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Reforming Public Health Agencies: A Post-COVID Agenda

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KEY TAKEAWAYS

America's federal public health agencies revealed serious weaknesses in responding to the Covid-19 pandemic.

Officials politicized public health guidance, pushed unwarranted school and business closures, forced illegal mandates, and tried to suppress scientific dissent.

The Administration and Congress can take steps to improve federal public health agencies to avoid future mistakes and rebuild trust in our public health response.

There can be no COVID-19 closure without public health reform. Too much went wrong during the dreadful pandemic that cost an estimated 1.2 million Americans their lives. Trump Administration officials should therefore resist the powerful temptation to jettison that unhappy experience down the Orwellian "memory hole." Simply putting that divisive episode behind us would be a serious public disservice. Perhaps Dr. Scott Atlas, Hoover Institution Senior Fellow and former White House adviser, has said it best:

> Turning the page on modern history's worst societal failure would be extraordinarily harmful. Failure to demand and issue official statements of truth about the pandemic management after the devastation endured by millions would eliminate all accountability. And accountability is just what we need to restore trust in institutions and among fellow citizens.[1]

That might seem to be a tall order, but much of the crucial spadework has already been done. Specifically, the Trump Administration is the chief beneficiary of three years of outstanding congressional oversight work conducted primarily by the House Oversight and Accountability Committee's Select Subcommittee on the Coronavirus Pandemic and the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations. Taking advantage of this mammoth undertaking, the new Health and Human Services Secretary Robert F. Kennedy Jr. and his colleagues have the chance to build on what went right, correct what went wrong, and take bold steps to transform federal public health agencies and thus improve America's response to future pandemics.[2]

Rich Resources. Congressional investigators have provided the Administration with a treasure trove of valuable and actionable information. They have chronicled in meticulous detail what the new presidential Administration should *not* do: confuse the public with mixed messaging on everything from the utility of masks to the effectiveness of vaccines; recommend massive, unwarranted and sustained business and school closures; impose unprecedented federal mandates, most notably illegal vaccine mandates; undercut the professional advice of personal physicians; politicize Centers for Disease Control and Prevention (CDC) guidance; and pressure social media corporations to censor legitimate scientific dissent and discourage robust debate among medical professionals.

On some of the biggest and bitterest controversies of the COVID-19 pandemic, federal health officials got it wrong. They were *not* "following the science;" they were *not* politically disinterested; and, in many cases, they were *not* truthful. The examples are too numerous to recount here, but it is worth noting that in early 2020, officials in the National Institutes of Health (NIH) and their heavily funded grantees promoted a "natural" origin of the coronavirus without sufficient evidence (an intermediate animal host) while denouncing proponents of a "lab leak" hypothesis as "conspiracy theorists."[3] In 2021, President Joe Biden and his appointees insisted falsely that the pandemic was a "pandemic of the unvaccinated."[4] Similarly, the CDC's recommended school closures were not based on science but instead were influenced by politics, and its masking advice was inconsistent and confusing.[5]

The Kennedy Agenda. Secretary Robert F. Kennedy Jr. has launched a major reorganization of the U.S. Department of Health and Human Services (HHS). Based on the poor performance of the department and its sub-agencies during the COVID-19 pandemic—notably the CDC and NIH—comprehensive reform is long overdue.

With an annual budget of $1.7 trillion, HHS is a giant bureaucratic empire with many powerful and sometimes competing kingdoms. The department's budget grew by 38 percent over the past four years along with a 17 percent growth in agency personnel. This stunning expansion has not improved the department's performance or operations, and the organization of agency responsibilities is not aligned with Kennedy's primary mission: to improve Americans' health and reverse the growth of childhood chronic illness.[6]

Kennedy's ambitious restructuring agenda would consolidate the operations of 28 existing agency divisions into 15 and reduce the number of the department's regional offices from 10 to five. The consolidation is designed to improve internal coordination and cooperation, reducing the duplication and "silo" effect that hampers efficient administration. HHS projects that the administrative changes and restructuring will reduce personnel by about 10,000 full-time employees.[7]

Fixing the Agencies

For the future of public health, Secretary Kennedy's proposal to reform and upgrade the Centers for Disease Control and Prevention is crucial. It would refocus the agency's mission on combating communicable disease and providing more effective assistance to states and local public health agencies during a national medical emergency. The Administration for Strategic Preparedness and Response (ASPR), an existing department sub-agency, would be transferred to CDC to assist in the agency's core mission of meeting and defeating emerging threats to public health, primarily from communicable diseases.

