetes, smoking, and obesity as well as birth defects, domestic violence, and suicide. These are all important problems, but there are other government agencies more suitable to addressing them. We need an agency laser-focused on acute threats from pathogens; we need to restore the CDC to its original mission.
- Improve data sharing. Spotty information exchange between the CDC and the country's
 nearly 3,000 state and local public health agencies has been a recurrent problem throughout the pandemic as well as during other outbreaks. Rationalization of reporting requirements and protocols is an absolute necessity if our disease-fighting "generals" are to have
 accurate information from the front lines and those on the front lines are to act appropriately on directives from headquarters.
- Find an end-run around FDA's "business as usual." Actually, such an end-run already exists in the form of emergency use authorizations, such as those FDA used for initial approval of COVID vaccines. Even so, FDA's deep-seated caution and propensity for delay were frequently in evidence during the pandemic. And indeed, the political incentives favoring caution are so overwhelming that it is unclear how much good can be done by further reforms that push toward accelerating the review process during public health emergencies. Such reforms should be attempted, but perhaps the most efficacious approach would be to bypass the FDA when it stalls: Require the agency to approve any diagnostic, vaccine, or treatment for use in a public health emergency provided that it has already been approved by regulators in other advanced countries.
- Expand the Operation Warp Speed model. Operation Warp Speed offered a new and excellent model for incentivizing drug development in an emergency setting, but that model was followed inconsistently and incompletely. In the future, the government should regularly incentivize development of new vaccines and treatments by direct funding that is, through financial support for R&D and clinical trials and advance purchase agreements upon successful development instead of the usual indirect approach of awarding patents and granting temporary market exclusivity. There is no justification for granting or

^{8.} See my interview with Nikki Teran for a detailed discussion of how to improve pandemic preparedness.

- protecting patents in the event of a pandemic; patents inevitably misalign drug makers' incentives with the overriding goal of accelerating global vaccine distribution.
- Tighten oversight and regulation of pathogen-related research. It's possible that the COVID-19 pandemic began with a lab leak. We know that lab leaks are relatively common. And we know that scientists are engaging in so-called "gain of function" research in which they are deliberately trying to create more infectious and lethal pathogens. Although the U.S. imposed a moratorium on such research in 2014, it lifted the ban three years later. It's imperative now that we recognize the real potential for self-inflicted catastrophe and take steps to improve international oversight of biomedical research labs and outlaw research that poses unacceptable risks to lives around the world.¹⁰

An absence of vital state capacity has cost hundreds of thousands of Americans their lives during the COVID-19 pandemic, and the death toll continues to mount. The first step toward avoiding similar disasters in the future is to recognize the magnitude of the threat we face. Out there somewhere in the inky blackness of space, a comet with our names on it is heading our way. It's high time we look up and prepare to defend ourselves.

About the author

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Prior to joining Niskanen, Lindsey was vice president for research at the Cato Institute. From 2010 to 2012, he was a senior scholar in research and policy at the Ewing Marion Kauffman Foundation.

^{9.} My interview with <u>Priti Krishtel</u> contains an extensive discussion of the larger problems with current patent policy and in particular how patents act as a drag on pandemic response.

^{10.} See Teran interview, starting around 38:00.