Documents for the Record

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Subcommittee on Oversight and Investigations

1. Castor
   - LA Times Article – COVID
   - Politico Article – Florida Malaria
   - America Progress Article
   - Appropriations FY24 LHHS Summary
2. Tonko
   - Pediatrics Vaccines Letter
3. Cammack
   - COVID Table
4. Griffith
   - Letter to CDC
5. Rep. Dunn
   - SCC Report
   - No Testing Email Redacted
6. Palmer
   - Research Gate on Masking Children
7. Duncan
   - Heritage Report

Los Angeles Times

Main News; Metro Desk

How California, Florida COVID policies diverged

Rong-Gong Lin II Luke Money Sean Greene

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When California Gov. Gavin Newsom and Florida Gov. Ron DeSantis take the stage Thursday for their much-hyped televised debate, it will be perhaps the starkest visual representation of the divide between the two states.

While many social, political and economic factors contribute to that gulf, perhaps no topic better encapsulates the bicoastal conflict than the states' respective responses to the COVID-19 crisis -- the ramifications of which are still resonating and being debated half a year after the end of the pandemic's emergency phase.

On one side was California, which "trusted in science and data," as Newsom has put it, and was "the first state to issue a stay-at-home order, which helped us avoid the early spikes in cases." It was part of a strategy the Democratic governor reasoned was worth the sacrifice: "People are alive today because of the public health decisions we made."

And on the other was Florida, whose approach DeSantis touted as mindful of economic health -- attacking temporary business closures and vaccine mandates.

"We refused to let our state descend into some type of 'Faucian' dystopia, where people's rights were curtailed and their livelihoods were destroyed," the Republican governor said during a March speech at the Ronald Reagan Presidential Library in Simi Valley, referencing Dr. Anthony Fauci, one of the architects of the nationwide COVID-19 response, who has since retired.

Though the controversy over stay-at-home orders and mask mandates preoccupied the minds of many early in the pandemic, the deeper, more lasting debate surrounding COVID vaccines may be the most notable distinction between the states.

By the first winter wave of the pandemic, COVID-19 rampaged through swaths of California, sending patients to the hospital in droves, overwhelming Los Angeles' morgues with bodies and prompting officials to issue new stay-at-home orders.

Florida, with its more laissez-faire approach, seemingly saw a less severe winter, prompting supporters to take something of a victory lap.

But over the next year, as Florida officials adopted a more critical view of COVID-19 vaccines, the Sunshine State's fortunes waned. The following summer's surge, fueled by the Delta variant, was particularly deadly -- despite vaccines being widely available.

Given how different California and Florida are -- in terms of the age of their populations, overcrowded housing and the like -- it's hard to establish a definitive scorecard of who handled COVID-19 better in terms of policy. Structural factors may have provided one state an advantage at any point in time.

But in raw terms, significantly more Floridians died on a per capita basis during the COVID-19 emergency than Californians. Of the four most-populous states, California had the lowest cumulative COVID death rate: 2,560 for every 1

million residents. Florida's rate was 60% worse, with 4,044 COVID fatalities for every 1 million residents, according to a Times analysis of Johns Hopkins University data through early March, when the university ended its data tracking.

In other words, Florida's raw death tally -- 86,850 in early March -- came close to California's total, 101,159, despite California having roughly 18 million more residents.

The overall death toll, however, may not tell the whole story.

When factoring in demographics, another estimate has Florida with an age-adjusted COVID mortality rate that's only slightly higher than California's.

And when adjusting for how Florida's population is relatively unhealthier than California's, another estimate actually ranks Florida better.

Such caveats cut both ways, though. The pandemic revealed just how rapidly COVID can carve through overcrowded settings. That proved to be a big vulnerability in California, particularly in Los Angeles County, where more homes are overcrowded than in any other large U.S. county, according to a Times analysis of census data published last year.

And Florida's status as a state with one of the oldest populations in the country might have, counterintuitively, prevented the coronavirus from spreading as quickly in the pre-vaccine era. Many of Florida's seniors may have strictly avoided gatherings during that first winter while younger, restriction-weary Californians could have been more apt to travel, socialize and potentially pass the virus to more vulnerable family members.

DeSantis' message on COVID shots evolved from boasting about his state's high vaccination rate among seniors in early 2021 to this year accusing federal agencies of using "healthy Floridians as guinea pigs." He asserted that the latest inoculations "have not been proven to be safe or effective," despite strong evidence cited by the U.S. Centers for Disease Control and Prevention and U.S. Food and Drug Administration that they are.

Some health experts say Florida could've curbed its deadly 2021 summer surge had more younger adults gotten vaccinated and different mitigation policies been implemented.

By mid-June 2021, about 3 in 4 seniors in both Florida and California had completed their primary vaccination series.

But just 43% of Florida's younger adults had completed theirs, compared with 54% in California.

Earlier in the pandemic, only 20% of COVID-19 deaths in Florida were people younger than 65. But that share climbed to 40% during the peak of the Delta wave, according to Jason Salemi, associate professor of epidemiology at the University of South Florida.

"That was an astonishing number," he said.

The lower vaccine uptake in younger adults probably played a role.

"It didn't need to be as bad as it was -- because I felt like if we would have all kind of read the tea leaves and seen what was happening and started to ... do [more] mitigation efforts ... I think it would have resulted in a much lower morbidity and mortality rate during the Delta wave," he said.

As documented by Florida journalists, DeSantis changed his tone on COVID vaccines by spring 2021 and since has elevated voices skeptical of them.

Florida had an enviable early-vaccination rate among its seniors.

But when it came to boosters -- which first became available in fall 2021 -- the state had one of the nation's worst coverage rates for older adults by the end of the pandemic emergency in spring 2023.

By early 2022, as the highly infectious Omicron variant spawned what eventually would prove the second-deadliest surge of the pandemic nationally, 69% of California's seniors had received their first booster, compared with 59% of Florida's seniors, according to data from the CDC.

As of early May, 48% of California's seniors had received an updated booster formulated specifically to combat Omicron, compared with 31% of Florida's seniors.

Since DeSantis' shift on vaccines, Florida's cumulative COVID death rate began climbing at a faster pace than California's -- a pattern that continued through the end of the pandemic emergency in May.

That shift accelerated after DeSantis appointed a new health secretary and surgeon general, Dr. Joseph Ladapo, who has issued a number of recommendations and statements that have been roundly criticized by other medical officials and experts.

The CDC and FDA went so far as to write an extraordinary public letter rebuking some of Ladapo's claims -- such as his recommendation that young men not receive mRNA vaccines because of an increased risk of cardiac complications. The CDC and FDA said the assertion was "incorrect, misleading and could be harmful to the American public" and said the risk of stroke and heart attack are actually lower in vaccinated people, not higher.

Ladapo reiterated his critical stance on the latest COVID-19 vaccine formulation in September and recommended against the shots for those younger than 65. That defied official federal recommendations, which called for virtually everyone 6 months and older to get an updated vaccination this autumn.

COVID-19 continues to pose a "risk at all age groups," CDC Director Dr. Mandy Cohen said in an interview with "In the Bubble With Andy Slavitt" when asked about Florida's recommendations. "We also see a very safe vaccine."

California health officials have defended their approach to the pandemic as appropriately rooted in science, and ultimately effective.

"Do I think California did better than Florida? I think your crude numbers show that we did," said Dr. Mark Ghaly, California's health and human services secretary.

California and Florida had similar cumulative COVID-19 death rates in the first few months of the pandemic. But Florida's rate accelerated faster starting in summer 2020 as the state more quickly loosened restrictions.

California saw its own cumulative death rate rise at a faster pace than Florida's during the first pandemic winter, and the gap between the two states narrowed. Still, for virtually the entire pandemic, California's cumulative death rate has remained below Florida's.

A Times analysis of the unadjusted COVID mortality rate, based on the Johns Hopkins University tally, shows that Florida had the highest rate of the four most populous states -- and the 12th-worst of the 50 states. California's rate was 11th lowest of all states.

A separate calculation, which adjusts for age in a database run by the CDC, had Florida with a slightly worse ranking than California -- the 34th-highest age-adjusted COVID mortality rate versus the 38th-highest.

A third analysis, published in the medical journal the Lancet this year, looked at COVID-19 death rates through the end of July 2022 and calculated Florida as having a 43% worse unadjusted death rate than California. But when adjusted for differences in age, the gap was narrower -- with a 12% worse death rate in Florida. When also factoring in how Florida's population as a whole is unhealthier than California, in addition to the age adjustment, the roles reversed and California had a 34% worse adjusted death rate.

But California and Florida may be outliers. A broader look at data from the Lancet report shows that states in the South, Southwest and Rocky Mountains had worse COVID death rates, even when adjusted for age and health conditions, than the Northeast and Pacific Northwest.

"Our results suggest that vaccine coverage is linked to fewer COVID-19 deaths, and protective mandates and behaviors were associated with fewer infections," the Lancet analysis said. "The states that implemented and maintained more mandates were statistically associated, on average, with higher mask use and greater vaccine coverage rates, which in turn were associated with fewer infections."

Generally, the Lancet analysis found that poverty, lower educational attainment, higher rates of chronic health conditions, limited access to quality healthcare services and lower rates of "interpersonal trust" -- trust that people have in one another -- were statistically associated with worse COVID-19 mortality rates.

Some experts are wary about comparing death rates, given how vastly different states can be. Any state-level analysis may also paper over regional differences -- L.A. County's death rate, for instance, was much higher than the San Francisco Bay Area's.

The University of South Florida's Salemi called such comparisons "apples and oranges."

"There's so many factors at play that help a county or state navigate a pandemic. ... It's not just about these policies, it's not just about vaccination uptake -- although all of those things certainly matter. It's just such a challenging thing to isolate the independent effect of each," Salemi said.

In terms of overall judgment of policymakers in how they tried to tackle the COVID crisis, Dr. Robert Wachter, chair of the Department of Medicine at UC San Francisco, said he thought California was following the scientific evidence "better than many other states, including Florida."

"When you looked at the early curves of death rates, it was substantially lower in California than in many other states. I think a lot of lives were saved at that stage," he said.

There's lately been a lot of viewing the issue in hindsight, with some questioning whether the tough measures early in the pandemic were an overreaction, Wachter said. But generally, he said, "I don't know how you say that when you have well over a million Americans that have died."

Had Florida been in a vaccine-skeptical mood earlier, "there would be many, many, many more deaths in Florida," Wachter said. "So I'm grateful that -- in part because my mother lives there, and she's older -- that the early message at least was in keeping with what the science tells us to do."

PHOTO: A VISITOR from Florida wears a mask while enjoying the weather on the Santa Monica Pier in 2021.;PHOTOGRAPHER:Al Seib Los Angeles Times

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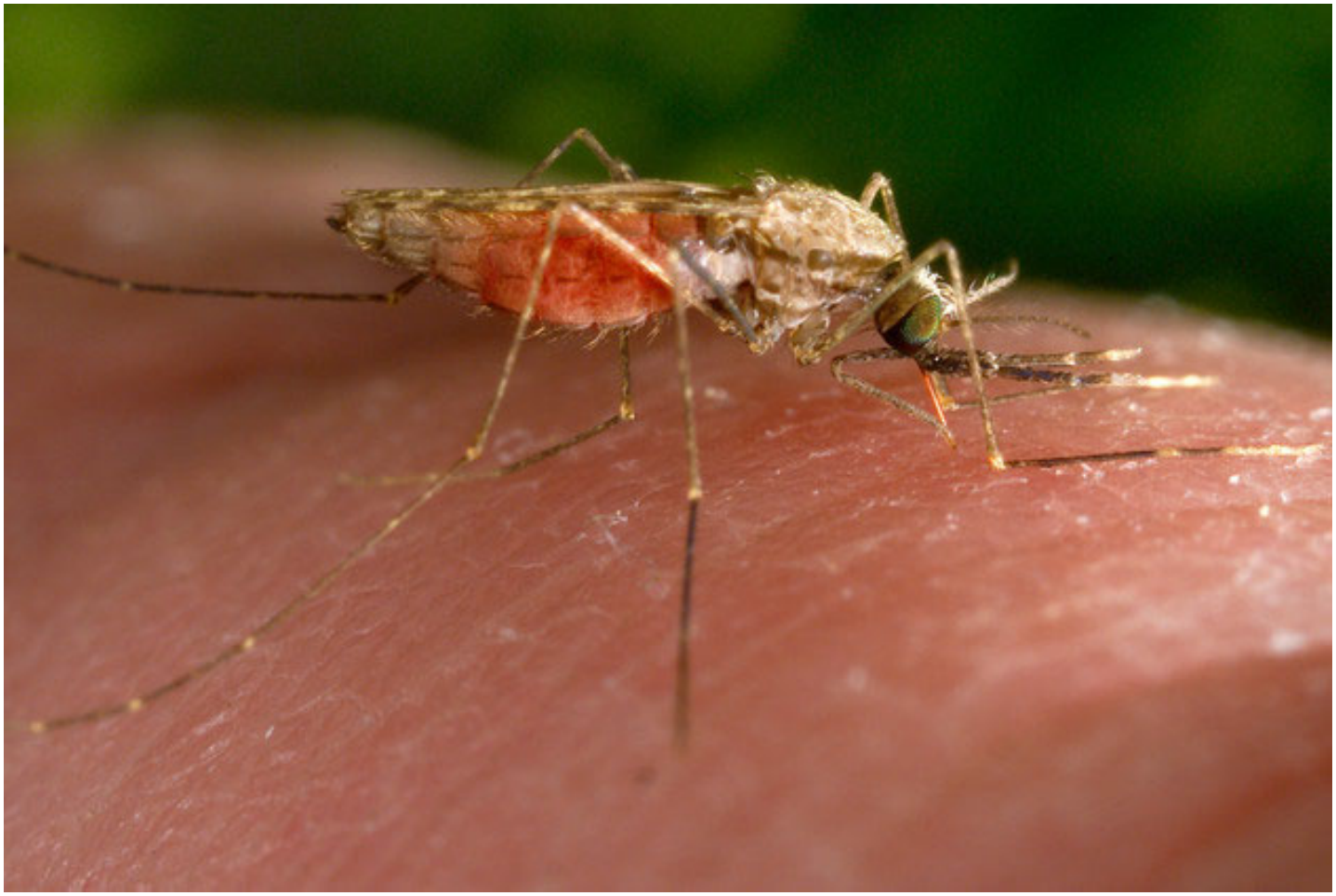
FLORIDA

Florida malaria cases baffle experts

"We regularly had this happen every couple of years before [2003]. So it's almost like, why hasn't this happened?" asked one expert.



It's possible someone contracted malaria while in a foreign country and then unwittingly spread it in America after a local mosquito bit them and then infected someone else. | James Gathany/CDC via AP Photo

By **MIA MCCARTHY**
08/20/2023 07:00 AM EDT

Locally transmitted malaria cases have been essentially non-existent in the United States for 20 years. Then a case popped up in Florida.

Then again. And again.

Incidents of the non-contagious disease — passed on by parasitic mosquitoes — are regularly diagnosed in the U.S., but all are tied to people who are infected when they travel abroad to countries where malaria is present. What makes the Florida and Texas infections so puzzling is that the patients contracted malaria here.

“We don’t think this is going to go into a big nationwide outbreak,” said Dr. Monica Parise, director of the Centers for Disease Control and Prevention’s Division of Parasitic Diseases and Malaria. ”It’s fairly localized and in general, when we’ve had these outbreaks before, they have tended to be quite localized.”

The last time a locally transmitted case of malaria was reported was in 2003, when eight people were diagnosed in Florida’s Palm Beach County. Jae Williams, spokesperson for the Florida Department of Health, said those Palm Beach County incidents are similar to what experts are seeing in Sarasota County now. The same species of malaria, plasmodium vivax, is present in both sets of infections.

Parise said this strain of malaria isn’t the most severe, though seven of the eight people infected this year were hospitalized, possibly in part because Americans have little immunity to it.

But why, after a 20 year absence, did locally transmitted malaria suddenly reappear? The short answer: It’s a mystery.

“We don’t really know why we went a gap of 20 years,” Parise said, adding that there’s no reason why there haven’t been similar cases in the past 20 years.

In the Florida case, it’s possible someone contracted malaria while in a foreign country and then unwittingly spread it in America after a local mosquito bit them and then infected someone else by biting them. About 2,000 travel-related malaria cases are identified in the U.S. every year, the CDC reports.

studies mosquitos said. “We don’t know the answer to that question yet.”

Stoddard, a former mayor of South Miami, said either people are getting bitten more by anopheles — the mosquito species that carry malaria — or there is more malaria present. He said he suspects more people nowadays are traveling to countries where malaria is endemic, such as Colombia. Florida is home to a large number of people with ties to Haiti, Venezuela, Nicaragua and other Latin American and Caribbean countries who often travel back and forth.

Homegrown malaria, more to come

BY **DANIEL PAYNE** | JUNE 29, 2023 10:00 AM

“We regularly had this happen every couple of years before [2003],” Parise said. “So it’s almost like, why hasn’t this happened?”

Climate change could also be indirectly increasing the chances of malaria cases in Florida. While rising temperatures may not directly correlate to more incidents of malaria, temperature and humidity changes can affect the lifespan of mosquitoes.

“We certainly know how [climate change] can have effects on both the mosquitoes as well as the development of the parasite in the mosquito,” Parise said.

Stoddard agreed, adding that environmental changes linked to global warming are altering the conditions in which mosquitoes may thrive.

In Florida, climate change is creating a longer wet season, which for Floridians means an expanded mosquito season. However, because these cases occurred in Florida’s regularly scheduled wet season, Stoddard said it seems unlikely to him that climate change was a factor in this outbreak.

“If you’re seeing malaria in June, it’s not really a longer part of the season yet,” Stoddard said. “If you’re telling me you’re seeing it in October, that’s interesting in terms of climate change.”

Florida’s health department is less focused on the why and more focused on the response which, Williams said, is “pretty textbook": Eradicate the mosquitoes, encourage people to wear clothing that covers them up and drain sitting water.

The cases overall are small compared to outbreaks of previous mosquito disease outbreaks, like dengue or zika, Stoddard said.

Covid-19, which is contagious, has spread more quickly in Florida this summer, state data shows. And in another baffling, unrelated issue, eight people have been diagnosed with leprosy in Central Florida this year, according to Florida’s Health Department. This is out of 15 total cases identified in the United States

it's more common.

"We've had the same number of cases of leprosy in Florida as we have malaria," Stoddard said. "And yet you don't see public health warnings going out telling people not to shake hands or bump elbows."

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ARTICLE NOV 13, 2023

House Republican Budget Threatens Public Education and Opportunity for Young People

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Building an Economy for All, College Affordability and Student Debt, Education +3 More

House Republican leadership's proposed funding bill would vastly cut support for economically disadvantaged students and eliminate important programs in the K-12 education, youth workforce development, and higher education spheres.

Unused desks are seen in an empty classroom at an elementary school in Kentucky, January 2022. (Getty/Jon Cherry)

The U.S. House of Representatives will soon consider a funding bill introduced by Republican leadership that would upend federal investments in public education and workforce programs that are intended to ensure the education system serves young people from all walks of life. Since President Lyndon B. Johnson's Great Society agenda of the 1960s—a defining effort to tackle poverty and increase opportunity—the federal government has invested in supporting the growth of the youngest minds through Head Start; providing equitable funding and highly skilled teachers to economically disadvantaged K-12 schools and their students; making higher education affordable for low-income students; and funding workforce training for youth who face barriers to employment. While there is still work to be done to achieve a truly great, more equitable society, these programs have undergirded nearly 60 years of social mobility, economic prosperity, and global competitiveness.

The proposed education funding plan jeopardizes this progress.

This column details some of the proposed funding bill's most significant cuts to K-12 education, youth programming, and higher education. If these cuts are

enacted, they will rob a generation of the opportunity to participate in the American dream.

The bill would eliminate funding for economically disadvantaged schools and students

Title I of the Elementary and Secondary Education Act (ESEA) is the bedrock federal investment in K-12 education, and House Republicans' proposal to cut it by $14.7 billion—nearly 80 percent—would leave low-income children and children of color with a vastly inferior public education by greatly increasing existing resource and achievement gaps.

Much of the funding for U.S. K-12 schools comes from the local level—and this produces extreme inequities by community wealth. When Congress passed the ESEA in 1965 as part of the Great Society agenda, the goal of Title I was—as it remains—to "provide all children significant opportunity to receive a fair, equitable, and high-quality education, and to close educational achievement gaps."

Currently, Title I supports the education of more than 26 million children, or more than one-third of U.S. students. Across the country, 3 in 4 students who identify as American Indian or Alaska Native, Black, and/or Latinx attend Title I schools. The proposed funding cut would force Title I schools to lay off up to 226,000 teachers, aides, and other staff members despite widespread and ongoing teacher shortages.

House Republicans have said pandemic-era investments made through Elementary and Secondary School Emergency Relief (ESSER) funds should be depleted before Congress approves Title I funding. Title I funds, however, are meant to support underfunded schools year in and year out, while ESSER funds were a one-time infusion to help schools combat the COVID-19 pandemic's disruption to learning. In light of the pandemic's persistent effects on students, schools were given several years to spend EESER funding in order to make the best possible use of it.

Supporters of defunding Title I have also said the funds disproportionately benefit urban schools. Although urban districts in most states do typically receive greater Title I funding per pupil than their suburban and rural counterparts, a good-faith effort to solve these disparities would direct additional funding to rural areas rather than slashing funds for all schools. House Republicans have also framed the proposed cuts as a response to the significant decrease in scores on the National Assessment of Educational Progress, despite research showing that targeting increased funding to low-income schools improves student performance.