Secretary Kennedy has rightly refocused the department on promoting the underlying health of the American people, and he and his team have initiated a long-overdue restructuring of the department, including the CDC, NIH, and Food and Drug Administration (FDA). He should work to implement these changes administratively where he can and work with Congress legislatively where he cannot.

Reforms for the Office of the Secretary. The department's managerial weaknesses in responding effectively in a pandemic were anticipated well before the onset of the COVID-19 crisis. The Government Accountability Office (GAO), for example, raised red flags as early as 2018 on the lack of clarity in roles and responsibilities in the decision-making required in a national crisis.

By 2022, during the pandemic, the GAO further reported that the HHS response was so poor that it designated the department's "programs and operations" as "high risk." In short, a true remedy would require not mere

tinkering, but "transformation."[8] Too many of the GAO's recommendations have been ignored or not addressed adequately. Secretary Kennedy and his team should begin by reviewing and responding to the GAO 's numerous recommendations. Beyond that, the Secretary should take additional steps by working with Congress to improve the department's capacity to meet the next medical emergency. Specifically:

- **Limit the Secretary's authority to extend public health emergency declarations.** On January 31, 2020, Secretary Alex Azar, citing his authority under the Public Health Service Act,[9] declared a public health emergency in response to the COVID-19 pandemic. On September 18, 2022, President Joe Biden declared that the pandemic was "over," but on October 13, 2022, the Biden Administration extended the national public health declaration for another 90 days. On January 11, 2023, after threatening to veto a November 2022 bipartisan Senate resolution declaring an end to the national medical emergency, the Biden Administration extended the declaration again.[10]

  It is not enough to declare the beginning of an emergency. Officials should also determine when, for all practical purposes, it is at an end and Americans can comfortably resume their normal lives. Specifically, just as with the deployment of military forces in foreign policy, Congress should set a time limit after which congressional approval is required for the Secretary to extend an existing public health emergency declaration further or issue a new public health emergency declaration with respect to the same (or substantially the same) pathogen or specific biomedical threat. Moreover, the end of a national medical emergency should also terminate the emergency use authorization (EUA) for a vaccine created specifically to respond to that emergency. Monitoring viral mutations, FDA must then formally decide on final approval.

- **Eliminate HHS's role as an adjudicator of vaccine injury claims.** The House Select Subcommittee on the Coronavirus Pandemic found not only that the federal government's systems for reporting vaccine injuries was inadequate, but also that the government system's performance for compensating these injuries was stunningly poor.[11] Created by Congress in 2005, the Countermeasures Injury Compensation Program (CICP) adjudicated claims for vaccine injuries incurred during a public health emergency, such as COVID-19. Congress should

amend the law to eliminate HHS as an adjudicator of claims under the CICP for vaccines that it has also approved and promoted. This should be a judicial, not an administrative function. Congress should create an alternative system for fair, efficient, and transparent adjudication of injury claims through the federal court system or through a new administrative law court system similar to that used today to settle Medicare claims. Congress should also revisit the National Childhood Vaccine Injury Act of 1986,[12] a law covering all vaccines the CDC recommends for children and pregnant women. Congressional investigators should review the law from the perspective of promoting patient safety and its effectiveness in compensating victims of vaccine injuries.

- **Protect scientific debate.** On January 20, 2025, President Donald Trump signed an executive order to prevent federal officials from abridging or censoring the constitutionally protected speech of all Americans. During the COVID-19 pandemic, federal officials went to extraordinary lengths to stifle legitimate scientific debate.[13] Congress should codify President Trump's executive order and determine whether it should enact additional protections of medical and scientific debate so that there is full and fair exploration of scientifically based information.

- **Review the performance of the National Foundation for the Centers for Disease Control and Prevention, the Foundation for the National Institutes of Health, and the Reagan–Udall Foundation for the Food and Drug Administration.** Congress created these foundations as nonprofit public charities to facilitate partnerships with the private sector and act as a conduit for major corporate funding. Because corporate interest may unduly influence agencies' policies or activities, the Trump Administration should reexamine the role and performance of these foundations. Moreover, these institutions, created by Congress, are also ripe for more extensive congressional oversight. Between 2014 and 2018, for example, the CDC foundation received $79.6 million in contributions from pharmaceutical corporations.[14] If the Administration determines after a review that such contributions foster regulatory capture, Congress can either eliminate them or enact a temporary reauthorization with stricter guidelines for private funding of projects or activities specifically authorized by Congress. Any reauthorization should be based on reportable performance metrics.

- **Ensure the free flow of public information.** Congress should transfer responsibility for responding to Freedom of Information Act (FOIA) requests to the agency Offices of Inspector General (OIGs). The OIG in every federal department and agency already has responsibility for internal oversight of agency operations. It is a mistake to permit agency officials to make judgments about the release of information to the public that could either embarrass them or compromise their own self-interest or their agency's institutional interests. No agency should be allowed to be a judge of its own cause.

- **Toughen enforcement of the Freedom of Information Act.** According to Health Advances, Secretary Kennedy has already promised to release documents requested under FOIA but previously unavailable.[15] Congress should go further and enact criminal penalties for violations of FOIA. The Trump Administration should work with Congress to put teeth into FOIA. Top federal officials at the NIH, for example, have gone to great lengths to conspire and hide what should have been publicly available information and have deployed various stratagems to subvert the law.[16] Federal officials should no longer be able to treat the public with such contempt with impunity.

- **Review and assess rules to prevent conflicts of interest.** The department distributes and spends an enormous amount of taxpayer money. At the same time, certain agencies are also recipients of substantial private funding, particularly from corporations. Approximately 75 percent of the funding for the FDA's drug division, for example, is supported by fees from pharmaceutical corporations. In 2018, Charles Piller, an investigative reporter for *Science* magazine, observed that:

> The Food and Drug Administration (FDA) says its rules, along with federal laws, stop employees from improperly cashing in on their government service. But how adequate are those revolving door controls? *Science* has found that much like outside advisers, regular employees at the agency, headquartered in Silver Spring, Maryland, often reap later rewards—jobs or consulting work—from makers of the drugs they previously regulated.[17]

With respect to those FDA external advisers, Piller also reported that from 2008 to 2014, 107 physicians advised FDA on drug approvals. Of that number, 66 had subsequently received corporate funding in the

form of consulting fees, research funding, and travel from companies whose drugs they had voted to approve.[18]

Unlike FDA, NIH is not a regulatory agency, but it does distribute tens of billions of dollars each year in research grants to private institutions. The agency also participates in research for drug development and receives royalties for its contributions, as do certain intramural scientists. From 1991 to 2019, the NIH as an institution, as well as some of its personnel, received approximately $2 billion in royalties from its research contributions to pharmaceutical development. Not surprisingly, the congressional watchdog GAO recommended greater transparency in its licensing of its intellectual property.[19]

Current law establishes both pre-employment and post-employment standards of conduct and imposes criminal penalties for their violation. Employees must recuse themselves in certain matters, such as participating in a review or adjudication of a product developed by a previous employer. Likewise, current law provides that senior HHS officials, career and non-career alike, are precluded for set periods of time in specific instances from communicating with the agency on behalf of a private client to influence policy after government service.[20] In the case of a senior FDA official, for example, this restriction would apply to representation of any pharmaceutical corporation, medical device company, biotech or medical technology company, or tobacco or food company.

Dr. Marty Makary of Johns Hopkins University, the new FDA Commissioner, is already planning to limit industry officials from participating in FDA advisory committees.[21] However, the public deserves a comprehensive review of conflict-of-interest rules that apply to *all* public health agencies. The matter is not simple. Americans need to know that public officials are working exclusively for the public and not taking advantage of their positions to enhance private or personal financial interests. At the same time, however, Americans should not be deprived of the services of highly competent private-sector professionals who are or may be discouraged from public service because of onerous post-employment restrictions. The Trump Administration should conduct a thorough internal review of these matters and share the findings with Congress.

Reforms for the Centers for Disease Control and Prevention. The CDC needs major streamlining and restructuring. Most importantly, Congress must authorize the agency itself and not just specific CDC programs and clearly define its statutory role as the lead agency in combatting communicable diseases. Pursuant to Secretary Kennedy's restructuring plan, CDC's role in many other areas, such as disease prevention and health promotion, should be consolidated and transferred to the new Administration for Healthy America and other subunits of HHS.