In another move that would deepen inequality, House Republicans have proposed a $35 million—or 25 percent—cut to the U.S. Department of Education's Office for Civil Rights (OCR), according to CAP calculations. This would severely curtail the OCR's ability to investigate instances of discrimination and ensure that all students have equal access to education. In fiscal year 2022 alone, the office resolved 16,515 cases of potential civil rights violations, protecting students across the country from discrimination based on race, religion, gender, sexual orientation, age, disability, and language ability.

The bill would eliminate funding for teacher and principal supports

Schools are nothing without teachers and principals who can offer the level of expertise and professionalism—not to mention sheer manpower—that it takes to nurture young minds. Investing in the ongoing development of educators is vital to increasing students' academic achievement and preparing them for the future.

The proposed funding bill would eliminate funding for Title II-A of the ESEA, which provides funding for preparing, training, and recruiting high-quality teachers, principals, and other school leaders through Supporting Effective Instruction State Grants. States and districts use these grants to provide professional development for educators, recruit and retain effective teachers and principals, reduce class sizes, and provide support for new teachers. One of the primary purposes of these funds is to give low-income students and students of color greater access to effective educators. To achieve this, states and districts use the funds to provide educators professional development specific to serving low-income students and students of color, to examine the equitable distribution of educators, and to implement strategies to improve within-district teacher equity.

In 2023, all 50 states, plus Washington, D.C., and Puerto Rico, were awarded a total of $2.19 billion in these grants, which helped fund programs including school leader mentoring and coaching models in Ohio, professional development to support students with disabilities in North Carolina, and partnerships to improve teacher preparation and increase the number of educators in Nevada.

Eliminating funding for Title II-A grants would mean eliminating many of these programs and could lead to hiring freezes, further exacerbate the teacher shortage, and ultimately stall academic recovery.

Since 1965, states have relied upon federal teacher development grants to increase student achievement. Ending them would be particularly devastating at a moment when the COVID-19 pandemic has exacerbated preexisting teacher workforce shortages. As of August 2023, estimates point to at least 55,000 teacher vacancies across the country, a 51 percent increase from last year. As levels of stress and burnout among teachers rise, teachers report feeling underpaid, overworked, and without adequate support. Furthermore, due to high turnover rates, more new teachers and principals are entering schools and in need of training.

Professional development not only benefits new teachers but also provides opportunities for veteran teachers to learn new technologies, curricula, and teaching methods and continue to hone their skills. The opportunities provided under Title II-A have been shown to increase teacher retention and better prepare teachers for the classroom, as well as enhance the recruitment of new teachers and principals.

The bill would eliminate funding for English learners

House Republicans also are proposing to eliminate a program aimed at the more than 5 million English learners who make up 10 percent of the total K-12 student population. Title III of the ESEA, also referred to as English Language Acquisition, seeks to ensure that English learners attain English proficiency and reach high levels of academic achievement. It does this by assisting teachers, principals, and other school leaders in providing effective programs for these students and promoting parental, family, and community participation in language instruction educational programs. With Title III funding, districts are

able to provide English learners with the resources necessary to meet the state academic standards all students are expected to meet—something that is much more of a challenge for students still mastering English.

Districts that receive Title III subgrants use the funds to implement activities that are rooted in evidence-based research. These may include hiring staff licensed to teach English learners, providing professional development for educators who work with them, and supporting the development and implementation of language instruction educational programs. These programs enable schools to partner with and provide resources to help parents and guardians become active participants in students' education. Resources include English courses for family members, family literacy programs, support groups, and general resources for navigating life in the United States.

Ending the federal allocation of $890 million would cause many of these efforts to disappear. Furthermore, the number of English learners in the United States is on the rise. While graduation rates for this population have increased in recent years, they still lag behind the national average. These students also are less likely to attend or complete college than their English-proficient peers, showing a possible need for further investment.

The bill would eliminate funding for youth workforce development

House Republicans are also proposing to eliminate the federal allocation of more than $948 million for the youth program in Title I of the Workforce Innovation and Opportunity Act (WIOA). Although the WIOA was first enacted in July 2014, its youth funding provisions have roots in the Comprehensive Employment and Training Act, signed into law by President Richard Nixon in 1973. The WIOA youth program serves young people ages 16 to 24 who face barriers to employment, including English learners, youth from low-income backgrounds or foster care, young people experiencing homelessness, and more.

Over the 2021–2022 program year, about 125,000 young people across the country participated in the program. Some attended tutoring programs or skills training, while others participated in pre-apprenticeship or internship programs or received comprehensive counseling to prepare them for higher education and the workforce. If federal funding were eliminated, all these local programs would be at risk of closure. Communities would suffer as a result: Evidence shows that youth employment programs provide critical skills, improve lifetime earnings, and reduce interactions with the legal system.

The impacts of these cuts would fall squarely on the nation's most disadvantaged youth. In the 2021–2022 program year, 85 percent of participants in the WIOA youth program were from low-income families, while 62 percent were English learners or faced cultural barriers to employment. More than 54 percent identified as individuals of color. About 1 in 5 participants had a disability.

The funding bill also proposes eliminating Job Corps, a $1.76 billion residential program that provides free education and job training, separate from the WIOA youth program, to tens of thousands of youth facing employment barriers. Job Corps dates back to the Great Society agenda and has served more than 2 million individuals since its inception. The program helps combat youth homelessness by offering students free room and board for up to three years. While the program has substantial room for improvement, particularly around ongoing safety and security concerns, it remains critical to helping disadvantaged youth join the workforce and establish a career.

The bill would cut need-based financial aid programs for college students

Similarly, the House budget proposal would deepen the crisis of college unaffordability. Appropriators seek to eliminate the $1.23 billion Federal Work-Study Program, which in 2022 subsidized on- and off-campus jobs for more than 600,000 students. While the program could do a significantly better job targeting Work-Study jobs to students' career goals, the jobs it offers are nevertheless much more likely to be clerical, managerial, or professional than are the jobs, frequently in the service sector, that students otherwise use to support themselves. This helps boost students' post-college opportunities. Students must demonstrate financial need in order to participate in the Work-Study program. Evidence suggests that students who do participate see improved graduation rates and career outcomes.

Also facing the threat of elimination is the Federal Supplemental Educational Opportunity Grant (FSEOG) Program, which provides $910 million per year to support grants for 1.7 million students. Priority is given to students with the lowest expected family contributions, and 80 percent of recipients either come from families earning below $30,000 per year or are independent and more likely to be low income.

Both of these forms of need-based aid would benefit from updated formulas to better target students attending broad-access institutions. In contrast, eliminating them would add to the already substantial barriers college students must overcome to reach graduation. Some students likely would be pushed off the path to graduation altogether, while others would be forced to borrow more in student loans—adding to the student debt crisis of $1.6 trillion. Both these things would make it more difficult for young people to pursue their dreams, such as launching new businesses and starting families.

The House Republican budget also proposes cutting funding for student aid administration by 13 percent—or nearly $265 million. Student aid administration is a critical government service that manages student loan repayment and $111.6 billion in federal student aid. This will hinder the efforts of the Department of Education to implement a simplified Free Application for Federal Student Aid (FAFSA); to improve the inadequate loan servicing system that too often impedes borrowers' abilities to pay off their loans; and to weed out waste, fraud, and abuse of student aid dollars.

Conclusion

Federal programs that support K-12 students, underserved youth, and college affordability deserve updates and improvements in some cases, as well as greater investment across the board. Congress must reject the House Republican budget in order to ensure that America's future remains bright.

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Labor, Health and Human Services, Education, and Related Agencies

Rules Committee Print for H.R. 5894 | Explanatory Materials for H.R. 5894

The 2024 Labor, Health and Human Services, Education, and Related Agencies funding bill provides $163.0 billion, a cut of $63.8 billion – 28 percent – below 2023. This year's Republican allocation was the lowest for the Labor, Health and Human Services, Education, and Related Agencies bill since 2008. This legislation:

- **Decimates support for children** in K-12 elementary schools and early childhood education.
- **Abandons college students and low-income workers** trying to improve their lives through higher education or job training.
- **Stifles lifesaving biomedical innovation** by cutting funding for cancer research, mental health research, and neurological research, and by slashing funding for advanced research projects intended to develop new cures and therapies.
- **Surrenders to ongoing public health crises** in mental health, opioid use, HIV/AIDS, and health disparities.
- **Harms women's health** by cutting programs that support maternal and child health, eliminating programs that provide access to health services and contraception, and adding numerous partisan and poison pill riders related to abortion and reproductive health.

State-by-state resources on how this bill denies education and training opportunities for students and job seekers at all stages of life are here.

Key provisions of the bill:

Department of Education (ED) – The bill includes a total of $57.1 billion in discretionary appropriations for ED, a cut of $22.5 billion – 28 percent – below the FY 2023 enacted level. Of this amount:

- The bill includes $3.7 billion for **Title I Grants to Local Educational Agencies**, a cut of $14.7 billion below the FY 2023 enacted level. This cut could force a nationwide reduction of 220,000 teachers from classrooms serving low-income students.
- The bill eliminates funding for **English Language Acquisition**, a cut of $890 million that would remove vital academic support for 5 million English learners nationwide.
- The bill eliminates funding for **Title II-A (Supporting Effective Instruction State Grants)**, a cut of $2.2 billion below the enacted level.
- The bill eliminates funding for **Promise Neighborhoods**, a cut of $91 million below the enacted level.
- The bill eliminates funding for **Social and Emotional Learning (SEL) grants** within the Education Innovation and Research program, a cut of $87 million below the enacted level.
- The bill eliminates funding for **Magnet Schools**, a cut of $139 million below the enacted level.
- The bill includes $100 million for **Full-Service Community Schools**, a cut of $50 million below the enacted level.
- The bill fails to provide an increase for the maximum **Pell Grant** award for the first time since 2012.

- The bill eliminates funding for **Federal Work Study**, a cut of $1.2 billion that would eliminate work-based assistance to 660,000 students nationwide
- The bill eliminates funding for **Federal Supplemental Educational Opportunity Grants**, a cut of $910 million that would eliminate need-based financial aid for 1.7 million students nationwide
- The bill includes $1.8 billion for **Student Aid Administration**, a cut of $265 million below the enacted level.
- The bill eliminates funding for **Teacher Quality Partnerships**, a cut of $70 million below the enacted level.
- The bill eliminates funding for **Child Care Access Means Parents in School**, a cut of $75 million below the enacted level.
- The bill eliminates funding for **Hawkins Centers of Excellence**, a cut of $15 million below the enacted level.
- The bill eliminates funding for **HBCU, TCU, and MSI Research and Development Infrastructure Grants**, a cut of $50 million below the enacted level.
- The bill includes $105 million for the **Office for Civil Rights**, a cut of $35 million below the enacted level.

Department of Labor (DOL) – The bill includes a total of $9.1 billion in discretionary appropriations for DOL, a cut of $4.7 billion – 34 percent – below the FY 2023 enacted level. Of this amount:

- The bill eliminates funding for **WIOA Adult Job Training** state grants, a cut of $886 million that would eliminate job training and employment services for 300,000 adults who face barriers to employment.
- The bill eliminates funding for **WIOA Youth Job Training** state grants, a cut of $948 million that would eliminate job training and employment services for 128,000 youth who face barriers to employment.
- The bill eliminates funding for **Job Corps**, a cut of $1.8 billion that would eliminate job training and employment services for 50,000 youth who face barriers to employment.
- The bill eliminates funding for the **Senior Community Service Employment Program**, a cut of $405 million that would eliminate community service positions for more than 40,000 low-wage seniors.
- The bill includes $1.4 billion for the **Worker Protection Agencies** at the Department of Labor, a cut of $313 million below the enacted level, including—
    - $153 million for the **Employee Benefits Security Administration**, a cut of $38 million below the enacted level.
    - $185 million for the **Wage and Hour Division**, a cut of $75 million below the enacted level.
    - $537 million for the **Occupational Safety and Health Administration**, a cut of $95 million below the enacted level.
- The bill includes $98 million for the **Office of the Solicitor**, a cut of $33 million below the enacted level.
- The bill eliminates funding for the **Bureau of International Labor Affairs (ILAB)**, a cut of $116 million below the enacted level.
- The bill eliminates funding for the **Women's Bureau**, a cut of $23 million below the enacted level (including the elimination of the Women in Apprenticeship & Nontraditional Occupations program).

Department of Health and Human Services (HHS) – The bill includes a total of $103.7 billion for HHS, a cut of $17.4 billion – 14 percent – below the FY 2023 enacted level. Of this amount:

- **National Institutes of Health (NIH) –** The bill includes a total of $44.6 billion for NIH, a cut of $2.8 billion below enacted level, including:

- $7.1 billion for the **National Cancer Institute** (NCI), a cut of $216 million below the enacted level.
- $2.7 billion for the **National Institute of Neurological Disorders and Stroke** (NINDS), a cut of $139 million below the enacted level.
- $2.2 billion for the **National Institute of Mental Health** (NIMH), a cut of $139 million below the enacted level.
- $5.1 billion for the **National Institute of Allergy and Infectious Diseases** (NIAID), a cut of $1.5 billion below the enacted level.

- **Advanced Research Projects Agency for Health (ARPA-H) –** The bill includes $500 million for ARPA-H, a cut of $1 billion below the enacted level.
- **Centers for Disease Control and Prevention (CDC)** – The bill includes a total of $7.6 billion for CDC, a cut of $1.6 billion below the enacted level.
  - The bill eliminates funding for **Firearm Injury and Mortality Prevention Research**, a cut of $12.5 million below the enacted level.
  - The bill eliminates funding for **Tobacco Prevention and Control**, a cut of $247 million below the enacted level.
  - The bill eliminates funding for the **Ending the HIV Epidemic initiative**, a cut of $220 million below the enacted level.
  - The bill includes $100 million for **Public Health Infrastructure and Capacity**, a cut of $250 million below the enacted level.
  - The bill includes $75 million for **Public Health Data Modernization**, a cut of $100 million below the enacted level.
  - The bill includes $371 million for **Global Health**, a cut of $322 million below the enacted level.
  - The bill eliminates funding for the **Climate and Health program**, a cut of $10 million below the enacted level.
  - The bill eliminates funding for the **Center for Forecasting and Analytics**, a cut of $50 million below the enacted level.
- **Substance Abuse and Mental Health Services Administration (SAMHSA) –** The bill funds SAMHSA at $7.1 billion, a cut of $234 million below the enacted level.

- **Health Resources and Services Administration (HRSA)** – The bill includes $7.3 billion for HRSA, a cut of more than $700 million below the enacted level. (The comparison does not include Community Project Funding included in the FY 2023 enacted bill.)
  - The bill eliminates funding for **Title X Family Planning**, a cut of $286 million below the enacted level.
  - The bill includes $781 million for the **Maternal and Child Health Block Grant**, a cut of $35 million below the enacted level.
  - The bill eliminates funding for **Healthy Start,** a cut of $145 million below the enacted level.
  - The bill eliminates funding for the **Ending HIV Epidemic initiative**, a cut of $322 million below the enacted level.
  - The bill eliminates funding for multiple programs to support diversity in the healthcare workforce, including—
    - **Health Careers Opportunity Program** ($16 million)
    - **Centers of Excellence** ($28 million)
    - **Nursing Workforce Diversity** ($24 million)

- **Agency for Healthcare Research and Quality (AHRQ) –** The bill eliminates funding for AHRQ, a cut of $374 million below the enacted level.
- **Centers for Medicare & Medicaid Services (CMS) –** The bill includes a total of $3.3 billion for CMS administrative expenses, a cut of $798 million below the enacted level.
- **Administration for Children and Families (ACF)** – The bill provides $28.3 billion for ACF, a cut of $4.8 billion below the enacted level.
    - The bill includes a total of $11.2 billion for **Head Start**, a cut of $750 million below the enacted level. This cut would result in more than 50,000 children losing access to Head Start programs.
    - The bill eliminates funding for **Preschool Development Grants**, a cut of $315 million below the enacted level.
    - The bill includes $457 million for refugee programs, including **Transitional and Medical Services** and **Refugee Support Services**, a cut of $414 million below the enacted level.
    - The bill includes $2.25 billion for the **Unaccompanied Children** program, a cut of $3.3 billion below the enacted level.
- **Administration for Community Living (ACL) –** The bill includes $2.5 billion for ACL, a cut of $22 million below the enacted level.
- **Office of the Secretary—General Departmental Management** – The bill includes $344 million for GDM, a cut of $258 million below the enacted level.
    - The bill eliminates funding for the **Teen Pregnancy Prevention Program**, a cut of $108 million below the enacted level.
    - The bill includes $26 million for the **Office of Minority Health**, a cut of $49 million below the enacted level.
    - The bill includes $28 million for the **Minority HIV/AIDS Initiative**, a cut of $32 million below the enacted level.
    - The bill includes $20 million for the **Office on Women's Health**, a cut of $24 million below the enacted level.

Related Agencies –

- The bill eliminates funding for the **Corporation for Public Broadcasting**, a cut of $595 million below the enacted level.
- The bill includes $661 million for the **Corporation for National and Community Service**, a cut of $652 million below the enacted level.
- The bill includes $200 million for the **National Labor Relations Board**, a cut of $99 million below the enacted level.
- The bill includes $13.8 billion for the **Social Security Administration**, a cut of $183 million below the enacted level.

Policy Riders –

- The bill includes multiple policy riders to block the Department of Labor from implementing regulatory changes that would improve working conditions for workers in various industries.
- The bill includes a prohibition on funding to conduct or support research using fetal tissue.
- The bill includes a prohibition on funding for Planned Parenthood health centers.
- The bill includes multiple policy riders to block access to abortion services or reproductive healthcare services.

- The bill includes multiple policy riders to block the Biden Administration's policies to ensure nondiscrimination on the basis of gender identity or sexual orientation.
- The bill includes a rider to amend the Public Health Service Act to create a right to monetary damages in a civil action for a violation of the Weldon amendment (which allows health care providers to discriminate against patients by refusing to provide, pay for, cover, or refer for abortion).
- The bill includes a rider to block the Department of Education from issuing a final rule to prevent sex discrimination and sex-based harassment at schools or a final rule to clarify how all students can participate in athletics.
- The bill includes multiple riders to block the Department of Education from implementing regulations related to student loans and income-driven repayment.
- The bill includes a rider to prevent the NLRB from implementing a rule related to Joint Employer status.
- The bill includes a rider to block funding related to Critical Race Theory.
- The bill includes multiple riders to prevent policies or programs intended to promote diversity, equity, or inclusion.
- The bill includes a rider to block funding to take action against a person who opposes marriage equality.
- The bill includes a rider to limit which flags can be flown over a federal facility.

Congress of the United States
Washington, DC 20515

November 29, 2023

The Honorable Mandy K. Cohen, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
395 E Street SW
Washington, DC 20024

Dear Director Cohen,

We write to you today out of concern for the health and well-being of many of our youngest and most vulnerable constituents. Over the last few months, we have consistently heard from constituents, ranging from parents to county health officials to pediatricians, regarding the ongoing barriers to accessing pediatric vaccines. Specifically, we have heard concerns about access to the updated COVID-19 vaccine for children under age three, the new respiratory syncytial virus (RSV) immunization for infants and toddlers, and the maternal RSV immunization for use during pregnancy.

We are currently in the midst of another season where various respiratory viruses are circulating and continuing to pose threats to our childrens' health and well-being. Since the onset of the COVID-19 pandemic, there have been over 15 million cases among children in the U.S. These cases also tend to surge during the winter months. Additionally, RSV poses severe threats to pediatric health in particular, as it is the leading cause of hospitalizations of infants less than a year old, and as many as 300 children under age five die due to RSV infection each year. With the invention and promotion of life-saving vaccines, such as the COVID-19 vaccine and RSV immunization, children and their families have the ability to safeguard their health against such potentially dangerous infections. However, they can only protect their health if these vaccines are readily available.

We are incredibly concerned by reports of inaccessibility of the updated COVID vaccine this fall. We have personally heard stories from parents and pediatricians about their struggles to access such vaccines in our respective states, as well as nationwide. For instance, Heather from Delmar, New York, contacted Congressman Tonko and shared that she had been trying to find a vaccine for her two-year-old child, but there were no available options. Their pediatrician did not have the vaccine, and her local pharmacies would only vaccinate children over three years old. Additionally, the closest location that would offer the vaccine to children under three was nearly two hours away in Hartford, Connecticut. She shared, "I would appreciate anything you can do, locally and/or nationally, to expedite the availability of COVID vaccines for our youngest residents. They deserve the same protection available to the rest of us, and we have a duty to ensure that they receive it." We could not agree more.

Unfortunately, this is not an isolated experience. A mother from Glenville, New York had a similar experience and struggled to find a nearby COVID vaccine for her baby with the closest availability being over an hour away in Vermont. Another mother from Albany, New York was

told by their pediatrician that they would have to wait until after the new year for COVID vaccines to be available for her toddler. However, these barriers to access are not limited to only the COVID vaccine.

We are also hearing concerning reports about the inability to access RSV immunizations for babies, toddlers, and pregnant individuals. We are aware that there is a shortage of the immunizations specifically affecting infants, toddlers, and pregnant individuals. A mother from Albany, New York shared that her toddler has asthma and is considered at a more severe risk for infection complications, yet the immunization is not available locally for her son. These are just a few of the anecdotes that have been relayed to us from our constituents, and it is concerning to estimate just how many more Americans are experiencing these barriers. Whether the barriers come from confusion, misinformation, cost and/or insurance coverage, shortages, or other limitations, we need to properly identify these barriers and ensure that we apply the lessons learned and knock out every barrier.

We are heartened that the Administration is taking steps to inform the public and roll out these vaccines in a timely manner while addressing supply issues. However, we urge more scrutiny over what can be done to make these life-saving vaccines more accessible for our nation's youngest.

With that goal in mind, please provide answers to the questions below:

1) Has the Centers for Disease Control and Prevention (CDC) assessed pediatric vaccine availability by different geographic regions in the country? If so, what are the differences by region? Which regions are still experiencing the largest gaps in vaccine access?
2) What steps is CDC implementing to improve vaccine access for our youngest children? Is CDC coordinating with other agencies to this end?
3) What steps is CDC implementing to improve vaccine access for pregnant individuals? Is CDC coordinating with other agencies to this end?
4) What is CDC doing to collaborate with pediatricians, pharmacists, and local health departments to assist them in delivering these newer vaccines to the community? Is CDC taking any specific steps on this for those under three years old?
5) Has CDC identified barriers to pediatric vaccine access that the agency can directly address? If so, what are these barriers? Which of these actions can be assisted through legislation, funding, or other actions from Congress?
6) Has CDC identified barriers to RSV immunization access for pregnant individuals that the agency can directly address? If so, what are these barriers? Which of these actions can be assisted through legislation, funding, or other actions from Congress?
7) For both populations, has CDC identified barriers that the agency cannot directly address? If so, what are these barriers? Which of these can be assisted through legislation, funding, or other actions from Congress?
8) We are hearing reports that there is confusion on whether pregnant individuals require a prescription to receive the RSV immunization at pharmacies and that this has led to delay or denial of access to the RSV immunization. Is CDC aware of this concern, and if so, how has the agency coordinated with providers and pharmacies to address this confusion?

9) Given the recurring pediatric vaccine shortages, what actions is CDC taking to ensure improved pediatric vaccine accessibility in future years?
10) Is CDC aware of any local health agencies that have struggled with funding since the end of the public health emergency? How could additional funding for these local agencies assist pediatric vaccine availability?
11) What is the agency doing to provide information to pregnant individuals about the RSV vaccine options? Has there been any confusion about safety?
12) Are there any other opportunities for federal coordination on pediatric vaccine accessibility?

Our nation's children are at risk, and we owe it to them to ensure that we do everything in our power to protect them and their families. We appreciate your attention to this matter. Thank you in advance, and we look forward to a response.

Sincerely,

Paul Tonko
Member of Congress

Kim Schrier, M.D.
Member of Congress

Yadira Caraveo, M.D.
Member of Congress

Table. Instances of numerical and statistical errors in CDC reporting of COVID data

	Claim/Statement	Error	Source of Error	Risks	Children-or-adult-specific data	CDC Notified	CDC Corrected
2021							
Feb 26	*MMWR stated that during the study period, the 7-day moving average of cases identified by PCR or antigen testing ranged from 152 to 577 cases*[19]	**Multiple errors. Reported case rates during the study period were described as a 7-day moving average of cases per 100,000 persons including PCR and antigen cases, but the paper actually reported the raw 7 day moving average (without adjusting for population) and for PCR only (not including antigen tests)**[20]	MMWR	Exaggerated	Children	Yes	Yes
Jul 26	*Delta Variant is as contagious as chicken pox*[9]	**Delta is not as contagious as varicella. The CDC overstated Delta R0 and understated chicken pox R0 (Delta estimate was overlaid directly on a New York Times graphic)**	CDC slide deck	Exaggerated	Both	No	No
Jul 27	*4% of COVID-19 deaths are in children 0-17*[8]	**Actual number was 0.04% based on original CDC estimated data. When the estimated data were updated later, the percentages were not updated. The actual percentage based on the updated data was 0.07%.**	COVID-19 website	Exaggerated	Children	Yes	Yes
Oct 15	*"COVID-NET data for the week ending Sept. 25 show that rates of COVID-19-associated hospitalizations in children ages 5–11 years are the highest they've been."*[21]	**COVID-NET hospitalizations were already falling from Sept peak. Rate was 1.1 week ending Sept. 11 and Sept. 25. (Now week of Sept. 11 shows 1.2)**[22]	Twitter @CDCgov	Exaggerated	Children	No	No
Oct 27	*CDC Director Walensky said "there have been 745 deaths in children less than 18."*[23]	**As of 10/27/21, NCHS data showed 558 deaths with COVID-19. Final NCHS data shows 679 pediatric deaths with COVID-19 through Oct. 30, 2021**[24]	White House Press Briefing	Exaggerated	Children	No	No
Nov 8	*Among ages 0-17, CDC's reported rate of symptomatic illness was less than the total infection rate (asymptomatic + symptomatic – an impossible claim), and this error occurred among children (infection rate also fell only for children from May 21 to Sept 21 estimates)*[17,25]	**Estimated infection rate was 35,490 per 100K, not 29,885 per 100K (symptomatic illness remained at 30,253 per 100K)**	COVID-19 website	Neutral	Both	Yes	Partially
Dec 20	*Omicron makes up 73% of new infections in the US*[10]	**Error with Nowcast estimate, a week later, they revised to 23% (outside the previous 95% CI)**	Data Tracker	Exaggerated	Both	No	Yes
2022							
Feb 24	*COVID-19 hospitalizations had a sudden >1.6-fold increase in Georgia per HHS/CDC data*[26]	**Very likely a dramatic multi-week increase was due to imputation error on behalf of the reporting state or municipality, yet this was not audited or detected**	Data Tracker	Exaggerated	Both	Yes	Yes
Mar 15	*Pediatric deaths on the Data Tracker demographics page were overstated while adult deaths were understated*[8]	**On 3/15/22, CDC removed 416 pediatric deaths from Data Tracker from 1755 to 1339 (still overstated) and almost 72,000 adult deaths, blaming an algorithm for classifying deaths as COVID-19 related**	Data Tracker	Mixed	Both	Yes	Partially
Jun 17	*COVID-19 is a top 5 cause of death in children of all age groups*[27]	**Pre-print had inaccurate data, and CDC chose the most extreme version of the flawed data. Specifically, for COVID-19 they used cumulative counts (which spanned more than 2 years), and death was attributed if it was one of any multiple cause of death, whereas for other causes of death, they used only a single year, and attributed it only if it was the single underlying cause of death)**	ACIP Meeting	Exaggerated	Children	Yes	No
Jun 23	*At a White House COVID-19 briefing, CDC Director Walensky cited the claim that COVID-19 is a "top 5 cause of death" in children*[12]	**Flawed pre-print,**[14] **authors already acknowledged that fact, and COVID-19 was not a top 5 cause of death**	White House Press Briefing	Exaggerated	Children	No	No
Jun 27	*ACIP web site includes the "top 5 cause of death" claim*[15]	**Flawed pre-print,**[14] **authors already acknowledged that fact, and COVID-19 was not a top 5 cause of death**	ACIP website	Exaggerated	Children	Yes	Yes
Aug 9	*COVID-19 has killed 1500 children ages 17 & younger*[28]	**As of 8/10/22, NCHS data showed 1201 deaths with COVID-19. As of 2/5/23, NCHS data shows 1323 pediatric deaths with COVID-19 through August 6, 2022**[24]	Twitter @CDCgov	Exaggerated	Children	No	No
Aug 12	*"COVID-19 hospitalizations for children and teens are increasing again in the U.S."*[29]	**CDC hospitalization data showed hospitalizations had peaked 2 weeks prior, on 7/29/22**	Twitter @CDCgov	Exaggerated	Children	No	No
Aug 22	*Alabama pediatric hospitalizations had a dramatic single week increase from <10/day to >50/day*[30, 13]	**Very likely a dramatic single week increase was due to imputation error on behalf of the reporting state or municipality, yet this was not audited or detected**	Data Tracker	Exaggerated	Children	Yes	Yes
Aug 26	*CDC Data Tracker made a single week jump of 186 pediatric deaths and 1679 adult deaths, which is unusually high for children and unusually low for adults*[31]	**Incorrect death data. CDC corrected this days later, removing 173 pediatric deaths and adding 2484 adult deaths**	Data Tracker	Mixed	Both	Yes	Yes
Sep 1	*ACIP Chair Grace Lee repeated the "top 5 cause of death" claim in ACIP meeting to approve bivalent booster*[7]	**Flawed pre-print**[14] **was corrected two months prior. Unknown if ACIP committee informed**	ACIP meeting	Exaggerated	Children	Yes	No
Nov 9	*Florida pediatric hospitalizations had a dramatic single week increase from 7 to 112 (7-day new admissions)*[32,13]	**Very likely a dramatic single week increase was due to imputation error on behalf of the reporting state or municipality, yet this was not audited or detected**	Data Tracker	Exaggerated	Children	Yes	Yes
Dec 30	*XBB.1.5 variant reported at 41% of new infections in the US*[33]	**A week later they revised to 18% (outside the original 95% CI)**	COVID-19 website	Exaggerated	Both	Yes	Yes
Dec 31	*North Carolina pediatric hospitalizations had a dramatic single week increase from 2 to 19 (7-day new admissions)*[13]	**Very likely a dramatic single week increase was due to imputation error on behalf of the reporting state or municipality, yet this was not audited or detected**	Data Tracker	Exaggerated	Children	Yes	No
2023							
Thru Mar 3	*Data Tracker continues to report too many pediatric deaths and too few adult deaths*[34]	**Inaccurate mortality data by age group is updated weekly on the CDC Data Tracker Demographics page**	Data Tracker	Mixed	Both	Yes	No
Feb 9	*Dr. Walensky testified before Congress that there had been "2000 pediatric deaths from COVID-19"*[35]	**This number comes from the flawed Data Tracker. Actual number is 1400-1500**	Data Tracker/ testimony	Exaggerated	Children	No	No
Jan 13	*Table 2 listed 62 events for children needing medical care as 13.9%*[36]	**It should be 1.9%. It is correct in the text, but not the table**	MMWR	Exaggerated risk of vaccine	Children	Yes	Yes
Feb 23	*ACIP slide claimed 1489 pediatric deaths in ages 6 months - 17 years*[37]	**They did not remove 305 deaths in infants <6 months. Actual number should have been 1184 using the NCHS data source cited on the slide**	ACIP meeting	Exaggerated	Children	No	No
Aug 20	*CDC Excess Mortality Dashboard overstated recent deaths in North Carolina & Connecticut*[38]	**Model for weighting due to death reporting lag was poorly adjusted**	CDC Excess Mortality Dashboard	Exaggerated risk of all-cause mortality	Both	Yes	Yes

ACIP: Advisory Committee on Immunization Practices; CDC: Centers for Disease Control and Prevention; COVID-NET: Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network; Data Tracker: CDC COVID-19 Data Tracker; HHS: Department of Health and Human Services; MMWR: Morbidity and Mortality Weekly Report.

CATHY McMORRIS RODGERS, WASHINGTON
CHAIR

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
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COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225-3641
Minority (202) 225-2927

October 24, 2023

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dr. Cohen,

The accuracy of data at the Centers for Disease Control and Prevention (CDC) must be paramount. As you tweeted on June 12, 2020, prior to becoming CDC Director, "Data-driven decision making first requires high-quality data."[1] Pursuant to Rules X and XI of the U.S. House of Representatives, the committee is investigating potentially misleading and erroneous CDC data related to overcounting how many children died from COVID-19 and whether this problem represents a systemic issue with CDC data.

On July 25, 2023, Majority committee staff posed the following straightforward question to the CDC: "What is the most accurate count that CDC can provide on the number of children and adolescents who have died from COVID?" On August 7, 2023, the CDC emailed the following to Majority committee staff:

> Through the week ending on July 29, 2023, 2,292 children ages 0-17 have died of COVID-19. This information continues to be available on CDC's COVID Data Tracker. Since the end of the public health emergency, the National Vital Statistics System (NVSS) death certificate data are the primary source for COVID-19 mortality data.

[1] Tweet from Dr. Mandy Cohen (copy of tweet attached).

This statistic of nearly 2,300 child and adolescent deaths from COVID was repeated in press reports, including a July 2023 article in the *New York Times*.[2] However, this figure was not the most accurate available number and is in conflict with the CDC assertion that NVSS death certificate data was now the primary source for death data.

Given the CDC's response, on August 8, 2023, Majority committee staff emailed a follow-up question to the CDC: "Thanks for the response. What does the NVSS death certificate data show for child covid deaths?" On October 5, 2023, the CDC emailed the following to Majority committee staff:

> The number of children ages 0-17 who died from COVID-19 through 9/27/23 was 1,696. That data can be found on this page: https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htmThe. This number comes from death certificate data collected by the National Vital Statistics System (NVSS), which provides the most complete and accurate information on all deaths in the United States.[3]

Thus, the NVSS number for child covid deaths was substantially lower than the COVID Data Tracker number, despite including an almost two-month longer timeframe.

The CDC's responses are consistent with concerns reported in the *British Medical Journal* (BMJ) and raised by other analysts.[4] On March 15, 2022, the CDC removed 72,277 deaths, including those of 416 children, from its COVID-19 Data Tracker after the overestimates were attributed to "coding logic errors." The inaccuracies were detected by Kelly Krohnert, a former IT programmer from Atlanta, Georgia, on February 23, 2022. She tweeted: "It appears [CDC's COVID] Data Tracker has major issues when it comes to pediatric death reporting. We deserve accurate data when so much is on the line for our kids!" Krohnert and another mother

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[2]Sharon LaFraniere, Patricia Mazzei and Albert Sun, The Steep Cost of Ron DeSantis's Vaccine Turnabout, New York Times (July 23, 2023)("This disease [Covid] has killed nearly 2,300 children and adolescents, and nearly 200,000 have been hospitalized.").

[3] CDC elaborated on the basis for that claim: "Through NVSS, the 57 vital registration jurisdictions (50 states, New York City, District of Columbia, and 5 U.S. territories) send the National Center for Health Statistics (NCHS) information on all birth, death, and fetal death events occurring each year. NVSS captures **all deaths from all causes across every state** in the nation. NCHS then collects, analyzes, and disseminates these data to create the nation's official vital statistics. NVSS provides the most complete and continuous data available to public health officials at the national, state, and local levels and are a critical component of the national health information system. More information on NVSS can be found here."

[4] Jennifer Block, Covid-19: US tracker overestimated deaths among children, The BMJ (March 29, 2022). *See also* David Zweig, New York Times Cites False CDC Covid Data, Inflating Pediatric Mortality Count, Silent Lunch (July 24, 2023). Kelley Krohnert, Alyson Haslam, Tracy Beth Hoeg, Vinay Prasad, *Statistical and Numerical Errors Made by the US Centers for Disease Control and Prevention During the COVID-19 Pandemic*, SSRN (March 23, 2023). https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4381627

had been writing to the CDC since May 2020 about these concerns. The overcounting also raises questions about whether CDC used inaccurate data that led to decisions harmful to children.

To assist our inquiry, please provide the following by November 7, 2023:

1. All documents related to CDC assessments of the accuracy of COVID tracker data since January 1, 2020.

2. All documents related to the CDC's decision to disseminate COVID tracker data for COVID mortality data after the public health emergency was ended, given CDC's admission that NVSS provides "the most complete and accurate information on all deaths in the United States."

3. All documents related to CDC assessments of the accuracy of NVSS data since January 1, 2020.

4. All documents related to CDC analyses of child COVID deaths since January 1, 2020.

5. All documents related to CDC decisions that relied on child COVID death data from the COVID Data Tracker.

6. All documents related to CDC plans to improve data quality since August 1, 2022.

If you have any questions, please contact the Majority committee staff at (202) 225-3641. Thank you for your attention to this request.

Sincerely,

Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce

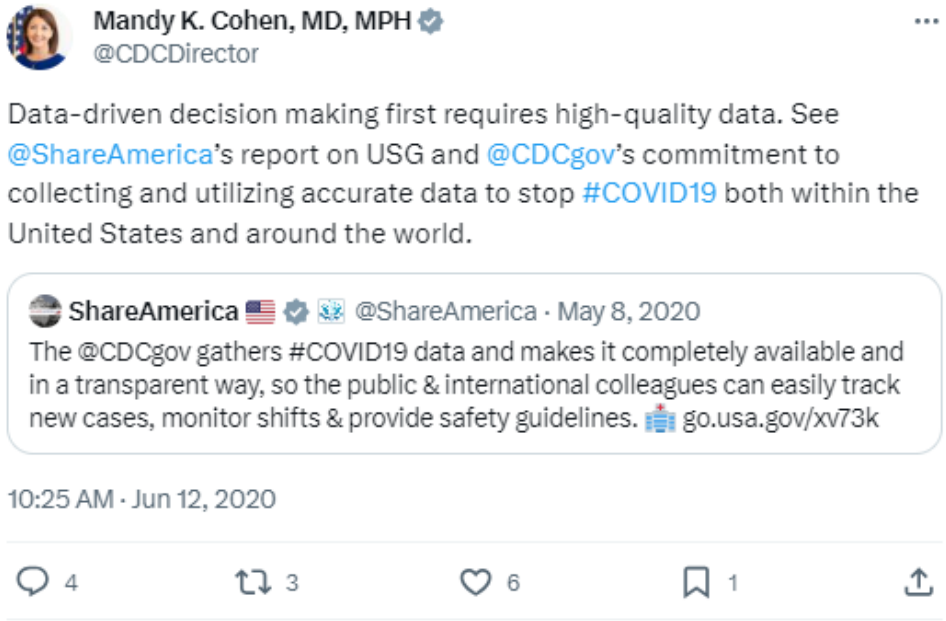
H. Morgan Griffith
Chair
Subcommittee on Oversight and Investigations

Brett Guthrie
Chair
Subcommittee on Health

Attachment

CC: Frank Pallone Jr., Ranking Member, Energy and Commerce Committee
Anna Eshoo, Ranking Member, Subcommittee on Health
Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations

Attachment


Mandy K. Cohen, MD, MPH
@CDCDirector
Data-driven decision making first requires high-quality data. See @ShareAmerica's report on USG and @CDCgov's commitment to collecting and utilizing accurate data to stop #COVID19 both within the United States and around the world.
ShareAmerica @ShareAmerica · May 8, 2020
The @CDCgov gathers #COVID19 data and makes it completely available and in a transparent way, so the public & international colleagues can easily track new cases, monitor shifts & provide safety guidelines. go.usa.gov/xv73k
10:25 AM · Jun 12, 2020
4
3
6
1

THE SELECT COMMITTEE ON THE
CHINESE COMMUNIST PARTY
FREEDOM IS THE VICTOR

INVESTIGATION INTO THE REEDLEY BIOLAB

TABLE OF CONTENTS

FOREWORD
BY CONGRESSMAN JIM COSTA

As the Representative of California's 21st Congressional District, I am proud to represent the city of Reedley. Located southeast of Fresno in the San Joaquin Valley, Reedley is a rural community of about 26,000 people, known as the Fruit Basket of the World due to its prosperous agricultural industry. With a bustling and historic downtown, this is the last place you would expect to find a case like this.

In March 2023, I was made aware of the warehouse, which housed a biolab that did not appear to be in compliance with the law. Within a day of having been alerted, my staff and I mobilized officials from Fresno County, the State of California, and Federal agencies to assist Reedley in the investigation and abatement of the unregulated laboratory that contained 1,000 transgenic mice and infectious diseases, among other concerning findings. I have stayed in contact with local and federal officials – including sharing information, encouraging cross-agency collaboration, and working with the Select Committee on the Chinese Communist Party during its investigation.

My top priority is health and public safety. The presence of infectious diseases that were poorly stored in a populated area of town without anyone's knowledge is of major concern. That is why the Select Committee on the Chinese Communist Party coordinated a bipartisan Congressional report that is succinct, thorough, and impactful while maintaining the trust of the American public. I appreciate the Select Committee's efforts on this matter.

This report outlines troublesome gaps that exist in federal law that allow bad actors to take advantage of the system. I look forward to continuing our work to address the existing gaps that allowed an illegal biolab like this to threaten the health and safety of the people in Reedley. It is my hope no other town in any Congressional district will endure what my constituents have through this experience.

I did not come to Congress expecting to handle a situation like the one outlined in this report. But my job is to advocate for my constituents and to ensure that the federal government is working for them in partnership with their other elected officials at all levels of government.

Thank you to the local first responders and officials for your collaboration during this investigation. I look forward to continuing this important partnership to protect the health and safety of our neighbors in Reedley and nationwide.

CONGRESSMAN JIM COSTA

INTRODUCTION

In December 2022, Code Enforcement Officer Jesalyn Harper noticed a green garden hose sticking out of a hole drilled into the side of a warehouse located at 850 I Street, right in the heart of Reedley, California. Reedley is a rural town of 26,000 residents. The hose was a clear violation of Reedley's building code in a building known to be vacant for over a decade. She walked around to the front of the warehouse and knocked on the door. Officer Harper showed her badge and asked to enter the site. Upon entering, Officer Harper found a vast warehouse filled with laboratory equipment, manufacturing devices, and what appeared to be medical-grade freezers. She observed several individuals who identified themselves as PRC nationals wearing white lab coats, glasses, masks, and latex gloves working inside. As she stepped further into the warehouse, she noticed that some of the freezers and containment units had glass doors. Inside, she saw thousands of vials of biological substances. Many were unlabeled. Others were labeled in a foreign language later identified as Mandarin. Others still were labeled in some kind of code. A few of the vials, however, had labels in English. Some of these labels listed substances that Officer Harper at the time did not recognize. She did, however, recognize the names listed on several labels, such as HIV.

Officer Harper continued down the hallways of freezers and laboratory equipment to find the source of the green garden hose. What she found was a makeshift storage room emanating a foul odor. Inside were approximately 1,000 laboratory mice in crowded conditions. Officer Harper would later learn that these were transgenic mice, specifically genetically modified and bred to simulate the human immune system for the purpose of laboratory experimentation. On future inspections, she also saw that the mice were unwell and abused, with fraying hair, rashes, and distended bellies.

Officer Harper knew that this warehouse was not licensed or permitted for any laboratory functions. She also knew that there were over a half-dozen other building code violations that she spotted in her brief walk inside the building. What Officer Harper did not know, however, was that her investigation of this green garden hose would uncover a laboratory filled with thousands of vials containing pathogens and other unknown biological and chemical substances.