In August 2022, former CDC Director Rochelle Walensky issued a candid assessment of the agency's performance: "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."[22] Dr. Walensky acknowledged, among other things, that CDC was defective in its communications with the public and state public health agencies and should have been timelier in the release of scientific information. Writing in *Health Affairs Forefront*, Dr. Brian J. Miller of Johns Hopkins University and colleagues identified a larger structural problem: CDC has succumbed to the bureaucratic disease of "mission creep," thus taking on responsibilities beyond its core mission of combating communicable disease. These responsibilities should be transferred to other agencies.[23]

Working with Congress, Secretary Kennedy and the new CDC Director should undertake major structural and operational changes. Specifically:

- **Authorize the CDC in statute.** Congress should formally authorize the CDC as an agency, as recommended by the House Subcommittee on Oversight and Investigations,[24] and clearly define its role and responsibility as the lead federal agency in detecting, monitoring, and combating infectious disease. This would be consistent with Secretary Kennedy's decision to transfer the ASPR to the CDC. The Trump Administration should also move the CDC's headquarters from Atlanta, Georgia, to Washington, DC, to facilitate secure face-to-face consultations, deliberations, and coordination with the President, senior White House staff, the HHS Secretary, and top officials of other federal agencies, and increase the number of non-career appointees in key policy positions to assist the Director in carrying out the Administration's priorities and responsibilities in framing and executing often complex and difficult public health policies.

  Finally, the Administration should create CDC offices around the country. A key problem that was evident early in the Covid-19

pandemic was the need for communication and rapid transmission of emerging data from state to federal authorities and vice versa. Such decentralization would enable the agency to collect and quickly analyze state-level data "on the ground" and act expeditiously to help state and local agencies to coordinate a public health response to an emerging medical crisis.

- **Transfer current CDC programs and activities that are not focused primarily on communicable diseases to other agencies within HHS.** This would accord with Secretary Kennedy's decision to ensure that the CDC is laser-focused as the leading agency in responding to health threats. Among other things, the CDC currently budgets for prevention programs for AIDS/HIV, injury prevention and control, tuberculosis, sexually transmitted diseases, birth defects and developmental disabilities, environmental health, tobacco use, and chronic disease prevention and health promotion. These programs should be transferred to Secretary Kennedy's newly created Administration for a Healthy America (AHA). With Kennedy's reorganization of HHS, the Assistant Secretary for Planning and Evaluation (ASPE) and Agency for Healthcare Research and Quality (AHRQ) will be incorporated into a new HHS Office of Strategy. It would therefore also be appropriate to transfer the CDC's National Center for Health Statistics to the new Office of Strategy, and any basic research on non-communicable diseases currently being conducted or funded through the CDC should be transferred to the NIH.

- **Prevent false claims of vaccine effectiveness.** The Biden–Harris Administration, while promoting an unprecedented vaccine mandate, made blatantly false claims about the effectiveness of the COVID-19 vaccines, insisting (in the teeth of scientific evidence) that the vaccines were effective in preventing transmission of the coronavirus. CDC officials were guilty of disseminating this misinformation. As recommended by the House Subcommittee on Oversight and Investigations, the CDC and other federal agencies should be strictly prohibited from making claims about vaccines that do "not reflect" the FDA-approved label.[25]

- **Require that CDC's schedule of recommended vaccines also include descriptions of each vaccine's benefits and risks—derived from and consistent with the product's FDA-approved label.** Such accompanying statements should also include disclaimers

about patient subpopulations for which the FDA label states that there is insufficient evidence to determine safety and/or efficacy.

- **Show respect for human life and rights of conscience in public health guidelines.** As Roger Severino, Heritage Foundation Vice President of Domestic Policy and former Director of the Office of Civil Rights at HHS, has noted:

  > The CDC oversaw and funded the development and testing of the COVID-19 vaccines with aborted fetal cells lines, insensitive to the consciences of tens of thousands to hundreds of thousands of people who objected to taking a vaccine with such a link to abortion. As evidenced by litigation across the country, it is likely that thousands were fired unjustly because of their exercise of their consciences or faith on this question, which could have been avoided with a modicum of concern for this issue from CDC.[26]

- **Establish a CDC forum for the free and rapid exchange of clinical information.** During the COVID-19 pandemic, frontline physicians and other medical professionals were learning about the progression of the coronavirus and heavily engaged in treating patients seriously ill with the disease. New information about the course of the disease, including massive inflammation and autoimmune responses, required new and rapid medical interventions. Unfortunately, the CDC did not convene any regular forum (either virtually or otherwise) for the regular and ongoing exchange of crucial clinical information among medical professionals when it was most urgent and necessary.[27] The new CDC leadership should establish such a forum and activate it when appropriate, especially with the onset of a national medical emergency.