A subsequent investigation revealed that the laboratory was operated by a wanted fugitive from Canada, who is a PRC citizen. The said fugitive had previously stolen millions of dollars of intellectual property from American companies and was part of an ongoing transnational criminal enterprise with ties to the PRC for which he was ultimately charged in federal court.

More importantly, the investigation stemming from Officer Harper's actions revealed systemic and profound risks in American biosecurity that merit Congressional attention.

INVESTIGATION INTO THE REEDLEY BIOLAB: FINDINGS

On September 6, 2023, the Select Committee on Strategic Competition between the United States and the Chinese Communist Party ("Select Committee") issued its first subpoena as part of its ongoing investigation into the illegal facility that local authorities uncovered in Reedley, California. The subpoena, signed by the Chairman with an on-site visit by the Select Committee's Chief Investigative Counsel and two investigative staffers, uncovered thousands of pages of documents, hundreds of photographs, and hours of video. This evidence, alongside interviews of local officials and other investigative steps, revealed troubling gaps in federal pathogen safeguards. These gaps allowed a wanted fugitive from Canada, who is a PRC national who had previously stolen millions of dollars of American intellectual property, to operate an illegal facility that contained "thousands of vials of potentially infectious agents" in Reedley, California.[1]

The Select Committee engaged in this investigation based on public requests and expressions of concern from both Republican and Democratic Members of Congress and in coordination with Congressman Jim Costa, who represents the district where Reedley is located.[2] After the Select Committee issued the subpoena, Congressman Costa stated, "It is my hope that we work in a bipartisan, coordinated manner to fully understand the scope of this lab and prevent any future labs like this one from operating illegally in our communities."[3] The Select Committee shares these goals and drafted this report, in part, as an essential step towards accomplishing them.[4]

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[1] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023) at Ex. D – CDC Letter.

[2] David Taub, *Speaker McCarthy Calls for Congressional Investigation into Reedley Bio Lab*, GV Wire (Aug. 3, 2023); John Houghton, *'Disturbing: McCarthy, Schiff on Illegal Reedley Lab,* Your Central Valley (Aug. 4, 2023, 3:50 PM) ("'They might be experimenting with things that could be of profound health risk […] We need to make sure that you can't have labs operating without the knowledge of public health departments without adequate inspections,' [says] Schiff.")

[3] Press Release, Congressman Jim Costa, Costa Statement on the Congressional Subpoena of Reedley (Sept. 13, 2023) ("In issuing these congressional subpoenas, Congress is taking an important step to further collect information and address this matter.").

[4] In the words of the Select Committee's Chairman, "Americans learning about this biolab will ask an entirely reasonable question: how many other clandestine laboratories exist in the United States? What I find the most disturbing is not necessarily that we do not know the answer to this question, it is that no one does. Due to deep institutional failures and a lack of basic safeguards, our nation lacks essential biosecurity at a moment of competition with the CCP when we need it most. We're going to work to tighten up our nation's biosecurity laws to ensure nothing like this ever happens again." In the words of the Ranking Member, "strengthening biosafety regulations in our country is an area of bipartisan concern. While I am concerned about certain problematic narratives regarding this issue that have been used online, this report is a serious effort that shows why we must avoid speculation and take action to protect public health."

I. APPARENT PATHOGENS AND OTHER DANGEROUS SUBSTANCES DISCOVERED AT THE REEDLEY BIOLAB

A. Local Officials Discover the Reedley Biolab

The Reedley Biolab was discovered in a warehouse located at 850 I Street in Reedley, California. It was across the street from a residential neighborhood, next to a railway line, and a short walk from the town's high school, city hall, and water supply. Officials ultimately learned that Jiabei "Jesse" Zhu, under the false identity of David He, had set up a facility engaged in fraudulent sales of medical device kits and, other biological laboratory activity—the "Reedley Biolab." Zhu did so after he and his associates had to hastily move from their previous location in Fresno, "an illegal laboratory similar to the Reedley site" due to a fire and threat of eviction.[5] Zhu operated the Biolab through the corporation Universal Meditech Incorporated (UMI) and, later, Prestige Biotech Incorporated (Prestige Biotech).

Figure 1 *- Aerial view of Reedley, with Reedley Biolab in blue, major landmarks in red, and residential areas in yellow. Source: Google Earth.*

Officials first learned about the Reedley Biolab thanks to the work of Code Enforcement Officer Jesalyn Harper, who identified the aberrant garden hose building code violation outside the warehouse in December 2022. Upon being let

[5] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023). The factual statements contained in these and other court filings and relied on in this report were "declare[d] under the penalty of perjury." *Id.*

inside, Officer Harper observed three women who identified themselves as PRC nationals, wearing white lab coats, glasses, masks, and latex gloves. The women appeared to be packaging items for shipment. Officer Harper identified numerous building code violations, including unlawful electrical rewiring. She also observed samples of potentially dangerous pathogens and biohazard signs. Further inside, she discovered what appeared to be approximately 1,000 white laboratory mice, which, according to the employees on site, "were being tested."[6]

Officer Harper referred the matter to Fresno County and to the Federal Bureau of Investigation. Approximately two months later and according to local officials, the FBI informed her that it had closed its investigation because the Bureau believed that there were no weapons of mass destruction on the property. The FBI continued to engage with local officials. As detailed later in this report, Zhu was subsequently charged with federal offenses relating to fraud and false statements in an FDA-led investigation.[7]

After consultation with California state and Fresno County officials, Officer Harper led a small group to the Reedley Biolab and again requested entry.[8] Two individuals, one of whom refused to identify himself, were present but quickly left after authorities arrived. Upon entering, Officer Harper noticed that there were now padlocks barring entry to most of the facility.

[6] Select Committee Interviews with Local Officials.

[7] Press Release, Department of Justice, Arrest Made in Central California Biolab Investigation, (Oct. 19, 2023); *United States v. Jia Bei Zhu*, No. 1:23-MJ-00123-SKO, (E.D. Cal. Oct. 18, 2023) (Criminal Complaint).

[8] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023).

B. March 16, 2023 Inspection by Local Officials of the Reedley Biolab

Local officials then obtained an inspection warrant, which they executed on March 16, 2023.[9] Inside the Reedley Biolab, officials "observed blood, tissue and other bodily fluid samples and serums; and thousands of vials of unlabeled fluids and suspected biological material," raising the concern that they contained pathogens.[10] Some of these vials were labeled with the names of pathogens in English or Mandarin. Many were unlabeled. Others were labeled in code. Officials never found the full key that would translate this code, meaning that the nature of these vials' contents is unknown to this day.

***Figure 2** - Contents of a fridge found in the Reedley Biolab, including sera and chemicals. Source: City of Reedley.*

Officials also found laboratory equipment, including "a biological safety cabinet and centrifuge[,]" as well as "cold temperature storage units, which included 2 ultralow temperature freezer units (-80- and -60-degree C) and 29 refrigerators/freezers (-20 degrees C). The Reedley Biolab operators had locked the -80 C ultralow freezer. These ultralow temperature freezers increased local officials' concerns that UMI was storing infectious agents on site."[11]

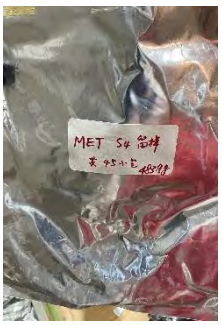
[9] *Id.*

[10] *Id.*

[11] *Id.*

The facility contained other storage containers labeled with biohazard signs and medical cabinets filled with what authorities later identified as highly flammable, explosive, and corrosive chemicals. They also found trace narcotics, laboratory equipment, and hundreds of boxes containing faulty medical devices subject to an FDA health embargo. The warehouse's electrical system was jury-rigged to power over 30 of these freezers.

Figure 3 and 4 *- Blood and fluids found in two of the thirty refrigerators and deep freezers of the Reedley Biolab. Source: City of Reedley.*



Figures 5, 6, and 7 *- Bags labelled "MDMA," "Coca," and "Met" found in freezers in the Reedley Biolab. "Coca" and "Met" presumably mean "cocaine" and "methamphetamine," respectively. Other bags found were labelled "THC" and "Amp" (likely meaning "amphetamine"). Source: City of Reedley.*

Approximately 1,000 mice were kept in inhumane, overcrowded conditions. When local officials asked a worker who "appeared to be in control" of the mice, she replied that they were transgenic mice that simulate the human immune system that were "genetically engineered to catch and carry the COVID-19 virus."[12]

In subsequent interviews with individuals who were at the warehouse, local officials learned that workers were tasked with caring and cleaning for the mice and, on numerous occasions, the Reedley Biolab operators had held back their pay. One of the workers who tended to the mice told Officer Harper that he and his

[12] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023).

children had become sick close in time to when he was tending the mice. The worker stated that he was instructed to discard any dead mice that he found into a dumpster.[13] The worker thereafter stopped communicating with officials. Local officials later confirmed that "UMI and Prestige Biotech were disposing of deceased laboratory mice, considered to be medical waste, without the use of a licensed medical waste hauler."[14]

Shortly thereafter, Prestige Biotech representative Xiuqin Yao emailed City of Reedley officials and asked about the mice. She stated that the mice were a "special purebred population that took six years to build up" and are "of special significance in the study of immunology and oncology." Yao furthermore said that the transgenic mice were "biological assets" that were worth "hundreds of thousands or even one million" dollars.[15] Yao said that she cannot go to the Reedley Biolab, as she is currently in the PRC and unable to enter the United States due to a visa backlog. Despite repeated requests, she "failed to provide any certifications or licenses from any state or federal agency for storage and experimentation on mice and other laboratory activities" at the Reedley Biolab.[16] Moreover, the "[p]roperty, UMI and Prestige Biotech were not listed as a licensed laboratory" and were likewise "not registered with CDPH as a medical waste generator."[17]

Ultimately, while the City of Reedley tried to care for the transgenic mice, their condition continued to deteriorate. Reedley retained a veterinarian specializing in laboratory specimens that the California Department of Public Health (CDPH) recommended. On March 24, it had the veterinarian review the transgenic mice for risk of biohazards. She confirmed the earlier assessments of overcrowding and inhumane conditions. When on site, she found 773 living mice and another 172 mice carcasses. She saw evidence of cannibalism, including the devouring of newborn mice, severe fight wounds, and indications of high stress. As of the time of her review, the veterinarian did not identify any immediate risk to humans

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[13] *See generally* *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023), Decl. of Jesalyn Harper in Support of Application for Abatement Warrant and Order Authorizing Entry on the Property to Abate Public Nuisance (Mar. 29, 2023) at Ex. B.

[14] *Id.* They furthermore learned that "UMI and Prestige Biotech have not employed the services of a licensed medical waste hauler during the course of the operation of the warehouse." *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

being near the mice. On April 12, upon recommendation from the veterinarian and pursuant to court order, City officials had the veterinarian euthanize the mice.[18]

As part of their review, local officials uncovered marked and unmarked "fire danger and explosion hazards created by the corrosive, toxic, and highly

Figure 8 *- At least ten dead mice, including at least nine decaying carcasses, were found in just one box at the Reedley Biolab. Source: City of Reedley.*

Figure 9 *- Evidence of wounds on seven mice found at the Reedley Biolab, indicating inhumane living conditions for the animals. Source: City of Reedley.*

flammable chemicals stored" in the Reedley Biolab.[19] These materials were highly dangerous. Were a fire to occur, Fire Department officials assessed that the City of Reedley would need to evacuate at least one city block around the warehouse.[20] The "proposed evacuation zone would include the City of Reedley Police Department, City Hall, the Kings Canyon Unified District main office, and approximately 12 residential homes."[21] The potential blast radius would increase significantly if the fire spread to the gas station located next door.

While the inspection process was ongoing, Jesse Zhu, using the false name "David He," began communicating over the phone and via email with local officials. He said that he was a "special representative" of UMI.[22] Zhu asked for local officials not to destroy the pathogen samples. Instead, he asked that they allow him to move them off-site using a company that is unlicensed for medical

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[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *Id.* at Ex. B – Letter from Jerry Isaak, Chief of the City of Reedley Fire Department.

[22] *Id.* at Ex. F – Email Correspondence.

waste or pathogen transportation.[23] Local officials did not permit Zhu to do so. Zhu also provided contact information for corporate officers, all of whom were in the PRC.[24]

C. April 21 and May 1, 2023 Inspections by County and State Officials

Fresno County public health officials inspected the premises on April 21, confirming and expanding on the prior findings.[25] "Fresno County Public Health staff observed biologicals stored and kept in hazardous and non-compliant conditions, the presence of multiple infectious agents (later confirmed by CDC) and pursuant to Title 17 California Code of Regulations Section 2500."[26] Fresno County public health staff also "observed the 32 refrigerators and freezers. A number of these refrigerators and freezers had either stopped functioning or were failing due to an inadequate power supply."[27]

The CDPH inspected the premises on May 1-2. In addition to the "32 refrigerators and freezers" containing apparent pathogens, "CDPH staff also observed several pieces of laboratory equipment, such as incubators and centrifuges." Inside several freezers, CDPH "observed containers labeled as serum or plasma (of unknown origin) and/or with the name of an infectious agent. A substantial number of the containers were unlabeled and CDPH staff was unable to discern the contents of these containers."[28] "Many of the indecipherable containers appeared to contain blood, or a blood product, such as serum, or other bodily fluids."[29] CDPH did not inspect a -80C freezer and another freezer due to potentially dangerous biologicals stored within.[30] CDPH also observed a biohazardous waste container "shrink wrapped" (but not properly sealed) and other forms of biohazards throughout the Reedley Biolab.[31]

D. Abatement Action and Centers for Disease Control and Prevention (CDC) Response

Based on their initial observation in March 2023, local officials began to reach out to additional federal authorities for assistance. Local officials spent months repeatedly trying to obtain assistance from the CDC, both directly and through CDPH. According to local officials, the CDC refused to speak with them and, on a

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[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

number of occasions, it was reported by local officials that the CDC hung up on them mid-conversation. Local officials were similarly unable to get any help from other federal agencies that may have concurrent authority to investigate and/or remediate the biohazardous substances found at the Reedley Biolab.[32]

Ultimately, local officials contacted their local Member of Congress, Representative Jim Costa, asking him for help obtaining federal assistance. It was only then, following Congressman Costa's advocacy on Reedley's behalf, that the CDC responded to California state government and local official requests.

After significant effort, local officials were able to convince the CDC to inspect the Reedley Biolab. CDC arrived on site on May 2, 2023 and finished the onsite support on May 4. Upon reviewing the site, the CDC reported, based on existing labels, that the facility contained "at least 20 potentially infectious agents," including HIV, Tuberculosis, and the deadliest known form of Malaria. The CDC specifically listed the following pathogens:[33]

Potentially infectious bacterial agents present:

- *Chlamydia trachomatis*
- *E. coli* (recombinant strains)
- *Helicobacter pylori*
- *Mycobacterium tuberculosis*
- *Mycoplasma pneumoniae* and general *Mycoplasma* species
- *Neisseria meningitidis*
- *Nostoc* species
- *Sphingobacterium heparinum*
- *Streptococcus pneumoniae* and *Streptococcus* species
- *Toxoplasma gondii*

Potentially infectious viral agents:

- Hepatitis B virus
- Hepatitis C virus
- Dengue virus
- Human Immunodeficiency Virus (HIV) 1 and 2
- Human Herpes virus 1 (Herpes simplex virus)
- Human Herpes virus 5 (Human Cytomegalovirus)
- Respiratory Syncytial virus
- Rubella virus
- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

Potentially infectious parasites:

- Malaria (believed to be *P. falciparum* from Nigeria from the year 2000)

[32] This section and subsequent sections draw on Select Committee interviews with local officials to provide information about the local and federal responses.

[33] *Id.* at Ex. D – CDC Letter.

The CDC noted that these potentially infectious agents fall into "risk group 2 and risk group 3."[34] Risk Group 2 agents "are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available, [and] [t]hese agents represent a moderate risk to an individual but a low risk to the community.[35] Risk Group 3 pathogens are "associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community."[36] The CDC also noted that American laboratories supplied many of these pathogens.[37] There was also evidence that imported pathogens were present in the Reedley Biolab.

CDC officials confirmed that the CDC made this list of pathogens based solely on the labels that were placed on samples. The CDC did not test these samples to assess whether the listed labels were correct or otherwise in a cipher that the workers used for a more dangerous pathogen. It likewise did not test any of the apparent pathogen samples that were labeled in a code (i.e., a combination of partial Mandarin symbols or English letters with numbers) despite the fact that neither the CDC nor local officials ever found a key to decipher the code.[38] The CDC did not even test the wholly unlabeled samples. It did not test the samples labeled "COVID," even though both SARS-CoV and a chimeric version of the currently endemic COVID-19 are both Select Agents—biological agents that the

[34] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023) at Ex. D – CDC Letter. Based on their physical appearance, the CDC noted that it believed that the "Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Mycobacteriumtuberculosis (RG3 agents) appear . . . to be diagnostic specimens, not isolates or culture." It did not test the substance or engage in further review to confirm this hypothesis.

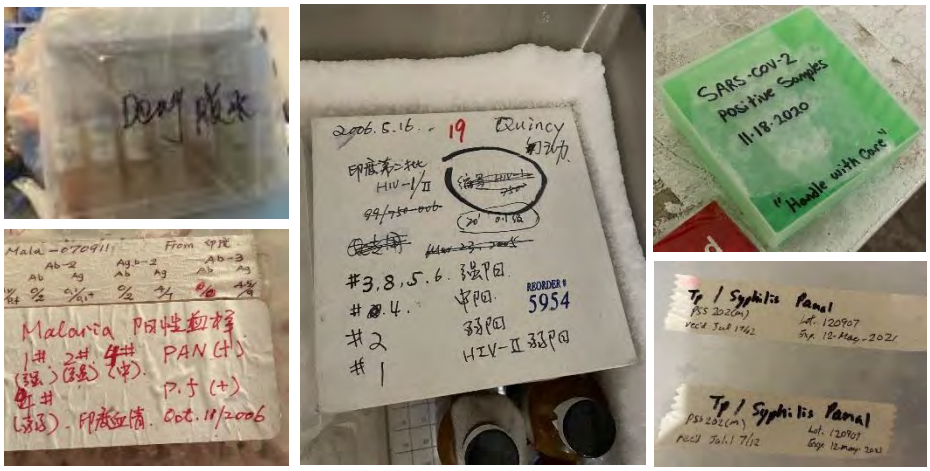
[35] *Risk Groups*, Public Health Emergency (Nov. 13, 2015) .

[36] *Id.*

[37] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023) at Ex. F – Email Correspondence.

[38] The CDC report does note, however, that "representative[s] provided a limited key that was reported to contain proprietary or trade secret information." *Id.* at Ex. D – CDC Letter.

U.S. government has determined "have the potential to pose a severe threat to public health and safety."[39]



Figures 10-14 *- Examples of pathogen-labeled containers from the Reedley Biolab. From left to right, going clockwise: dengue fever, HIV, SARS-CoV-2, syphilis, and malaria. Source: City of Reedley.*

CDC's refusal to test left local officials unable to assess the danger to the City of Reedley community or inform the community about what steps, if any, it should take to protect public safety. Local officials informed the CDC about their concerns. The CDC continued to refuse to test any samples.[40] According to local officials, they also asked if the CDC could at least test a random sample of the pathogens. The CDC still refused. Despite their limited local budget, local officials then offered to pay the CDC for the entirety of the cost of testing these samples. The CDC still did not and left the site.[41]

The CDC summarized its findings in a three-page report, in which it stated that the Biolab contained "[t]housands of vials [with] unclear labeling, coded labeling, or no identifications."[42] Lab workers appeared to have labeled some items

[39] *Select Agents and Toxins*, CDC (Sept. 10, 2020). Select Agents are a specially regulated group of biological agents and toxins that have the potential to pose a severe threat to public health and safety.

[40] In addition to written and verbal statements from local officials, the Select Committee obtained an email from CDC officials who stated that they "don't see an urgent need to test samples at the moment" because "most of the material [CDC was] able to identify were proteins, antibodies, or pathogens (e.g. E.coli, HAIV, SARS CoV-2, Hepatitis, Malaria, Mycoplasma, etc.) that would not be regulated under our authority (i.e. select agents) or considered a serious threat to public health" even though the samples included "'unknowns,' illegible, or [those] coded in a way that we could not interpret." This email was in response to a Fresno County email offering to pay for the packaging and shipment of the samples to an appropriate testing facility.

[41] This conversation was summarized in the email described above.

[42] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023) at Ex. D – CDC Letter.

they "believe[d] to be dangerous."[43] Although some of the pathogens could have come from Nigeria or Canada ("[d]uring the move to the U.S., infectious material may have been imported"), "there were no import or shipping records available at the time of the visit" to establish "conclusive evidence of violations of 42 C.F.R. § 71.54 for the importation of infections agents."[44]

Despite the fact that the Reedley Biolab was an illegal enterprise, the CDC suggested that local authorities "request[] all records of importation for infectious agents" to see if the violation occurred.[45] Among the CDC's action items would be to send the company advisement letters on import requirements and federal requirements for Select Agents, and add the company to an importation watchlist.[46]

Even though it had not tested any samples from the Reedley Lab, the CDC concluded that "[t]here was no evidence of select agents or toxins."[47] According to local officials, the CDC knew that absent testing, local officials would have to destroy all samples pursuant to a forthcoming abatement order. The CDC likewise instructed state officials not to test any remaining samples of transgenic mice based on concerns over the accuracy of potential testing.[48]

In sworn statements, local and county officials expressed "grave[] concern[] about the storage of potentially infectious bacterial, viral, and parasitic agents present at the Property and the health and safety risk to the public by these infectious agents."[49]

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[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.* Specifically, the CDC stated that it would "[i]ssue an Import Permit advisement letter to Prestige Biotech to ensure they know the Import Permit Regulations for importing infectious substances into the U.S." and "[i]ssue a Federal Select Agent Program advisement letter to Prestige Biotech informing them of the requirements for possession, use, and transfer of select agents and toxins if the entity decides to possess them." Among other items, it also called for "add[ing] Prestige Biotech and associated entity names to the CDC Import Permit Program watch list, in case the entity attempts to apply for a CDC Import Permit. If submitted, the application will be reviewed carefully, considering previous observations, and the program will inspect the facility before issuing any permit."