- **The CDC should collaborate with the Department of Defense (DOD) and Central Intelligence Agency (CIA) to improve the protection of Americans from emerging biological threats overseas.** It is evident that the COVID-19 pandemic emerged in Communist China long before it was widely recognized in the West in January 2020. In fact, COVID-19 antibodies were discovered in blood samples in the Veneto region of Italy as early as September 3, 2019.[28] The Trump Administration should create a special CDC/DOD/CIA task force to keep abreast of emerging biosecurity threats to the United States and its allies and deploy joint agency staffing to monitor

public health developments on the ground overseas. The Administration should detail Department of Energy and FBI analysts to assist in this effort.

In tandem with this initiative, as recommended by The Heritage Foundation's nonpartisan Commission on China and Covid-19, the Trump administration should work with Congress to restrict any public-sector or private-sector biotechnology investments in Communist China.[29] No such investments in a country that is an avowed adversary of the United States, particularly in the wake of its irresponsible behavior at the inception of the pandemic, should be permitted. Nor should any such investments in any other state actor that could pose a bioweapons threat to the United States and its allies be permitted.

Reforms for the National Institutes of Health. The National Institutes of Health, with 27 specialized institutes, has a budget of $48 billion, and virtually all of its funding is allocated for biomedical research, provided overwhelmingly through grants to universities and medical research institutions.[30] Reviewing the value of these grants—the returns of this vast public investment—should be a top priority for the new team. NIH officials should also ensure that future grant funding focuses on combating chronic disease.

Given the likelihood that the COVID-19 pandemic most likely had a laboratory origin, the most important focus of a comprehensive grant review should be the nature and scope of past NIH funding of viral gain-of-function research—laboratory experiments designed to increase the virulence or transmissibility of pathogens. As Andrew Noymer, Professor of Population Health at the University of California, Irvine, has observed, "To avoid a repeat of COVID, we need better regulation of gain-of-function virology, and full transparency about coronavirus research in the years leading up to the pandemic."[31]

President Trump has recently reinforced that mission by issuing a comprehensive executive order for "Improving the Safety and Security of Biological Research." Among other things, President Trump's order ends all federal funding of such research conducted in foreign "countries of concern" such as China, ends funding of other "life sciences research" that could pose a threat to public health in countries where oversight is weak and safety protocols are substandard, strengthens the government's "top down oversight" to ensure compliance, and provides for revocation of grant funding for institutions in violation of the order for up to five years. The Director of the White House Office of Science and Technology Policy (OSTP)

is authorized to develop a strategy to focus on regulating privately funded gain-of-function research that could also endanger public health, including a legislative proposal to close any gaps in the government's authority to protect the American people.[32]

The Trump executive order is an overdue corrective to bad policy. "The Biden Administration," as the President noted, "allowed dangerous gain-of-function research within the United States with insufficient levels of oversight" and "actively approved, through the National Institutes of Health, Federal life-science research funding in China and other countries where there is limited United States oversight or reasonable expectation of biosafety enforcement."[33]

Many scientists, including Dr. Anthony Fauci, have long argued that the benefits of such research, designed to develop antiviral countermeasures, are worth the risks.[34] Just two years after Dr. Fauci made that argument, however, the Obama Administration discovered a number of disturbing safety lapses at federally funded laboratories. Like President Trump, President Barack Obama in 2014 ordered a pause in taxpayer funding of gain-of-function research.

Based on the events of the past four years, including the likelihood that the pandemic originated in a laboratory, President Trump's order is even more urgent. Trump Administration officials have the opportunity to conduct a comprehensive assessment of such research in American laboratories, as well as in federally funded facilities overseas, and the levels of biosecurity and existing protocols that govern such research. In any case, henceforth, any permissible research of this nature that is justified on the grounds of national security should be strictly limited and conducted at the highest levels of laboratory safety in America's most secure laboratories.[35]

Dr. Jay Bhattacharya of Stanford University is the new Director of the National Institutes of Health. His appointment should mark a major sea change in the agency's institutional culture, including an openness to new research topics and full transparency of agency operations. Dr. Francis Collins, former NIH Director, dismissed Professor Bhattacharya in 2020 as a "fringe" epidemiologist because of his opposition to comprehensive lockdowns during the COVID-19 pandemic. In truth, Bhattacharya had an international reputation for the high quality of his scholarship.[36]

Dr. Bhattacharya is taking the helm of a troubled agency. During the pandemic, NIH leaders tried to discredit dissenting views within the scientific community, including the politically inconvenient hypothesis that a Chinese laboratory was the origin of the deadly new coronavirus. NIH officials also failed to monitor risky coronavirus research grants, such as

gain-of-function research, effectively while resorting to scandalous violations of the Freedom of Information Act to hide vital information from the public. In addition, NIH officials have received substantial royalties from pharmaceutical and other companies, thus creating a strong appearance of conflict of financial interest. As Roger Severino has noted:

> In 2018, it was revealed that a $100 million NIH study on the benefits of moderate drinking was funded by the beer and liquor industry. More recently, the National Institute of Allergy and Infectious Diseases (NIAID), Anthony Fauci's division of the NIH, owns half the patent for the Moderna COVID-19 vaccine, among thousands of other pharma patents. Rather than providing grants to university-based investigators to run the clinical trials on their own Moderna vaccine, the NIH conducted this research internally—a clear conflict of interest.[37]

The new Director of NIH could take several steps to rehabilitate and strengthen the agency. Specifically:

- **Create an independent commission to review gain-of-function research grants.** Going beyond the terms of the Trump executive order, the Administration should remove final approval of any gain-of function research grants from the NIH as recommended by congressional investigators and transfer that responsibility to an independent commission comprised of top-tier scientific advisors and national security experts free of institutional agency biases or private financial interests.[38]

- **Revise NIH employment rules and contracts to reflect common practices in the private sector with respect to ownership of intellectual property (IP).** If an employee's work results in the creation of intellectual property, any rights to such IP belong to the employer, not to the employee. At the same time, to encourage innovation, the NIH should also offer its employees other incentives (such as large one-time bonus awards) for creating intellectual property.

- **Impose term limits on top NIH career officials.** Dr. Anthony Fauci, for example, served as Director of the National Institute of Allergy and Infectious Diseases (NIAID) for 38 years, beginning with the Reagan Administration in 1984 until his retirement during the Biden Administration in 2022. As Severino has noted, "Funding for scientific research should not be controlled by a small group of highly paid and

> unaccountable insiders at the NIH, many of whom stay in power for decades."[39]

Reforms for the Food and Drug Administration. The FDA is responsible for approving drugs and vaccines for safety and effectiveness. Under current law, the pharmaceutical industry (through special fees) finances roughly 75 percent of the work of the agency's drug division.[40] Whatever the Administration's plans regarding the future of financing and drug approvals, it cannot ignore the festering issue of COVID-19 vaccine safety and reporting. Full transparency in these matters is long overdue.

On May 21, 2025, Senator Ron Johnson (R–WI), chairman of the Senate Permanent Subcommittee on Investigations, issued an explosive report on the topic of COVID-19 vaccine safety.[41] It details the Biden Administration's failure to warn the American people about serious health risks posed by the COVID-19 vaccines, primarily myocarditis (heart inflammation) among young people. Based on internal documents, officials were aware of the problem in February 2021 when Israel's Ministry of Health brought the emerging myocarditis problem to their attention. The Senate report's findings reflect Secretary Kennedy's release of 2,473 pages of records to Senate investigators, including internal communications among CDC, FDA, and White House officials.

Chairman Johnson recently repeated his previously ignored request for full disclosure from company executives, and FDA can assist the Senator by releasing any related information, especially any communications with vaccine developers.[42]

As noted, Dr. Marty Makary of Johns Hopkins University is the new FDA Commissioner. He can build on the genuine strengths of the agency and advance Secretary Kennedy's agenda for making America healthier. Dr. Makary has been a leading contributor to scientific medical literature and is also keenly aware of the serious weaknesses in the federal response that surfaced during the COVID-19 pandemic.

Writing recently in *The New England Journal of Medicine*, Commissioner Makary and Dr. Vinay Prasad have argued that federal recommendations for COVID-19 booster shots, for example, are overly broad and unjustified by the data, making the United States an outlier among our European friends and allies. Thus:

> While other high-income nations confine vaccine recommendations to older adults (typically those older than 65 years of age), or those at high risk for severe Covid-19, the United States has adopted a one-size-fits-all regulatory framework and has granted broad marketing authorization to all Americans

> over the age of 6 months. The U.S. policy has sometimes been justified by arguing that the American people are not sophisticated enough to understand age and risk-based recommendations. We reject this view.[43]

Makary and Prasad believe that continued COVID-19 vaccination would make sense for persons over age 65 and for those with a variety of underlying health conditions that would lead to severe illness, while the benefits of Covid vaccination for healthy persons between age six and age 64 should be based on randomized controlled clinical trials combined with effective post-market surveillance.[44] Meanwhile, Secretary Kennedy announced that the Administration would no longer recommend COVID vaccines for healthy young children and pregnant women.[45]