[47] *Id.* It also found "insufficient evidence at [that] time to conclude that there has been a violation of 42 CFR 71.54 or 42 CFR part 73."

[48] As part of its investigation, the Select Committee reviewed an email on August 28, 2023 where a CDC official stated the opinion above.

[49] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023)

E. Local Officials Report Discovering a Refrigerator Labeled "Ebola" that Contains Biological Samples

Thereafter, local officials had to handle the abatement ("ending" or destruction) process for all pathogens and toxic materials with only minimal guidance from federal experts. They secured the facility and contracted with a hazardous waste removal firm to assist with the abatement action. On July 5-7, local officials and a private firm specializing in pathogenic remediation handled potential pathogenic threat abatement.[50] On July 28, and pursuant to court order, local officials and contractors continued the abatement process pursuant to an additional court order.[51] Ultimately, local officials had to dispose of approximately 103.73 tons of general waste (including laboratory equipment) and 448 gallons of medical and biological waste.[52]

Figure 15 *- More than 40 trash can-sized containers of biohazardous waste were removed from the Reedley Biolab after its abatement. Source: City of Reedley.*

Up to the point at which they began the abatement process, local officials had not thoroughly investigated several of the freezers for fear of encountering a dangerous pathogen. During the abatement process, however, they had to review every freezer for evidence of potential pathogens that they needed to destroy. While doing so, local officials and contractors reported that they found a freezer labeled "Ebola" with silver sealed bags found inside consistent with how the Reedley Biolab operators stored sensitive biological and other materials.[53]

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[50] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 20, 2023).

[51] *See In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Aug. 16, 2023).

[52] *Id.*

[53] *Ebola Disease*, CDC (Mar. 23, 2023). Ebola "is a rare and often deadly" disease that results in hemorrhagic fevers, with a case fatality rate ranging from 25% to 90% in past outbreaks. Symptoms appear within 2-21 days of infection and are often severe. While Ebola's rapid onset and high lethality make it unlikely to spread into a pandemic, it can cause many localized deaths. *See also* *Ebola Disease*, WHO.

Local officials noted their concern to CDC officials in writing. In email correspondence, they informed CDC that, during the abatement process, they had uncovered a freezer labeled with the word "Ebola." In the email, a local official asked the CDC, "[w]hen you [] are going through and looking for select agents, do the containers need to be labeled individually with what is in it to count as one? We are doing the abatement here in Reedley and a fridge [freezer] had a label on it and one of the words in English was Ebola," while noting that the containers within were not expressly labeled "Ebola." The CDC official responded by stating, "Yes, we would typically look for the vial to be labeled as Ebola" and noted that they did not recall seeing the Ebola label. He did not cite any CDC policy when making this pronouncement. The court-ordered abatement action required local officials to destroy the samples under a defined timeline. Local officials emailed CDC on the afternoon of July 6, 2023, and CDC responded the following morning. Local officials had already destroyed the samples.

The CDC did not note an Ebola label on the freezer in its report. When asked about the freezer labeled Ebola in a subsequent email, the CDC official noted that the CDC "would typically look for the vial to be labeled as Ebola," that they "didn't recall seeing a fridge labeled as Ebola," and asked for a photograph of the freezer. A photograph was not available. The Select Committee has received written statements reporting the presence of the label. Ebola is a Select Agent.[54]

F. The Investigation and Lack of Testing Leave Many Unknowns

The CDC's refusal to test any potential pathogens with the understanding that local officials would otherwise have to destroy the samples through an abatement process makes it impossible for the Select Committee to fully assess the potential risks that this specific facility posed to the community. It is possible that there were other highly dangerous pathogens that were in the coded vials or otherwise unlabeled. Due to government failures, we simply cannot know.

In its refusal to test, the CDC likewise did not offer to connect local officials with any other federal agency or authorized lab that may be able to test the samples.[55] Based on statements from local officials and briefings the Select Committee received from the CDC, the CDC did not contact the National Biodefense Analysis and Countermeasures Center, the government biodefense laboratory located in Fort Dietrich, Maryland that could potentially have provided greater assistance.

According to local official accounts, in a subsequent conversation with the CDC in early September 2023, local officials again pressed the CDC on why they refused to test any potential pathogens. A CDC official informed the local officials

[54] *HHS and USDA Select Agents and Toxins*, CDC (Aug. 1, 2023).

[55] The Select Committee was unable to find any emails or other communications where the CDC offered to make these connections to agencies with similar authorities. Local officials reported that the CDC did not do so.

that it was illegal for the CDC to test any samples that were not expressly labeled as a Select Agent. City Manager Nicole Zieba expressed shock at this fact. She asked whether, if that were the case, the CDC had any authority to stop a terrorist in the United States who simply removed the label off a vial of a deadly virus. The CDC official said that the CDC had no authority to test the deadly virus in that hypothetical and that it was a noted gap in its authority.[56] This characterization of the CDC's authority appears to be false.[57]

II. THE REEDLEY BIOLAB, JESSE ZHU, AND THE PEOPLE'S REPUBLIC OF CHINA

The Reedley Biolab operated under the direction and control of Jiabei "Jesse" Zhu, through the corporation Universal Meditech Incorporated (UMI).[58] UMI owned and operated the Reedley Biolab. Zhu is a PRC citizen[59] associated with PRC-government linked companies.[60] He is currently wanted in Canada for contempt of court, where he is the subject of a CAD $330 million judgment for stealing American intellectual property. Zhu appears to have fled the Canadian courts and entered the United States unlawfully given that he had an active arrest warrant in Canada, assuming the false identity of "David He." Zhu then set up a new network of companies. Zhu appears to have accumulated thousands of vials labeled as dangerous pathogens, as well as expensive medical equipment. Based on the labeling found at the lab by local officials after the CDC's inspection, the Reedley Biolab operators may have possessed the Ebola virus, one of the deadliest viruses known to humanity. He was able to acquire these apparent pathogens even though he was a wanted fugitive and operated an unlicensed and unregistered laboratory.

A. Jiabei "Jesse" Zhu Leads PRC Government-Controlled and Directed Companies in the PRC

While living in the PRC in the early 2000s, Zhu served as the Vice Chairman of a PRC state-controlled enterprise based in Xinxiang, Henan Pioneer Aide Biological Engineering Company Limited ("Pioneer Aide China"). PRC government entities exercised a controlling interest in Pioneer Aide China as

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[56] Information obtained through Select Committee conversation with local officials.

[57] *See, e.g.*, John Lancaster and Susan Schmidt, *When anthrax-laced letters terrorized Washington and New York* (Oct. 24, 2018, 1:02 PM) (describing how CDC officials tested unlabeled suspected anthrax spores).

[58] Zhu employed many passthrough and shell companies as part of his ventures. This behavior continued in his management of the Reedley Biolab, where he created other corporations such as Prestige Biotech to obfuscate the true actors involved. For ease of reference, this report will hereafter refer to UMI and all its affiliated and associated entities as "UMI."

[59] *United States v. Jia Bei Zhu*, No. 1:23-MJ-00123-SKO, (E.D. Cal. Oct. 18, 2023) (Criminal Complaint) ("Customs and Border Patrol records show that [Zhu] is a citizen of China").

[60] *See* Figures 17-20, *infra*.

beneficial owners and shareholders through a series of passthrough joint venture companies, including Henan Investment Group Company Limited, a company involved in military-civil fusion for the PRC.[61]

Zhu also served as Chairman of the Board and General Manager of Aide Modern Cattle Industry (China) Company Limited ("Aide Cattle China"), a company whose directors included an executive for a PRC defense firm and a company on the U.S. Entity List. Shareholders in Aide Cattle China include PRC state-controlled entities and individuals who have invested in other PRC state-controlled entities. Through Aide Cattle China, Zhu was the primary shareholder of 11 PRC cattle companies.[62]

After Zhu moved to Canada and created additional corporations there, his Canadian company, IND Modern Cattle Development Group Corporation (IND Group), became a minority shareholder in Pioneer Aide China.

Henan Pioneer Aide Biological Engineering Company Limited 河南创业爱德生物工程有限责任公司

Zhen Central Road,
Gaoxinjizhukaifa District,
Xinxiang, Henan, PRC

PRC Government Ownership: 46.50%
Central SOE Ownership: 2.7%
Military-Civil Fusion Ownership: 31.8%
Government Revoked

Legal Representative

Zhao Zhiyong 赵志勇	Chairman, General Manager, Legal Representative

Executive Board Members

Zhu Jiabei 祝佳贝	Vice Chairman
Gao Yingmo 高应墨	Director
Li Qianjin 李谦谨	Director
Ouyang Yalian 欧阳雅莲	Director
Qian Jin 钱进	Director
Shi Yunfu 时运福	Director

Direct Shareholders

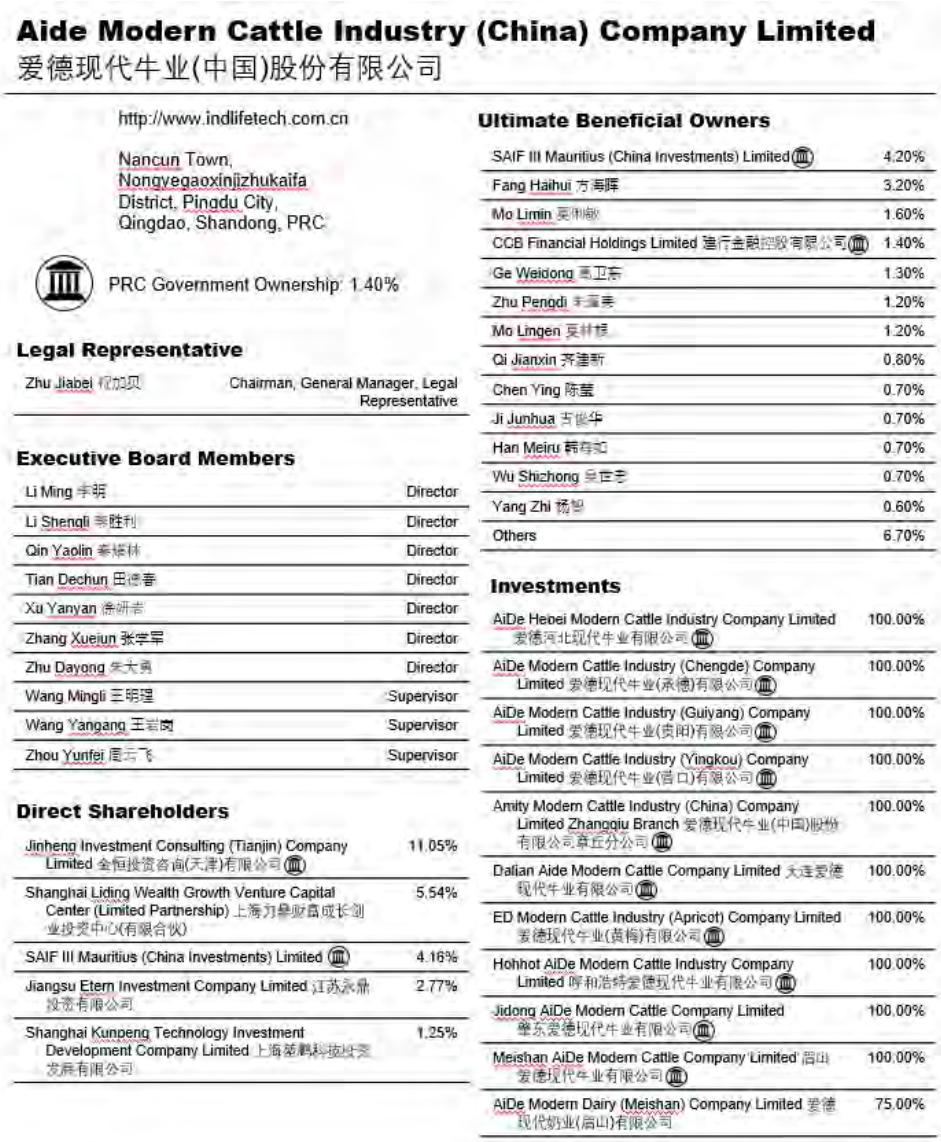
Henan Venture Capital Company Limited 河南创业投资股份有限公	46.52%
IND Modern Cattle Development Group Corporation IND现代牛业发展集团公司	Unknown
Xinxiang Kangli Agricultural Products Company Limited 新乡市康利农业产品有限公司	Unknown
Zhengzhou Yawei Industrial Corporation 郑州亚卫实业总公司	Unknown

Ultimate Beneficial Owners

Henan Province Department of Finance 河南省财政厅	28.90%
Henan Yuneng Holdings Company Limited 河南豫能控股股份有限公司	4.90%
State-Owned Assets Supervision and Administration Commission of the State Council (SASAC) 国务院国有资产监督管理委员会	2.40%
Zhengzhou High & New Technology Industries Development Zone Management Committee 郑州高新技术产业开发区管委会	2.20%
State-Owned Assets Supervision and Administration Commission of Jiaozuo Municipal People's Government 焦作市人民政府国有资产监督管理委员会	2.20%
Nanyang City Department of Finance 南阳市财政专项资金管理处	2.20%
Zhengzhou Economic and Technological Development Zone Construction Investment Company Limited 郑州经济技术开发区建设投资有限公	1.30%
Xinxiang Municipal People's Government 新乡市人民政府	0.80%
State-Owned Assets Supervision and Administration Commission of the People's Government of Beijing Municipality 北京市人民政府国有资产监督管理委员会	0.60%
National Council for Social Security Fund (SSF) 全国社会保障基金理事会	0.30%
International Cultural Exchange Media Company Limited 国际文化交流传媒有限责任公司	0.30%
Zhang Lei 张雷	0.30%
Tongbai Zhongnan Mining Development Company Limited 桐柏县中南矿业发展有限公司	0.10%

[61] *See* Figures 16-17, *infra*.

[62] Zhu also used complex corporate forms, such as using Cayman Island holding companies like IND Lifetech Group Limited that he wholly controlled, to create other various PRC companies. *See* Figures 16-19.



Aide Modern Cattle Industry (China) Company Limited
爱德现代牛业(中国)股份有限公司

http://www.indlifetech.com.cn

Nancun Town,
Nongyegaoxinjizhukaifa
District, Pingdu City,
Qingdao, Shandong, PRC

PRC Government Ownership: 1.40%

Legal Representative

Zhu Jiabei 祝加贝	Chairman, General Manager, Legal Representative

Executive Board Members

Li Ming 李明	Director
Li Shengli 李胜利	Director
Qin Yaolin 秦耀林	Director
Tian Dechun 田德春	Director
Xu Yanyan 徐研岩	Director
Zhang Xuejun 张学军	Director
Zhu Dayong 朱大勇	Director
Wang Mingli 王明理	Supervisor
Wang Yangang 王岩岗	Supervisor
Zhou Yunfei 周云飞	Supervisor

Direct Shareholders

Jinheng Investment Consulting (Tianjin) Company Limited 金恒投资咨询(天津)有限公司	11.05%
Shanghai Liding Wealth Growth Venture Capital Center (Limited Partnership) 上海力鼎财富成长创业投资中心(有限合伙)	5.54%
SAIF III Mauritius (China Investments) Limited	4.16%
Jiangsu Etern Investment Company Limited 江苏永鼎投资有限公司	2.77%
Shanghai Kunpeng Technology Investment Development Company Limited 上海昆鹏科技投资发展有限公司	1.25%

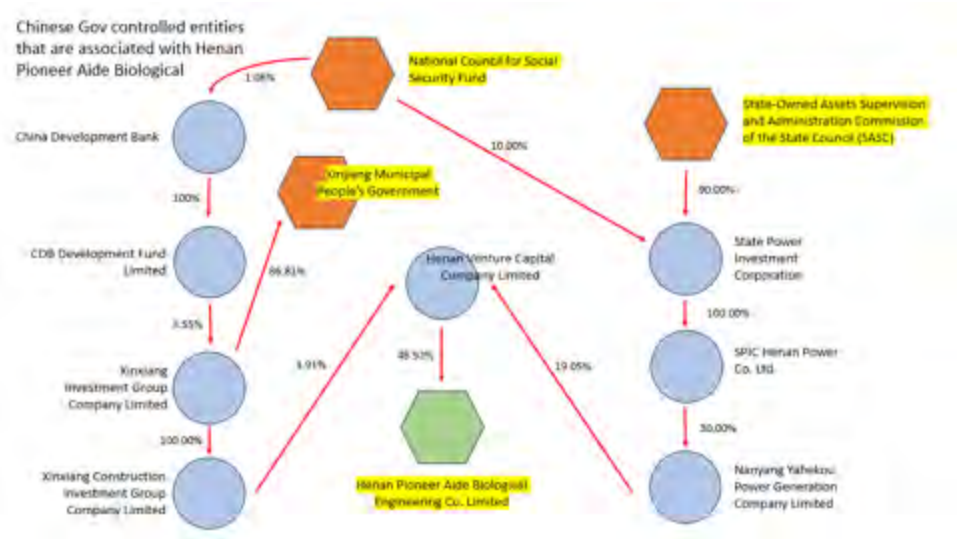
Ultimate Beneficial Owners

SAIF III Mauritius (China Investments) Limited	4.20%
Fang Haihui 方海晖	3.20%
Mo Limin 莫利敏	1.60%
CCB Financial Holdings Limited 建行金融控股有限公司	1.40%
Ge Weidong 葛卫东	1.30%
Zhu Pengdi 朱鹏弟	1.20%
Mo Lingen 莫林根	1.20%
Qi Jianxin 齐建新	0.80%
Chen Ying 陈莹	0.70%
Ji Junhua 吉俊华	0.70%
Han Meiru 韩存如	0.70%
Wu Shizhong 吴世忠	0.70%
Yang Zhi 杨智	0.60%
Others	6.70%

Investments

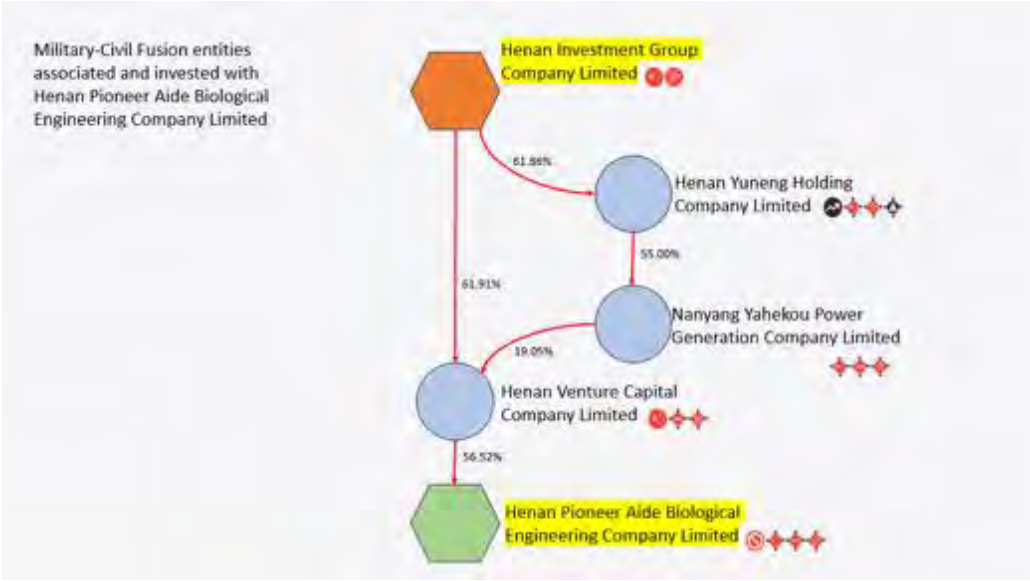
AiDe Hebei Modern Cattle Industry Company Limited 爱德河北现代牛业有限公司	100.00%
AiDe Modern Cattle Industry (Chengde) Company Limited 爱德现代牛业(承德)有限公司	100.00%
AiDe Modern Cattle Industry (Guiyang) Company Limited 爱德现代牛业(贵阳)有限公司	100.00%
AiDe Modern Cattle Industry (Yingkou) Company Limited 爱德现代牛业(营口)有限公司	100.00%
Amity Modern Cattle Industry (China) Company Limited Zhangqiu Branch 爱德现代牛业(中国)股份有限公司章丘分公司	100.00%
Dalian Aide Modern Cattle Company Limited 大连爱德现代牛业有限公司	100.00%
ED Modern Cattle Industry (Apricot) Company Limited 爱德现代牛业(黄梅)有限公司	100.00%
Hohhot AiDe Modern Cattle Industry Company Limited 呼和浩特爱德现代牛业有限公司	100.00%
Jidong AiDe Modern Cattle Company Limited 蓟东爱德现代牛业有限公司	100.00%
Meishan AiDe Modern Cattle Company Limited 眉山爱德现代牛业有限公司	100.00%
AiDe Modern Dairy (Meishan) Company Limited 爱德现代奶业(眉山)有限公司	75.00%

Figures 16-17 *–Corporate data of two of Zhu's PRC companies involved in theft of American intellectual property. Derived from State Administration for Industry & Commerce (SAIC), PRC Ministry of Commerce, the U.S. Securities and Exchange Commission, exchange filings, and company announcements. This data was analyzed using proprietary third-party software.*



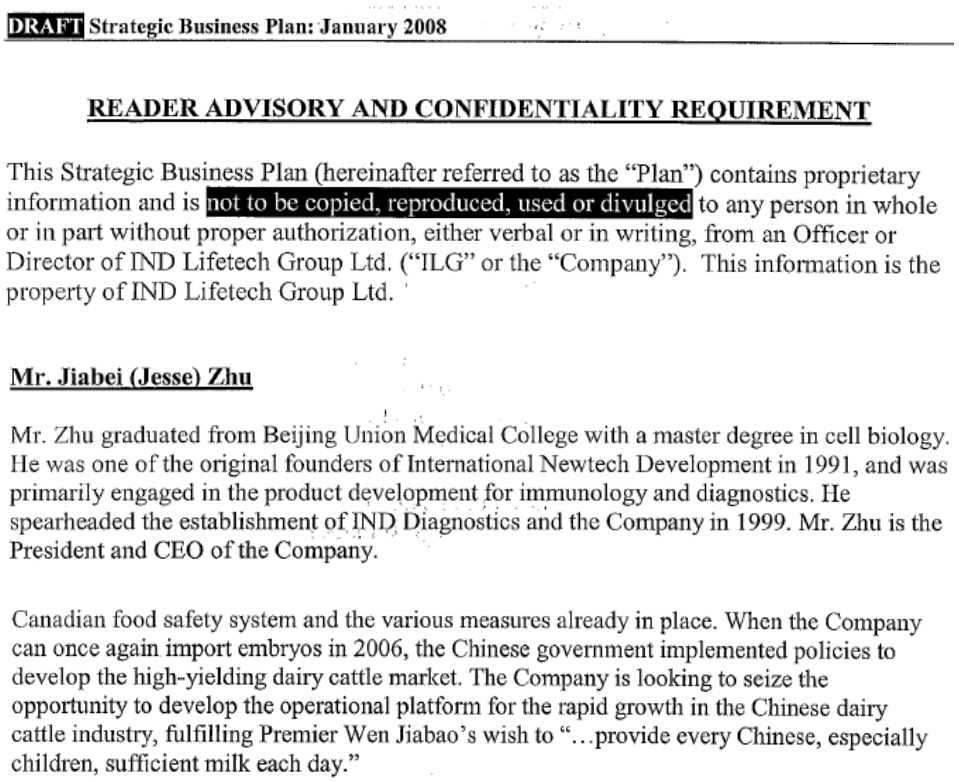
Figures 18-19 *– Analysis of PRC corporate data for Zhu's Henan Pioneer Aide Biological Engineering Co. Ltd. showing PRC government ownership and funding.*

Corporate data derived from State Administration for Industry & Commerce (SAIC), PRC Ministry of Commerce, the U.S. Securities and Exchange Commission, exchange filings, and company announcements. This data was analyzed using proprietary third-party software.