Another institutional weakness that surfaced during the pandemic was the failure of public health officials to deploy diagnostic testing quickly. The complex and counterproductive federal regulatory regime directly damaged the nation's ability to stand up early and effective systems of diagnostic testing, thus leaving public health officials blind to the true extent of the COVID-19 contagion. After the CDC attempted to create and then recall a flawed test, delaying vital surveillance, the FDA's pre-existing regulatory regime worsened the American response by blocking the provision of private-sector testing alternatives. The nation cannot afford a repeat performance. Other problems surfaced with the monitoring and reporting of COVID vaccine safety and effectiveness, including failure to report the risks of myocarditis in a timely fashion and respond to congressional inquiries on the topic, as well as a lack of transparency on vaccine ingredients and quality. Therefore, the FDA should:

- **Release any and all COVID vaccine safety and effectiveness data.** **S**enator Johnson has already requested this information from the corporate files of BioNTECH, Pfizer, Moderna, and Jonhson and Johnson. In his April 2, 2025, letter to Moderna, Johnson warned,

  > I expect you to fully comply with this request, but I am mindful that your company may choose to mimic the Department of Health and Human Service's past efforts to conceal records about the development, safety and efficacy of the COVID-19 vaccines. Any attempt to obstruct or delay responses to this request will result in compulsory process.[46]

  The FDA should assist the Senator and release all of the data received from the Covid vaccine manufacturers, as well as any remaining data

held in the files of the FDA that had been withheld during the Biden Administration. Needless to say, full disclosure would also apply to vaccine-related data in the files of the National Institutes of Health.

Commissioner Makary has already announced his intention to undertake "intense and comprehensive research" into vaccine safety and effectiveness.[47] Moreover, Secretary Kennedy has also recently declared that all *new* vaccines will be tested against a placebo (a substance having no effect on the human body) to determine their safety before final approval.[48] This is a significant change in federal vaccine policy.

- **Make the FDA responsible for the Vaccine Adverse Event Reporting System (VAERS) and upgrade the agency's vaccine safety monitoring programs.** Today, the VAERS program is jointly administered by the CDC and FDA. The FDA should be the sole agency responsible for post-market vaccine safety monitoring—just as it is for other regulated medical products. Unlike the CDC, the FDA is a regulatory agency that can and does act on post-market information to require product labeling changes when appropriate or ban the sale or distribution of regulated products. The VAERS data system is currently fueled by self-reporting of alleged vaccine injuries and events and therefore is an utterly unsuitable platform for determining with any precision the causal relationships between events and vaccines. It is vulnerable to both underreporting and overreporting.

  The FDA must, therefore. upgrade its capacity to detect and publicly report adverse events accurately to ensure an appropriate regulatory response. Dr. Makary has already taken a step forward to accomplish this objective by using real-world data from electronic health records in Health Information Exchanges, allowing clinicians to share patient information quickly, instead of relying on VAERS.[49] FDA staff have long experience and historic responsibility for post-market vaccine and drug surveillance, and the new Administration can significantly improve upon the profoundly defective VAERS system.

- **Release the full list of COVID-19 vaccine ingredients.** The federal government provided an estimated $31.9 billion to vaccine manufacturers to develop and produce the COVID-19 vaccines.[50] Despite this enormous public investment, neither the FDA nor the relevant

pharmaceutical manufacturers have been transparent in releasing the full list of ingredients or the methodology employed in testing the vaccines for their quality. "Without a list of ingredients or testing methodology," as Dr. David Gortler, a senior advisor to the FDA Commissioner during the first Trump Administration has observed, "it is impossible for anyone else outside of the FDA or manufacturers to know precisely how to check for product consistency. It is especially troublesome since new, preliminary data using independent methodology has produced troubling evidence of contamination in mRNA COVID product."[51] There is no excuse for hiding information from the public that the public so generously has funded.

- **Work with Congress to clarify and streamline the regulatory regime governing diagnostic testing.** It should be clear, for example, that the FDA alone is responsible for ensuring that all diagnostic lab tests are safe and effective. During the national medical emergency, Centers for Medicare and Medicaid Services (CMS) regulation prevented non-clinical labs from performing diagnostic testing.[52] CMS regulatory authority under the Clinical Laboratory Improvement Amendments (CLIA) of 1988[53] should be clearly confined to regulating personnel and facilities performing clinical testing.