B. Jesse Zhu Steals American Intellectual Property and Transfers It to the PRC, Leading to a $330 Million Judgment and Arrest Warrant

This connection to cattle was important because, at some point while Zhu managed these PRC businesses, he traveled to Canada and created dozens of companies in Canada, the PRC, and elsewhere. These companies engaged in massive theft of American cattle-related intellectual property, resulting in a CAD $330 million judgment against Zhu and his coconspirators. As Zhu stated in documents that the Select Committee obtained from the Reedley Biolab, "the Company is looking to seize the opportunity to develop the operational platform for the rapid growth in the Chinese dairy industry, fulfill[ing] [PRC] Premier [and CCP Politburo Member] Wen Jiabao's wish to 'provide every Chinese, especially children, sufficient milk every day.'" At that time, China faced a pressing milk crisis and the PRC's government was pursuing "policies to develop the high-yielding dairy cattle market."[63]



DRAFT Strategic Business Plan: January 2008

READER ADVISORY AND CONFIDENTIALITY REQUIREMENT

This Strategic Business Plan (hereinafter referred to as the "Plan") contains proprietary information and is not to be copied, reproduced, used or divulged to any person in whole or in part without proper authorization, either verbal or in writing, from an Officer or Director of IND Lifetech Group Ltd. ("ILG" or the "Company"). This information is the property of IND Lifetech Group Ltd.

Mr. Jiabei (Jesse) Zhu

Mr. Zhu graduated from Beijing Union Medical College with a master degree in cell biology. He was one of the original founders of International Newtech Development in 1991, and was primarily engaged in the product development for immunology and diagnostics. He spearheaded the establishment of IND Diagnostics and the Company in 1999. Mr. Zhu is the President and CEO of the Company.

Canadian food safety system and the various measures already in place. When the Company can once again import embryos in 2006, the Chinese government implemented policies to develop the high-yielding dairy cattle market. The Company is looking to seize the opportunity to develop the operational platform for the rapid growth in the Chinese dairy cattle industry, fulfilling Premier Wen Jiabao's wish to "…provide every Chinese, especially children, sufficient milk each day."

Figure 20 *- Extracts of a 2008 strategic business plan for IND Lifetech described Zhu as the President and CEO of the company and outlined IND Lifetech's mission in the context of Premier Wen Jiabao's vision. Source: Select Committee.*

[63] *See generally* Tania Branigan, *China executes two for tainted milk scandal* (Nov. 24, 2009, 11:36 AM).

Specifically, Zhu created IND Lifetech Group—an affiliate of IND Group—and entered into a business relationship with XY, Incorporated, a U.S. company that specialized in biological engineering techniques that allowed for a high rate of selection for female (and thus milk-producing) Holstein cattle.[64]

During the decade or so following his arrival in Canada, Zhu created dozens of corporations (including IND and Ai De / Aide) in China, Canada, the United States, the British Virgin Islands, the Cayman Islands, and Uruguay. Court records indicate that, while Zhu employed many PRC nationals in these companies and even had them named as shareholders, they "were only shareholders 'on paper' and that, 'in reality,' Zhu owned these companies."[65] Additionally, "[a]lthough the various companies appear to have been set up for different purposes, they were, from Zhu's point of view, interchangeable as his wishes dictated" as "they were all under the common control and direction of Zhu as he dictated for his own purposes."[66]

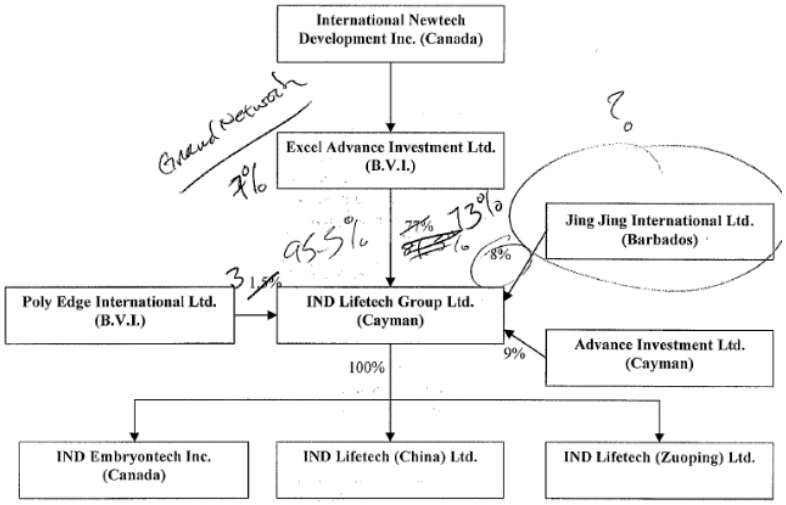


***Figure 21** - IND's corporate web, as outlined in corporate documents obtained by the Select Committee. It appears the web is not fully comprehensive of IND subisidiaries. Source: Select Committee.*

Zhu used these corporations to steal valuable American intellectual property and unlawfully transfer it to the PRC. Zhu accomplished this in part by directing the wrongful transfer of confidential information and technology obtained from XY in Canada to IND's PRC arms and affiliated PRC-based entities and individuals.[67] (IND's presence in the PRC was significant—by October 2014, Zhu employed between 400-500 workers in the PRC at just one of IND's location in

[64] *XY, LLC v. Canadian Topsires Selection Inc.*, 2016 BCSC 1095 ("Zhu was the 100% owner of IND").

[65] *Id.*

[66] *Id.*

[67] *Id.* at 216.

Qingdao.[68]) Zhu estimated that this intellectual property would greatly benefit him and PRC state-affiliated entities indicating in a 2013 business plan that the combined market value of assets he brought to the PRC was "estimated at $1.37 billion."[69]

In 2016, after years of litigation with XY over his IP theft, the Supreme Court of British Columbia, found Zhu guilty of "fraud on an 'epic scale' that 'resulted in one of the largest awards in a Canadian court.'"[70] The court found that "Zhu, whose operations extend to China as well as Canada, plann[ed] to steal the technology to the point where XY's market would collapse."[71] The IP theft directly benefited PRC state-controlled enterprises like some of Zhu's PRC-based companies, and it also benefited IND Group's "two head offices in China, in Beijing and Qing[d]ao."[72]

The court found that Zhu and his PRC co-conspirators made many disturbing statements as part of their plan. These include instances where Zhu, in response to a co-conspirator's reference to "American imperialism," replied that "the law is strong, but the outlaws are ten times stronger."[73] In another instance, Zhu claimed that his fraudulent activity would help "defeat the American aggressor and wild ambitious wolf!"[74]

The Canadian court found Zhu and his co-conspirators guilty of civil IP theft, conspiracy, and other claims, issuing a $330 million judgment against them in June 2016. Zhu failed to appear before the court for sentencing, resulting in the judge issuing an arrest warrant for civil contempt of court, which carries a prison sentence of six months.[75] Zhu then fled Canada.

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[68] *Id*. Zhu operated additional companies, who are also codefendants in the Canadian court case, in Qingdao as well, including Ai De Qingdao, which is linked to the PRC affiliate of Universal Meditech Incorporated, the corporation involved in the Reedley lab. *See id.*; *infra* at pg. 32.

[69] *XY, LLC v. Canadian Topsires Selection Inc.*, 2016 BCSC 1095.

[70] Keith Fraser, *B.C.-Based Businessman Employees Ordered to Pay $330m in Damages*, Vancouver Sun, (Jun. 12, 2016).

[71] *Id*.

[72] *XY, LLC v. Canadian Topsires Selection Inc.*, 2016 BCSC 1095.

[73] *Id*.

[74] *Id*. These statements are from 2011 and 2010, respectively.

[75] Keith Fraser, *Canadian businessman facing jail over fraud has appealed stayed following no-show*, Vancouver Sun (Jul. 14, 2016).

Canadian businessman facing jail over fraud has appeal stayed following no-show

Keith Fraser

Join the conversation

In a ruling posted online, B.C. Court of Appeal Justice Elizabeth Bennett said that it would be an abuse of process of the court to hear the appeal without Jesse Zhu present. The issue then became whether Zhu's appeal would be dismissed or stayed with conditions. PHOTO BY FELICITY DON /Vancouver Sun

B.C.-based businessman and employees ordered to pay $330m in damages

Keith Fraser

Published Jun 21, 2016 • 3 minute read

Join the conversation

A judge has ordered a Canadian businessman and several of his employees to pay a total of more than $330 million for profiting from the theft of technology related to the separation of sex chromosomes from bull semen. Leah Hennel/Calgary Herald files PHOTO BY LEAH HENNEL /Calgary Herald

Figure 2 *- Canadian media reported on Zhu's trial civil conviction. Source: Vancouver Sun.*

C. Jesse Zhu Enters the United States and Assumes the Alias "David He"

At some point, Zhu appears to have entered the United States unlawfully, given that he was subject to a Canadian arrest warrant. While in the United States, he began to operate under the false identity of "David He."[76]

The following evidence establishes that Zhu is using "David He" as an alias. First, federal law enforcement confirmed this information in their federal complaint.[77] Second, employees working in the Reedley Biolab told local officials that "David He" is in fact Jesse Zhu. Third, Select Committee investigators discovered numerous documents belonging to IND Group and Jesse Zhu in the Reedley Biolab. These include thousands of pages of (i) IND Group, AIDE, and other Zhu companies' corporate documents; (ii) tax records for Zhu and these companies; and (iii) personal notes that appear to be addressed to Zhu. Fourth, Zhu's prior official photograph from the early 2000s (though ~20 years younger), matches the facial characteristics of "David He." Finally, financial documents found in the Reedley Biolab and other financial records show transfer of funds and shipments from Zhu's IND Group to UMI and Prestige Biotech.

[76] Zhu also managed to acquire false identification documents as "He."

[77] Press Release, Department of Justice, Arrest Made in Central California Biolab Investigation (Oct. 19, 2023); *United States v. Jia Bei Zhu*, No. 1:23-MJ-00123-SKO, (E.D. Cal. Oct. 18, 2023) (Criminal Complaint).

Figure 23 *- An FBI photograph of Jiabei Zhu (left), and texts between Code Enforcement Officer Harper and a former UMI employee (right) confirming the man they worked for is named "Jesse." Source: City of Reedley.*

Figure 24 *- A printout of a driver's license and a copy of an Employment Authorization Card for David He. Source: City of Reedley.*

Figure 25 *– Copy of Zhu's prior CA driver's license with contemporary photograph.*

D. Zhu Continues to Operate a Web of Interconnected PRC- and US-Based Companies Used in His Fraudulent Activities

In perpetrating IP theft in Canada, Zhu used a network of interconnected companies in the PRC, Canada, and elsewhere that were notionally distinct but, in practice, all subject to Zhu's direction and control. The Supreme Court of British Columbia found in 2016 that:

> Zhu uses his companies, and nominee shareholders and directors, with little or no regard for the notional separate personality of his companies. Rather, he creates corporations and appoints nominees to create the false appearance that a company is not owned or controlled by him, or otherwise to carry out his intentions which, in this case, were unlawful. This is also done to shield himself from liability for such unlawful actions.[78]

While operating in the United States, even the limited evidence available to the Select Committee demonstrates that Zhu continued to engage in a similar pattern of behavior with UMI and the other entities Zhu controlled. For example, documents found at the Reedley Biolab indicate that UMI borrowed $240,000 from two of Zhu's previously established companies—IND Dairytech USA Inc. and International Newtech Development—in 17 installments between January 3, 2021 and September 24, 2022. IND and its various holdings, which were implicated by the Canadian court judgment, were supposed to be defunct in 2021. Even earlier in 2020, a deposit amounting to $125,000 was deposited in IND Dairytech USA Inc.'s bank account.

UMI 向 IND DAIRYTECH USA INC 借款记

*如在当月还款，则不计息。如果超过一个月，利息按每月1%计算。

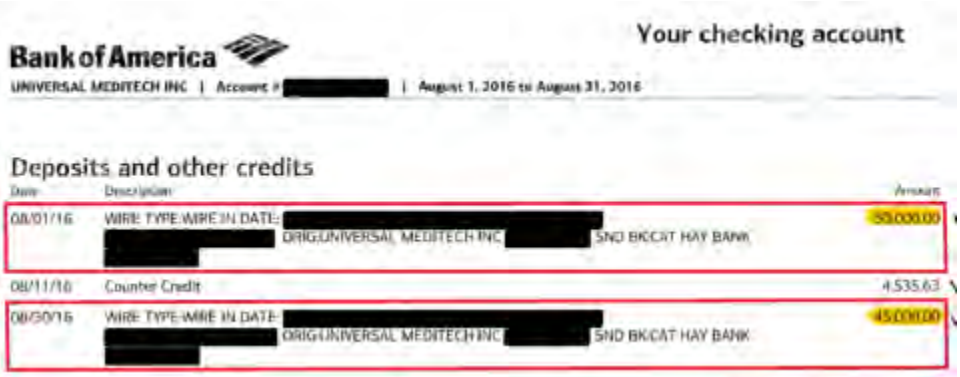
序号	UMI借款日期	借款金额	汇款公司名称	备注
1	05/28/21	$20,000.00	INTERNATIONAL NEWTECH DEVELOPMENT INC	6/28/21 前还款免利息
2	06/07/21	$20,000.00	IND DAIRYTECH USA INC	7/07/21 前还款免利息
3	06/14/21	$20,000.00	IND DAIRYTECH USA INC	7/14/21 前还款免利息
4	06/30/21	$20,000.00	IND DAIRYTECH USA INC	7/01/21 前还款免利息
5	07/12/21	$20,000.00	IND DAIRYTECH USA INC	8/12/21 前还款免利息
6	07/23/21	$20,000.00	IND DAIRYTECH USA INC	8/23/21 前还款免利息
7	07/27/21	$20,000.00	INTERNATIONAL NEWTECH DEVELOPMENT INC	8/27/21 前还款免利息
8	08/04/21	$10,000.00	INTERNATIONAL NEWTECH DEVELOPMENT INC	9/04/21 前还款免利息
9	09/01/21	$10,000.00	INTERNATIONAL NEWTECH DEVELOPMENT INC	10/01/21 前还款免利息
10	09/14/21	$10,000.00	IND DAIRYTECH USA INC	10/14/21 前还款免利息
11	09/14/21	$10,000.00	INTERNATIONAL NEWTECH DEVELOPMENT INC	10/14/21 前还款免利息
12	09/17/21	$10,000.00	IND DAIRYTECH USA INC	10/17/21 前还款免利息
13	9/24/2022	$10,000.00	IND DAIRYTECH USA INC	09/24/21 前还款免利息
14	10/04/21	$10,000.00	INTERNATIONAL NEWTECH DEVELOPMENT INC	11/04/21 前还款免利息
15	10/04/21	$10,000.00	IND DAIRYTECH USA INC	11/04/21 前还款免利息
16	10/14/21	$5,000.00	ROMANUS ANAYO OKAFOR	代收
17	10/18/21	($5,000.00)	IND DAIRYTECH USA INC	代付
18	01/03/22	$10,000.00	IND DAIRYTECH USA INC	02/03/22 前还款免利息
19	01/04/22	$10,000.00	IND DAIRYTECH USA INC	02/04/22前还款免利息
20	01/12/21	$5,963.00	AGHAEGBULAM H UGA CECILIA	代收
		$245,963.00		

本金	$240,000.00
2022年2月28日止利息	$14,300.00
本金加利息：	$254,300.00
代收款	$5,963.00
合计	$260,263.00

***Figure 26** - UMI corporate records showing a loan plan between UMI and IND Dairytech USA. The total amount loaned to UMI through the plan was $240,000. Source: Select Committee.*

[78] *XY, LLC v. Canadian Topsires Selection Inc.*, 2016 BCSC 1095. ("[I]t is manifestly clear that Zhu uses his companies, and nominee shareholders and directors, with little or no regard for the notional separate personality of his companies. Rather, he creates corporations and appoints nominees to create the false appearance that a company is not owned or controlled by him, or otherwise to carry out his intentions which, in this case, were unlawful. This is also done to shield himself from liability for such unlawful actions.").

Other documents reveal further ambiguous financial interactions between the IND and other companies from Zhu's prior network and UMI. For example, UMI used a packaging company affiliated with and previously used by Aide Modern Cattle China to ship materials to California.[79] Moreover, additional documents show that Ai De Diagnostic Co., Ltd. wired $34,980 to UMI on June 26, 2017, for unknown reasons. The Supreme Court of British Columbia found International Newtech Development and Ai De Diagnostic Co, Ltd. to be "own[ed] and control[led]" by Zhu, and IND Dairytech USA Inc. also appears to be tied to Zhu.



Bank of America — Your checking account

UNIVERSAL MEDITECH INC | Account # [redacted] | August 1, 2016 to August 31, 2016

Deposits and other credits

Date	Description	Amount
08/01/16	WIRE TYPE:WIRE IN DATE: [redacted] ORIG:UNIVERSAL MEDITECH INC [redacted] SND BK:CAT HAY BANK	55,000.00
08/11/16	Counter Credit	4,535.63
08/30/16	WIRE TYPE:WIRE IN DATE: [redacted] ORIG:UNIVERSAL MEDITECH INC [redacted] SND BK:CAT HAY BANK	45,000.00

Figure 28 *- UMI bank records obtained by the Select Committee. A Cathay Bank account wired $90,000 to UMI in a one month period. Source: Select Committee.*

Bank of America — Your checking account

UNIVERSAL MEDITECH INC | Account # [redacted] | June 1, 2017 to June 30, 2017

Deposits and other credits

Date	Description	Amount
06/05/17	AMZN(3F7CMCX [redacted] INDN:Universal Meditech Inc CO [redacted]	7.20
06/12/17	CA TLR transfer	16,000.00
06/15/17	PAYPAL DES:TRANSFER [redacted] INDN:UNIVERSAL MEDITECH INC CO [redacted]	500.00
06/15/17	PAYPAL DES:TRANSFER [redacted] INDN:UNIVERSAL MEDITECH INC CO [redacted]	400.00
06/16/17	Counter Credit	408.00
06/19/17	CA TLR transfer	1,000.00
06/19/17	PAYPAL DES:TRANSFER [redacted] INDN:UNIVERSAL MEDITECH INC CO [redacted]	150.00
06/26/17	WIRE TYPE:WIRE IN DATE: [redacted] ORIG:AI DE DIAGNOSTIC CO., LTD [redacted] SND BK:THE BANK OF NEW YORK MELLON [redacted]	34,980.00

Figure 27 *- UMI bank records obtained by the Select Committee. AI DE Diagnostic sent UMI tens of thousands of dollars. Source: Select Committee.*

[79] *See generally* Figures 16-19.

Figure 28 *- A counter deposit check for IND Dairytech USA found amongst UMI financial paperwork. $125,000 from an unknown source was deposited over the counter. Source: Select Committee.*

As "David He," Zhu claimed that he was merely the "special representative" for UMI and Prestige Biotech. Employees have stated, however, that Zhu is the "main man" and "owner" who actually controls the UMI/Prestige Biotech operations at the Reedley Biolab. In addition, he is the only person local officials have engaged with who appears to have actual decision-making power at the organizations.

This is consistent with Zhu's former practice. The Supreme Court of British Columbia described Zhu as the "directing mind" of a large corporate network engaged in fraud. It appears that Zhu continues to operate as the "directing mind" of the UMI corporate network. Zhu, as "He," continued to use the same corporations in China and hire many of the same individuals to run his PRC operations. For instance, Universal Meditech Inc (UMI) / Prestige Biotech Inc. executives Yao Xiuqin and Wang Zhaoyan share the names with the heads of Ai De Biopharmaceutical in Qingdao, China: 姚秀芹 (Yao Xiuqin) and 王朝艳 (Wang Zhaoyan). He also continued to tie his PRC companies (such as Ai De Diagnostic) in with UMI and Prestige, such as using UMI as Ai De's U.S. Agent. According to import records and documents recovered at the Reedley Biolab, Ai De Biopharmaceutical (which shares the same address as Ai De Diagnostic) in Qingdao has made many shipments of medical supplies to

Figure 29 *- In FDA registration records, Ai De Diagnostic is listed as having the same registration address as a former UMI address in Fresno. Ai De Diagnostic's contact address places it in the Qingdao High-Tech Industrial Park. Source: FDA website.*

UMI and Prestige. Zhu's PRC companies are located in the Qingdao High-Tech Industrial Park.[80] The Qingdao High-Tech Industrial Park is a specialized area that the CCP established and oversees for the development of biomedical science and technology.[81] Currently, the Qingdao High-Tech Industrial Park is overseen by an individual who is also the Deputy Secretary of the CCP Chengyang District Committee, and who joined the CCP in 1992.

78	Shandong Province	Jinan High-tech Industrial Development Zone
79		Weihai Torch High-tech Industrial Development Zone
80		Qingdao High-tech Industrial Development Zone
81		Weifang High-tech Industrial Development Zone
82		Zibo High-tech Industrial Development Zone
83		Jining High-tech Industrial Development Zone
84		Yantai High-tech Industrial Development Zone
85		Linyi High-tech Industrial Development Zone
86		Tai'an High-tech Industrial Development Zone
87		Zaozhuang High-tech Industrial Development Zone
88		Laiwu High-tech Industrial Development Zone
89		Dezhou High-tech Industrial Development Zone
90		Yellow River Delta Agricultural High-tech Industry Demonstration Zone

Figure 30 *- PRC website showing PRC control of Qingdao High-tech Industrial Zone.*

E. Zhu's Fraudulent Activities in the United States

After arriving in the United States, Zhu hired Accountant 1 (an individual known to the Select Committee) to help Zhu—a wanted international fugitive—set up several companies in the United States.[82] Accountant 1 also helped with

[80] *See generally,* Ai De Diagnostic website.

[81] *High-tech Industrial Development Zone*, CCP Ministry of Science and Technology of the People's Republic of China.

[82] *See generally* Alex Joske, *The Party Speaks for You*, American Strategic Policy Institute (Jun. 9, 2020). The UFWD is a CCP Central Committee department with over 40,000 employees that coordinates and carries out hybrid government and private sector activities to benefit the CCP.

bookkeeping for those companies. Accountant 1—not Zhu himself—has incorporated and performed work for organizations whose leadership is linked to CCP leadership and to the United Front Work Department.[83] These include organizations that advocate for CCP control over Taiwan and the "repatriation" of overseas PRC citizens, set up "little red classrooms" in Nevada's public schools that promote CCP ideology, and promote the CCP's narrative about the COVID pandemic. One such organization, which advocates for CCP control over Taiwan, is directly tied to the radicalization of David Chou, a PRC national and a Nevada resident who went on an armed shooting spree at a Taiwanese church in 2022.[84]

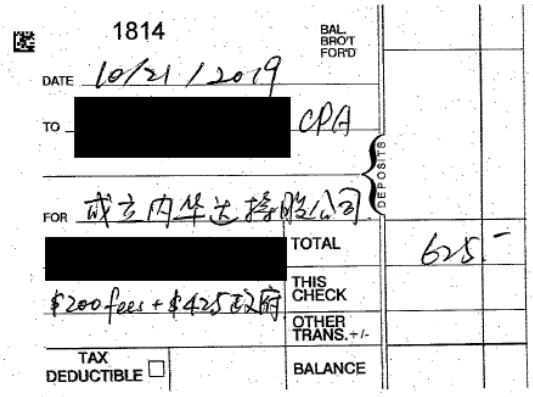


***Figure 31** - UMI internal receipt showing a $625 payment to Accountant 1 for setting up a "Nevada holding company." Source: Select Committee.*

The companies that Accountant 1 set up for Zhu engaged in fraud and operated the unlicensed and illegal Reedley Biolab. As described above, this involved obtaining and storing vast quantities of apparent pathogens, biological, and chemical materials, and preserving them at great expense. It is unclear when Zhu began obtaining these apparent pathogens and other materials—hand-written labels appear to indicate that he obtained some as early as 2009. If that is correct, Zhu appears to have transported them across the northern border when he entered the United States unlawfully due to the active arrest warrant in Canada, a pathogen importation violation.

Zhu rented out large warehouses, purchased and maintained at least 1,000 transgenic mice, bought expensive medical-grade and other freezers and refrigerators, and rewired electrical circuits to draw in enough power to keep these freezers at a sufficiently low temperature.

[83] Sources include publicly available documents, media reporting, and information related to business filings. Sources on file with Select Committee.

[84] Information was derived using a blend of specialized resources and analytical methods, complemented by data extracted from publicly available sources, following established reporting guidelines.

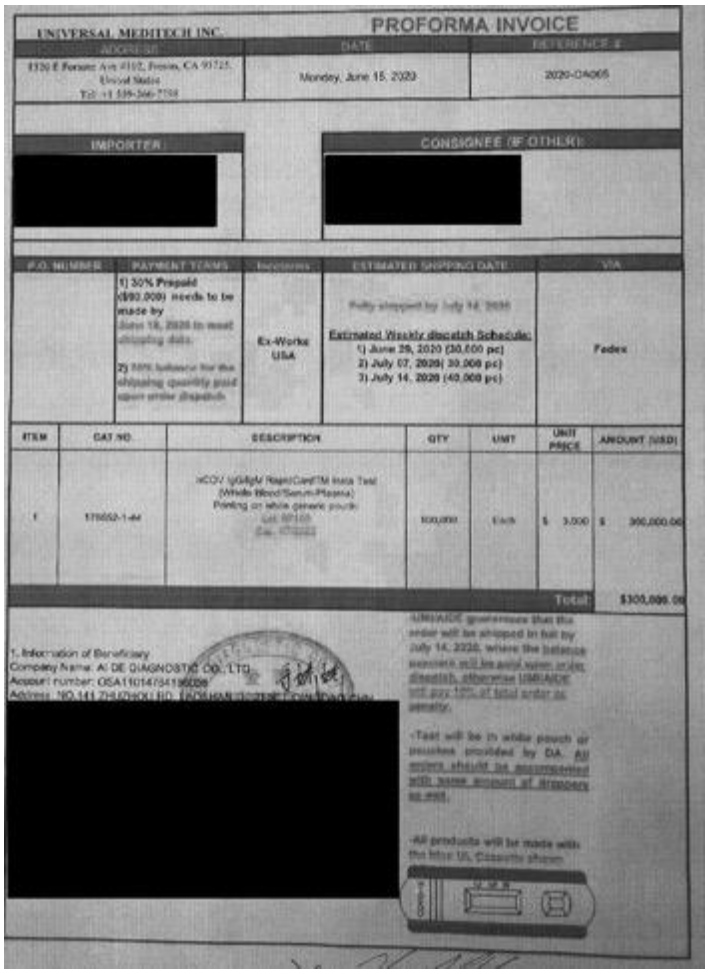
The Select Committee's investigation did not produce a complete record of Zhu's activities in the U.S., but it revealed that Zhu had previously operated a similar unlicensed facility in the city of Fresno, California. At the Fresno location, it appears that Zhu and his associates had rewired the electrical system in a way that may have caused the fire that forced Zhu to flee. When that location was no longer available, Zhu proceeded to find a second potential laboratory and again go through the elaborate process of retrofitting it for his illicit operation. It appears that Zhu has had to move medical equipment, transgenic mice, and apparent pathogens several times over the years, incurring significant costs in the process.

The Select Committee has obtained evidence indicating that Zhu and his associates at the Reedley Biolab were purchasing counterfeit test kits from the PRC and re-selling them in the United States as "Made in the USA." The Reedley Biolab contained dozens of large boxes full of PRC-made medical device test kits, shipping manifests for these items from the PRC, and bills indicating the acquisition of these test kits from PRC companies (in some cases, companies affiliated with Zhu). These kits were allegedly used to test for COVID-19, pregnancy, ovulation, and certain narcotics. The Food and Drug Administration (FDA) determined that UMI's test kits "may not be 'safe and effective,'" and issued a recall.[85] This evidence matches allegations made in lawsuits against Zhu's companies for this fraudulent practice.[86]

Figure 32 *- One of the pregnancy tests offered by UMI. The cassette in the bottom left corner, above the "Made in USA" stamp, is identical to cassettes UMI imported from the PRC.*
Source: City of Reedley.

[85] FDA warns against pregnancy tests from illegal bio lab, The Business Journal (Aug. 14, 2023, 2:05 PM).

[86] *See, e.g.*, *Sensiva Health vs. Universal Meditech*, No. 21-598, 2022 WL 17576345 (E.D. La. Nov. 18, 2022) (Judgment).


UNIVERSAL MEDITECH INC.

PROFORMA INVOICE

ADDRESS	DATE	REFERENCE #
1120 E Fresno Ave #102, Fresno, CA 93725, United States Tel: +1 559-366-7758	Monday, June 15, 2020	2020-DA065

IMPORTER: [redacted]

CONSIGNEE (IF OTHER): [redacted]

P.O. NUMBER	PAYMENT TERMS	Incoterms	ESTIMATED SHIPPING DATE	VIA
	1) 30% Prepaid ($90,000) needs to be made by June 18, 2020 to meet shipping date. 2) 70% balance for the shipping quantity paid upon order dispatch.	Ex-Works USA	Fully shipped by July 14, 2020 Estimated Weekly dispatch Schedule: 1) June 29, 2020 (30,000 pc) 2) July 07, 2020(30,000 pc) 3) July 14, 2020 (40,000 pc)	Fedex

ITEM	CAT NO.	DESCRIPTION	QTY	UMT	UNIT PRICE	AMOUNT (USD)
1	170052-1-4#	nCOV IgG/IgM RapidCard™ Insta Test (Whole Blood/Serum/Plasma) Printing on white generic pouch Lot: 20105 Exp: 07/2022	100,000	Each	$ 3.000	$ 300,000.00
					Total:	$300,000.00

1. Information of Beneficiary
Company Name: AI DE DIAGNOSTIC CO., LTD
Account number: OSA110147041[redacted]
Address: NO.141 [redacted]

UMIAIDE guarantees that the order will be shipped in full by July 14, 2020, where the balance payment will be paid upon order dispatch, otherwise UMIAIDE will pay 10% of total order as penalty.

-Test will be in white pouch or pouches provided by DA. All orders should be accompanied with same amount of droppers as well.

-All products will be made with the blue UL Cassette shown

Figure 33 *- A UMI invoice for a U.S.-based customer purchasing from Ai De Diangostic in the PRC. The invoice, which notes a shipment from the PRC of 100,000 tests, includes a picture of the test cassette. The cassette is identical to the one shown in Figure 26. Source: Select Committee.*

Figure 34 *– a China Chamber of International Commerce Certificate for Exportation of medical devices.*

Figure 35 *- Additional UMI testing products, primarily pregnancy tests. The box second from the right includes a picture of the same PRC-origin cassette as Figures 26 and 27. Source: City of Reedley.*

Figures 36-38 *- Of the equipment in the Reedley Biolab, most was for packaging products. Pictured above, left and going clockwise: a PRC-origin automatic packing machine, a PRC-origin automatic separating and cutting machine, and an automatic folding machine. Source: City of Reedley.*

F. Zhu's Lab Appears to Have Contained Biological Pathogens, Medical Equipment, and Transgenic Mice That Had No Clear Purpose in His Fraudulent Sale of Fake Test Kits.

The Select Committee did not find evidence that the Reedley Biolab was engaged in active diagnostic test kit manufacturing—instead, the available evidence indicated that Zhu and his associates were simply purchasing counterfeit tests, falsely relabeling them as American-made, and selling them to American consumers.

There is also no evidence that the Reedley Biolab was selling test kits for any pathogen except for COVID-19. The Select Committee reviewed documents found at the Reedley Biolab (such as UMI printed sales brochures), fake test kits found on site, FDA recall notices, and archived web data. These materials showed that, aside from COVID-19 test strips, UMI was not selling any diagnostic test strips relating to any pathogens while it operated in Reedley.[87]

Moreover, there is little to no market for test kits that would test the majority of the pathogens that the Reedley Biolab appeared to contain, let alone test kits created in an unlicensed laboratory. The Select Committee did find evidence that at least one pathogen may have been tested on the mice at the Biolab, but the purpose and scope of such testing is unclear.

While Zhu's fraudulent activity itself required little overhead, maintaining large numbers of apparent pathogen samples, medical equipment, potentially hazardous chemicals, and transgenic mice was expensive. More importantly, they posed significant health risks both for individuals who worked in the facilities and to the broader community.

The apparent presence of Ebola samples at the Reedley Biolab is the clearest example of the lack of apparent legitimate (or even profit-motivated criminal) motive in the operation of the illegal facility. The need for Ebola tests is minimal and the potential market is extremely small. Experimenting with Ebola (even for benign purposes) is very dangerous—case fatality rates for Ebola have ranged between 25-90% in past outbreaks.[88] Handling Ebola requires a Biosafety Level 4 (BSL-4) facility, "the highest level of biological safety."[89] Only a few laboratories in the world have the equipment, licenses, and safety protocols required.[90] The Reedley Biolab clearly does not. It is unclear how any non-BSL-4 facility, let alone the Reedley Biolab, would potentially be able to acquire this deadly pathogen in the first place.

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[87] As noted above, the other alleged test kits were focused on pregnancy, ovulation, and certain narcotics tests. The Select Committee did uncover earlier brochures and archived web data from early 2010s listing three other pathogens: Malaria, Hepatitis B, and Hepatitis C. This was before the establishment of the warehouse in Reedley. While these pathogen diagnostic test kits were listed on the brochure and online, it is unclear whether Zhu's companies actually developed these kits or instead sold counterfeit test kits, in conformance with their recent medical device kit activities. None of the evidence accounts for the majority of labeled pathogens found in the biolab.

[88] *Ebola Disease* CDC (Mar. 23, 2023). Ebola "is a rare and often deadly" disease that results in hemorrhagic fevers, with a case fatality rate ranging from 25% to 90% in past outbreaks. Symptoms appear within 2-21 days of infection and are often severe. While Ebola's rapid onset and high lethality make it unlikely to spread into a pandemic, it can cause many localized deaths. *See also* *Ebola Disease*, WHO.

[89] *Training: Recognizing the Biosafety Levels*, CDC.

[90] *Infographic: Biosafety*, CDC (Aug. 30, 2021, 9:40 AM).

G. Zhu Receives Large Unexplained Payments from the PRC

The Select Committee investigation uncovered documents and other records showing that, while Zhu was selling fraudulent kits and engaging in unknown pathogen-related activity, he was also receiving unexplained payments via wire transfer from PRC banks.[91] In a few years, these payments totaled over $1.3 million. This number may significantly underestimate the total amount he received via suspicious payments, because the Select Committee only has access to partial data and records. These payments do not accord with Zhu's fraudulent activity, as he should have been paying money *to* PRC firms for the test kits and receiving payments *from* American individuals or companies who purchased the counterfeit test kits. These payments may be indicative of money laundering. These payments deserve continued scrutiny.

H. FDA Agents Arrest Zhu in Connection with Federal Charges Relating to Fraud and False Statements

On October 19, 2023, federal agents arrested Zhu on a criminal complaint for manufacturing and distributing misbranded medical devices in violation of the federal Food, Drug, and Cosmetic Act (FDCA) and for making false statements to the FDA.[92] In addition to confirming his identity, the criminal complaint discussed Zhu's ties to the Reedley Biolab site and the business therein.[93] It also described Zhu's multi-year fraudulent activities and false statements he made to federal agents in order to conceal his identity.

III. PUBLIC HEALTH RISKS, SAFEGUARDS, AND THE FEDERAL RESPONSE

A. The Public Health Risks Posed by the Lab Are Unknown and, at This Point, Unknowable

With the exception of Ebola, the labeled pathogens (which CDC accepted at face value) are inconsistent with the operation of a bioweapons program. Most fall into Risk Groups 2 and 3, which may pose a high risk to individuals (i.e., infecting specific people with HIV, tuberculosis, or malaria through targeted attacks or contamination of a specific area) but are unlikely to cause a mass casualty event.

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[91] *See, e.g.*, analysis in II.D, *supra*. The Select Committee's investigative authorities are limited with respect to the potential investigatory steps related to financial records.

[92] The Select Committee notes that the Criminal Complaint charged Zhu with "manufacturing and distributing misbranded medical devices" in violation of 21 U.S.C. §§ 331(a) and (c). Charging instruments are charged in the conjunctive ("and") but proven in the disjunctive ("or"). *See* Justice Manual, 227. Conjunctive and Disjunctive Elements. In addition, the Select Committee is unaware of whether Zhu had the devices manufactured abroad or elsewhere..

[93] Press Release, Department of Justice, Arrest Made in Central California Biolab Investigation, (Oct. 19, 2023); *United States v. Jia Bei Zhu*, No. 1:23-MJ-00123-SKO, (E.D. Cal. Oct. 18, 2023) (Criminal Complaint).

While Risk Group 2 or 3 pathogens are unlikely to infect a city, they could still pose a substantial risk to the community. A blood supply infected with HIV, for example, or immunocompromised communities like nursing homes suddenly falling ill with tuberculosis, could spark a localized panic.

In addition, individuals can use even simple pathogens to great effect to harm a large population. For instance, in the 1984 Rajneeshee bioterror attack—the largest bioterror attack in U.S. history—attackers sickened more than 700 Oregonians by spreading salmonella they had purchased at a U.S. lab on a few local salad bars.[94] The pathogens found at the Reedley Biolab, such as the many different types of E. coli strains or a potentially antibiotic-resistant strain of Tuberculosis, could be used to an even deadlier effect.

February 28, 1985 CONGRESSIONAL RECORD—HOUSE 4187

of the implicated restaurants you had a very good chance of getting salmonella infection. But even the health authorities who assumed that the food handlers were the cause could find no evidence of any kind to determine how the food handlers got salmonella in the first place. Except by eating at the salad bars.

Consider the outbreak. Eight salad bars in one small town within a 2-week period were the primary source of 715 confirmed cases of salmonella. Indeed, in the second wave when, within a few days, about 600 people were poisoned. The salad bars accounted—according to the best statistical evidence—for most of the infections. Then consider that there are about 50,000 salad bars in restaurants in the United States according to the National Restaurant Association and none of them have been pinpointed as the cause of any salmonella outbreaks. They all have food handlers just as likely or unlikely to contract and pass on salmonella as the food handlers in The Dalles. But only eight salad bars in the United States—out of those 50,000—caused one of the largest eruptions of salmonella in our history. All in one small town within a 2-week period.

The Dalles is not in my congressional district but it is a town I particularly like. When I first read of the salmonella outbreak and the investigation it appeared so strange I became most interested. I talked with the health authorities involved in the investigation almost daily. I poured over the statistics as I received them. I analyzed them thoroughly. I rechecked my facts with the authorities. I talked with other people in The Dalles, including several of the restaurant man-

Is it possible to use salmonella for mass poisoning? It certainly is. Salmonella is quite easy to culture. Under the right conditions it grows quite rapidly. It can be transported easily in liquid. However, culturing salmonella and storing it and determining the proper mix for transporting it would best be done by a medical laboratory with trained lab technicians.

If one wanted to undertake a mass poisoning with salmonella, where would one go? The obvious places, where a customer of a restaurant comes in contact naturally and without suspicion with the food many of the other patrons will eat: the salad bars. A small vial of salmonella culture could be used to sprinkle the liquid in the salad dressings or salad mixes or on the lettuce or other foods on the salad bar as one helped themselves.

Who would do such a terrifying thing? Who would poison a whole town; or at least 715 of its citizens? Whoever did could not have known how many people they would poison, or whether someone might die from the poisoning. But the massive assault on the people of The Dalles was that: a massive assault, almost a war on the town. Who would want to do it? And who would have the capability to do it?

Is there a madman lurking in The Dalles? The poisoning was an insane act, an act of violent hatred, carried on with subtle means. There must be such a person or persons with the motive and ability to assault this town, for it actually happened.

RAJNEESHPURAM

A group of people arrived in Wasco County in 1981. They are the followers of a native of India who calls himself

people poured in, other residents of Wasco County became aroused. Among other things, they feared that the Rajneeshees would attempt to register and vote the street people in the coming election; possibly even elect county commissioners favorable to the Rajneeshees. Large protest meetings were held in The Dalles and other places. The issue became very hot and heavy, with both Rajneeshees and other Oregon citizens saying some very harsh things about each other.

The person who spoke for the Rajneeshees most frequently was a woman called Ma Anand Sheela, the personal secretary of the Bhagwan. On September 18 press reports quoted Ma Anand Sheela saying to a rally:

You tell your Governor, your attorney general and all the bigoted pigs outside that if one person on Rancho Rajneesh is harmed I will have 15 of their heads, and I mean it. You have given me no choice. Even though I am a nonviolent person I will do that.

Ma Anand Sheela has been photographed wearing a holster with a revolver in it.

On the next day, September 19, Ma Anand Sheela was again quoted in newspapers: "Wasco County is so bigoted it deserves to be taken over."

There were a number of reports of people who threatened to come to Rajneeshpuram with shotguns. But there were no reports of people who actually did. Nor were there reports of any Rajneeshees who were harmed by outsiders. Nor were there any reports of Rajneeshees harming anyone else.