Restoring Trust

HHS Secretary Robert F. Kennedy Jr. and his new team have a great opportunity to improve the performance of federal public health agencies and restore public trust in these institutions. It is absolutely essential that they do so well before the onset of the next national medical emergency.

Given the nation's recent experience with COVID-19, they should not only undertake an internal evaluation of the agencies but also take advantage of the external oversight and thoughtful recommendations provided by congressional investigators who have examined the performance of these agencies exhaustively over the past three years.

In retrospect, Dr. Sandro Galea, Dean of the Boston University School of Public Health, has remarked that with COVID-19, everybody at some point was wrong about something.[54] That was not and could not be surprising. The coronavirus was new and incredibly contagious; it was not immediately clear how it was transmitted, how the disease would progress, or whether it would affect the entire population or a subset of the population. Epidemiological predictions were often far off the mark.

The central failure of federal officials in responding to the pandemic was not a failure to undertake an urgent scientific investigation into the data available to them; it was a failure to acknowledge the need for a change in policy when it was clear that the data did not support their previous analyses or recommended interventions. Moreover, when they changed policy, they failed to communicate quickly and clearly the rationale for the change to state and federal officials and the public. That failure applied specifically to, among other things, masking, vaccine mandates, vaccine effectiveness, vaccine safety, social and economic lockdowns, and school closures.

Genuine scientific consensus on these policies was often absent. The problem has best been summarized by American Enterprise Institute Senior Fellow M. Anthony Mills: "The task for policymakers in these circumstances is to decide what to do in light of various and sometimes conflicting expert recommendations. This is all the more difficult when experts mislead policymakers and the public into believing that there is no expert disagreement or that the evidence supports only one policy choice."[55]

Secretary Kennedy's agenda to have the CDC focus on its core mission of protecting the public from communicable disease is the first great step in preparation for the next national medical emergency. The FDA must open all of its files on vaccine safety and effectiveness data, including information received from vaccine manufacturers, and improve the reporting of adverse vaccine events. Pursuant to the President's executive order, the NIH must not only halt viral gain-of-function research, but also undertake a comprehensive review of such research as well as its multibillion-dollar grant programs. All agencies must ensure that none of their employees are compromised by a conflict of interest. And all agencies, in keeping with Secretary Kennedy's commitment to "radical transparency," should ensure the free flow of information to Congress and the public and foster, not discourage, open and robust scientific debate.

Such a positive agenda will reinvigorate public health and reinspire public trust.

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Appendix

Beginning in 2023, following the end of the national medical emergency, the author focused on the need for comprehensive congressional oversight of the federal government's performance. The good news is that congressional investigators in both the House and Senate conducted an outstanding series of oversight hearings that yielded remarkable revelations that can provide a sound basis for major public health reforms. In pursuit of truth, few avenues of inquiry surpass testimony under oath. To paraphrase the great Dr. Samuel Johnson, the prospect of a perjury charge concentrates the mind wonderfully.

For an overview of this fruitful congressional oversight agenda, the reader should consult the following:

- Robert E. Moffit and Doug Badger, "Forging a Post-Pandemic Policy Agenda: A Road Map for Covid-19 Congressional Oversight," Heritage Foundation *Special Report* No. 265, January 30, 2023, https://www.heritage.org/sites/default/files/2023-03/SR265.pdf.

- Robert Moffit, "Restoring Trust in Public Health: Preventing Waste and Fraud in National Emergency Assistance," The Daily Signal, February 26, 2025, https://www.dailysignal.com/2025/02/26/restoring-trust-public-health-preventing-waste-fraud-national-emergency-assistance/.

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- Robert Moffit, "Restoring Trust in Public Health: Full Transparency and Cooperation with Congressional Inquiries," The Daily Signal, March 4, 2025, https://www.dailysignal.com/2025/03/04/restoring-trust-public-health-full-transparency-cooperation-congressional-inquiries/.

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- Robert Redfield and Robert E. Moffit, "President Trump Should Reinstate President Obama's Moratorium on Risky Biological Research,' *RealClearHealth*, February 11, 2025, https://www.realclearhealth.com/articles/2025/02/11/president_trump_should_reinstate_president_obamas_moratorium_on_risky_biological_research_1090852.html.

- Robert Redfield and Robert E. Moffit, "It's Time to Fix the CDC—and Better Respond to the Next Pandemic," *RealClearHealth*, May 6, 2025, https://www.realclearhealth.com/articles/2025/05/06/its_time_to_fix_the_cdc__and_better_respond_to_the_next_pandemic_1108272.html.

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