One of the things that first aroused my concern about the Rajneeshees was a statement I saw the Mayor of Rajneeshpuram make on a TV pro-

Figure 39 *– Congressional record discussing the Rajneeshee bioterror attack.*

The Reedley Biolab also presented an ongoing transmissibility risk to the wider community. The Reedley Biolab's precautions, if any, fell well below the standard of care for facilities containing these types of diseases. This in turn means that any worker there—including the workers forced to care for the transgenic mice that, per the other employees' own statements, were infected with diseases like COVID-19—could become a vector for a pathogenic outbreak within the community. In addition to respiratory-based pathogens, there are ongoing risks that a worker could suffer infection from blood-based pathogens through cuts or

[94] Scott Keyes, *A Strange but True Tale of Voter Fraud and Bioterrorism*, The Atlantic (June 10, 2014).

other openings in the skin. First responders could also be at risk, should they arrive on scene due to a fire or other emergency, and, if they are infected, lead to a broader outbreak. Lab-based infections occur even in professional laboratories with well-trained staff, and the risks to the community were much higher here.

B. The United States Lacks Effective Safeguards and Tripwires for Pathogenic Research

A disturbing realization is that *no one* knows whether there are other unknown biolabs in the United States because there is no monitoring system in place. Zhu, UMI, and other confederates at the Reedley Biolab were able to buy pathogens from accredited and respected U.S. laboratories. Zhu is a wanted fugitive in Canada and serial fraudster. UMI and its successor organizations like Prestige Biotech are little more than a corporate filing and a website. There does not appear to be any voluntary vetting of the purchase of pathogens or the equipment and materials needed to increase the lethality of pathogens. That is dangerous and requires reform.

The federal government and state authorities have implemented identification and reporting requirements related to acquiring other potentially dangerous substances. Federal law, for instance, requires that anyone purchasing items containing pseudoephedrine—a key ingredient in methamphetamine—has to provide a valid photo ID while the selling organization needs to keep a record of the purchase.[95] There are similar restrictions on the purchase of bulk fertilizer and certain types of chemicals.[96] However, there is no current requirement for acquiring pathogens (aside from Select Agents) or materials that allow for pathogenic research. Just as we require Americans to show a valid photo ID subject to government review in these instances, it is altogether reasonable to have similar policies in place for dangerous pathogens and equipment that can allow for malicious research relating to the same.

Similarly, the United States currently "does not conduct oversight of privately funded research, including enhancement of potential pandemic pathogens, if those pathogens are not select agents."[97] That means that pathogenic and other related research that could have benign or malicious intent—known as Dual Use Research of Concern (DURC)—are not currently under any oversight policies if they do not receive federal funding or conduct research with any harmful pathogen outside the 15 expressly listed in the policy.[98] In addition, the CDC Division of Select Agents and Toxins program has no oversight on laboratories engaging in pathogenic research if their research does not involve Select Agents

[95] Combat Methamphetamine Epidemic Act of 2005, Pub. L. No. 109-177, tit. VII (2006).

[96] *See, e.g.*, 18 U.S.C. § 842 (unlawful acts relating to explosive materials).

[97] *GAO-23-105455: Public Health Preparedness*, GAO (Jan. 2023).

[98] *Id.*

and toxins.[99] This is a substantial gap that, along with the presence of illegal biolabs, local communities are currently trying to address on their own.[100] There needs to be a comprehensive federal regulatory regime that safeguards Americans while still promoting responsible research.

C. The CDC's Response was Unacceptable

The CDC's response was inadequate and raises serious questions about its standard practices. It is unacceptable that the CDC, according to accounts of local officials, refused to take a phone call from city and county officials concerned about a biolab found in their region.[101] Even if the CDC normally works through state agencies, it could have given the necessary contact information to local officials. It should not require a Member of Congress – in this case, Congressman Jim Costa – to personally call the CDC or any other federal agency for them to provide meaningful support.

The CDC's refusal to test any samples is likewise baffling.[102] The CDC observed in its own reporting that "[t]housands of vials had unclear labeling, coded labeling, or no identifications," that biohazard signs were around many of these unlabeled vials, and that the labeled vials included Risk Group 2 and 3 pathogens.[103] Despite the probability that the unlabeled or coded vials contained additional unknown and dangerous pathogens, CDC officials refused to take any further investigative steps.[104] The fact that they seemingly took the word of biolab operators and noted fraudsters and concluded that the named labels are wholly correct is also strange. It is entirely within the realm of probability that the vials of *Toxoplasmi gondii*, for instance, were filled with an entirely different and potentially far more dangerous pathogen. Because of this, the Select Committee—and, more importantly, the American people—can never resolve what pathogens Zhu and the Reedley Biolab possessed.

The CDC's continuing refusal to test pathogens despite reasonable requests and the offer to pay from local officials facing a concerned populace simply does not make sense.[105] Despite the CDC official's statement to City Manager Zieba, there does not appear to be any law prohibiting the CDC from testing unlabeled

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[99] *Id.*

[100] *See generally* Brianna Willis, *Fresno lab transparency ordinance passes first vote by city council*, ABC News (Aug. 24, 2023).

[101] Select Committee conversation with local officials.

[102] *See* Footnote 40, *infra*.

[103] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023) at Ex. D – CDC Letter.

[104] *See* Footnotes 40 and 32, *infra* (referencing email correspondence and local official accounts).

[105] *Id.*

samples.[106] If the CDC knew that a specific sample was a Select Agent, it would not need to test it. Even if the CDC were limited to testing Select Agents, it falls well within its authority to test *suspected* Select Agents. Furthermore, if the CDC had a limited capability, other federal government organizations (like the Department of Homeland Security or the Department of Defense) may have had the means to assist. Yet the CDC did not even mention this as a possibility, let alone offer to connect them so that these organizations could conduct their own analysis of whether they should help this community.

Key aspects of the CDC report's recommendations are likewise hard to understand. It speaks of "[i]ssu[ing] an Import Permit advisement letter to Prestige Biotech to ensure they know the Import Permit Regulations for importing infectious substances into the U.S." and "[i]ssu[ing] a Federal Select Agent Program advisement letter to Prestige Biotech informing them of the requirements for possession, use, and transfer of select agents and toxins if the entity decides to possess them."[107] In these and other passages, the CDC acts as if the operators of biolab engaged in fraud are respected and trusted members of the research community. These particular recommendations were not actionable or helpful.[108]

The CDC's insisted that there was "no evidence" that Select Agents were within Reedley Biolab or that Zhu and UMI imported infectious agents and "insufficient evidence at this time" of legal violations. It seems to have made this claim without conducting any investigation beyond reading the labels that were in English on a limited number of the pathogenic samples.

The CDC also clearly did not review any of the many documents or containers found within the Reedley Biolab, as the Select Committee *did* find evidence showing importation of "infections agents, substances, or vectors" in violation of 42 CFR § 71.54.[109] This importation without a CDC permit would put the violation under the CDC's purview.[110] It would also reveal a potential gap in CDC's efforts

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[106] *See, e.g.*, John Lancaster and Susan Schmidt, *When anthrax-laced letters terrorized Washington and New York*, The Washington Post (Oct. 24, 2018, 1:02 PM) (describing how CDC officials tested unlabeled suspected anthrax spores).

[107] *Id.*

[108] *Id.* Other CDC recommendations included that "if the material is relocated, the California State Department of Health and the City of Reedley should ensure professionals or subject matter experts move the inventory to ensure there is no potential exposure to individuals or the environment." The CDC also did recommend "add[ing] Prestige Biotech and associated entity names to the CDC Import Permit Program watch list in case the entity attempts to apply for a CDC Import Permit."

[109] *In Re: Property Locate at 850 "I" Street, Reedley, California 93654*, No. 23CECG00912, (Cal. Super. Ct. Jun. 15, 2023) at Ex. D – CDC Letter.

[110] 42 CFR § 71.54(a) defines "infectious biological agent" and "infectious substances" as follows—

Infectious biological agent. A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.

to identity pathogen importation: when an importer does not tell the CDC, the CDC simply does not seem to have any idea.

Finally, we are concerned by the freezer labeled "Ebola" reported by local officials. It is concerning that, when this was brought to the CDC's attention, a CDC employee did not take meaningful action in response.

Congress should examine the state of biosafety in our country, and act to identify and remedy gaps in relevant statute or practice.

CONCLUSION

At a minimum, the Reedley Biolab shows the profound threat that unlicensed and unknown biolabs pose to our country. At worst, this investigation revealed significant gaps in our nation's defenses and pathogen-related regulations that present a grave national security risk that could be exploited in the future. It is therefore incumbent upon Congress and the Executive Branch to address these vulnerabilities now before it is too late.

Infectious substance. Any material that is known or reasonably expected to contain an infectious biological agent.

[redacted]

From: [redacted] (CDC/DDPHSIS/CPR/DSAT) [redacted]@cdc.gov>
Sent: Friday, May 5, 2023 8:34 AM
To: [redacted] CDPH
Cc: [redacted]
Subject: Re: Select Agent Screening

External

Good morning everyone,

The team and I are flying back to Atlanta this morning. Based on our assessment, we don't see an urgent need to test samples at the moment. Most of the material we were able to identify were proteins, antibodies, or pathogens (e.g., E. coli, HIV, SARS CoV-2, Hepatitis, Malaria, Mycoplasma, etc.) that would not be regulated under our authority (i.e., select agents) or considered a serious threat to public health.

As you are aware, there there were several samples that were "unknowns", illegible, or coded in a way that we could not interpret. I'm happy to discuss options for next steps at a later meeting.

Best,

[redacted]
Branch Chief
Division of Select Agents and Toxins
Office of Readiness and Response

Centers for Disease Control and Prevention (CDC)
[redacted]
[redacted]@cdc.gov

From: [redacted]@fresnocountyca.gov>
Sent: Thursday, May 4, 2023 7:47:09 AM
To: [redacted] (CDC/DDPHSIS/CPR/DSAT) [redacted]@cdc.gov>; [redacted]
Subject: Select Agent Screening

Good Morning,

In yesterday's call we discussed the possibility of screening some items for testing. If CDC and CDPH agree and you need to send samples our team from the lab can assist with the appropriate packaging and shipping to the State or LRN Network lab. Ted and Cindy have Ben's contact information to start the resource request. Thank you

[redacted]
Department of Public Health
[redacted]

Does equipoise exist for masking children for COVID-19?

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Does equipoise exist for masking children for COVID-19?

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A B S T R A C T

Clinical equipoise is characterized by genuine uncertainty within the medical community about the effectiveness of a medical intervention. Its existence is often deemed necessary for clinical trials and signals a need for higher quality evidence, most often with randomized controlled trials, before the intervention can be considered effective. A leading official of the United States' Centers for Disease Control and Prevention Director, when testifying before Congress in February of 2023, indicated there was no need for randomized controlled trials of masking because, owing to overwhelming evidence of benefit, there was no longer equipoise about masking children for COVID-19. We disagree with this statement and outline the reasons why in this piece. We review the concept of clinical equipoise specifically using the example of child masking. We list reasons equipoise still exists for masking children, including a lack of consensus among experts, contradictory medical evidence and recent and ongoing randomized efforts. Finally, we differentiate between clinical equipoise and ethical appropriateness. Despite ongoing equipoise about masking children, we outline why, owing to lack of evidence of net benefit, recommending this intervention does not currently appear to be medically ethical.

1. Introduction

On Feb 8, 2023, a leading official of the Centers for Disease Control and Prevention (CDC) testified before Congress and was asked why the agency did not perform any randomized controlled trials of masking, specifically with respect to children [1]. The CDC official replied, "I'm not sure anybody would have proposed a clinical trial because, in fact, there wasn't equipoise to the question anymore," and then alluded to a number of observational studies that had suggested evidence of benefit.

The position that equipoise does not exist for masking children for COVID-19 is contradicted by threer lines of evidence: 1. Disagreement among experts and variations in guidelines, 2. Ambiguity of evidence and 3. The presence of recent and ongoing randomized efforts.

We review the concept of equipoise, describe how equipoise appears in real life and at what point it may no longer exist. Finally, we discuss how, even if there is equipoise for masking children, most would consider it medically unethical to recommend any intervention when the totality of evidence fails to find a net benefit.

1.1. The history of clinical equipoise

The use of randomized trials to assess medical interventions dates back to a 1940s trial of streptomycin for tuberculosis [2]. At this time, the determination that there was sufficient uncertainty to warrant a randomized trial arose from individual clinicians having no treatment preference. This lack of treatment preference by an individual was termed "theoretical equipoise" by Benjamin Freedman in 1987 [3]. He argued a true lack of preference on the part of the investigator occurs so rarely that it would inappropriately preclude most trials [3]. For this reason, he proposed the broader "clinical equipoise," defined as "genuine uncertainty within the medical expert community … about the preferred treatment." [3] Though there have been critics of Freedman's "clinical equipoise," his argument that uncertainty within the medical community is a more appropriate prerequisite for clinical trials than an individual lack of preference has become generally accepted, particularly as we discover many interventions clinicians strongly *believed* worked went on to be found ineffective in randomized studies [4].

1.2. Disagreement among experts and evidence of ongoing equipoise

Beliefs about the effectiveness and appropriateness of mask-wearing for respiratory infections vary widely by geographic location, type of mask, age and circumstance. The U.S. CDC, as of September 2023, continues to recommend [5] that children as young as 2 years old wear a

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high-quality mask or respirator when their community COVID-19 disease burden is considered "high" (or at "medium" disease levels if they themselves are considered "high risk"). This is in contrast to the European Centre for Disease Prevention and Control (ECDC) [6], which never recommended masking for COVID-19 for children under the age of 12. The World Health Organization never recommended masks for children under 6 and now only recommends masks in indoor situations where risk of exposure or severe disease is high [7]. CDC and ECDC specifically recommend higher quality medical or respirator masks, while the WHO indicates cloth masks are "acceptable." [7] Thus there still appears to be equipoise about mask type. However, none of these international organizations recommend masking outdoors in non-crowded spaces, thus it seems there may no longer be equipoise for masking in this setting.

Multiple international experts have argued against masking children citing both a lack of high-quality evidence of benefit and concerns about harms to learning and development [8–10], especially among pre-school age children [10]. One review by physicians from Uruguay and the United States pointed to a long list of studies documenting harms associated with masking children including increased anxiety, physical discomfort, decreased learning ability and recognition of emotion and sound [11]. On the other hand, some experts from the United States [12,13] have pointed to the substantial effectiveness of masks noted in some observational studies against SARS-CoV-2 transmission as evidence masking children may even play a role in reducing systemic racism [13].

However, practically speaking, fewer and fewer people are wearing masks, even in most healthcare settings. This suggests there is a growing consensus about masking among the general public. At the same time, in the summer and fall of 2023, a number of educational programs [14,15,31]continue to require masks for children under certain circumstances based on the CDC's guidance. It is unclear if more masking requirements may return to schools over the coming winter months or for other respiratory infections. The different viewpoints heldby medical experts indicates equipoise continues to exist for masking children even down to the age of two.

1.3. Ambiguity of the current evidence

A fundamental reason for the continued lack of consensus about mask-wearing for respiratory viruses is ambiguity of evidence. However, data from the two existing Cochrane Reviews of randomized data have been consistent, and unsupportive of masking. These reviews published in 2020 and 2023 [16,17], included randomized trials of surgical/-medical masks and N95/P2 respirators, with some study participants as young as five. The first included 14 trials for influenza, influenza-like illness and respiratory syncytial virus in the community, healthcare and home settings. It concluded that masks did not result in a clear reduction of disease, although there was low to moderate certainty in their conclusions. The follow up review included 17 trails with 3 randomized trials for COVID-19 and, again, pooled results regarding medical or surgical masks compared with no masks concluded "wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks." The authors stated data were "very uncertain" about N95/P2 respirators.

1.4. Contradictory observational studies

Numerous observational studies conducted during the COVID-19 pandemic found mask wearing to be associated with lower case rates [13,18–20]. However, given places and people who wear masks tend to differ in many ways beyond mask-wearing, these studies face substantial, if not insurmountable, challenges when attempting to adjust for confounding variables [21,22]. Many studies did not include control or comparator groups [23–25]. Some associations between mask requirements and lower case rates may also be spurious due to limited study time frame or small population [22,26].

Observational studies are designed to look for an association between masking and lower case rates, but are, with very few exceptions, unable to infer causality. Some natural experiments can also substantially reduce confounding by choosing a situation where the only meaningful variable that differs is mask use. This appears to have been the case with a regression discontinuity study from Catalonia, Spain [27], which took advantage of 5- and 6-year-old children having differing mask policies [27]. Researchers found no significant difference in cases or transmission rates between the masked 6-year-olds and unmasked 5-year-olds.

However, other natural experiments, where a mask mandate disappears for one group but not another may face the challenge of not being able to adjust for confounding factors that change along with the mandate [13,22]. Randomized controlled trials are able to greatly reduce bias and are, assuming proper study design, much more reliable for ruling in or out specific causal relationships. However, these have not been conducted in all settings, including educational settings or limited to brief hospital encounters where N95/respirator masks are worn consistently. Ongoing disagreement in these circumstances likely stems from a lack of more certain evidence and is consistent with ongoing equipoise.

1.5. Recent and ongoing randomized investigations

The presence of numerous recent randomized trials of masking in the community and healthcare setting speaks to the fact that multiple independent expert groups simultaneously assessed the landscape of evidence and found it also compatible with equipoise. Randomized studies of masking were recently completed in Denmark, Bangladesh, Canada, Egypt, Israel, Pakistan, Guinea Bissau and there is one ongoing randomized study of masking in Norway. Notably, this ongoing study is not recruiting anyone younger than 18, thus will not provide specific data for children.

1.6. Masking children: medical ethics and the end of equipoise

Most of the world's population has immunity to COVID-19 and the severity of the disease has decreased drastically [28]. One study from the UK reported no omicron deaths in children who had already been infected [29], compared with an initial worldwide infection fatality rate in children of around 3/million [30]. Worldwide, adults in general are choosing not to mask. Thus, the question arises: Is there still *genuine uncertainty* about masking children for COVID-19. In other words, is there still equipoise?

As late as September of 2023, a group of experts and the US CDC [5] continues to recommend masking children two and older in certain circumstances. The ECDC and WHO continue to mention masking children over ages 11 and 5, respectively, as an option for disease mitigation [5,6]. Thus there appears to still be equipoise about masking children.

However, a careful discernment of the evidence reveals a lack of evidence of net benefit of this intervention. Thus ethically, according to the principle of non-maleficence, the intervention would be considered unethical. As public awareness increases about the absence of high-quality data demonstrating benefit, equipoise may disappear, though may once again reappear with the emergence or resurgence of another respiratory disease threat. At that time, it will be indicated to obtain high-quality evidence from randomized trials before concluding based on low-quality evidence that the benefits of masking children will outweigh the harms, even for a limited period of time.

2. Conclusion

A leading CDC official stated no randomized trials of masking were done in children due to a lack of equipoise, citing overwhelming benefits found in observational studies. However, the presence of widespread disagreement among experts, remaining ambiguity of evidence, with

pooled randomized trials being negative, and the presence of recent and ongoing randomized investigations all support the presence of equipoise. At the same time, weighing the current high-quality evidence with known and potential harms [11], recommending masking for children goes against basic medical ethics. Currently, the onus lies with the public health agencies that continue to recommend masking children, especially when this can lead to mandates, to produce high-quality data to guide their recommendations rather than rely on low-quality observational data as if it were settled science.

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References

[1] Energy & Commerce, Joint Oversight and Investigations Subcommittee and Health Subcommittee Hearing "The Federal Response to COVID-19, 2023. February 8, https://energycommerce.house.gov/events/joint-oversight-and-investigations-subcommittee-and-health-subcommittee-hearing-titled-the-federal-response-to-covid-19-1. (Accessed 16 February 2023).

[2] Medical research council, STREPTOMYCIN treatment of pulmonary tuberculosis, Br. Med. J. 2 (4582) (1948 Oct 30) 769–782. PMID: 18890300; PMCID: PMC2091872.

[3] B. Freedman, Equipoise and the ethics of clinical research, N. Engl. J. Med. 317 (1987) 141–145.

[4] V. Prasad, A. Vandross, C. Toomey, M. Cheung, J. Rho, S. Quinn, S.J. Chacko, D. Borkar, V. Gall, S. Selvaraj, N. Ho, A. Cifu, A decade of reversal: an analysis of 146 contradicted medical practices, Mayo Clin. Proc. 88 (8) (2013 Aug) 790–798.

[5] Centers for Disease Control and Prevention, Use and Care of Masks, Updated May 11, 2023, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html. (Accessed 28 July 2023).

[6] European Center for Disease Prevention and Control, Questions and Answers on COVID-19: Children Aged 1-18 Years and the Role of School Settings, 2022. Updated April 26, https://www.ecdc.europa.eu/en/covid-19/questions-answers/questions-answers-school-transmission. (Accessed 16 February 2023).

[7] World Health Organization, Coronavirus Disease (COVID-19): Children and Masks, Updated March 7th, 2022. Accessed July 28th, 2023, https://www.who.int/news-room/questions-and-answers/item/q-a-children-and-masks-related-to-covid-19.

[8] A.P.S. Munro, R.C. Hughes, Face coverings have little utility for young school-aged children, Arch. Dis. Child. 108 (2) (2023 Feb) 77–78, https://doi.org/10.1136/archdischild-2022-324809. Epub 2022 Nov 3. PMID: 36328440.

[9] S.N. Ladhani, Face masking for children - time to reconsider, J. Infect. 85 (6) (2022 Dec) 623–624, https://doi.org/10.1016/j.jinf.2022.09.020. Epub 2022 Sep 25. PMID: 36170896; PMCID: PMC9509699.

[10] R.C. Hughes, S.S. Bhopal, M. Tomlinson, Making pre-school children wear masks is bad public health, Public Health Pract (Oxf). 2 (2021 Nov), 100197, https://doi.org/10.1016/j.puhip.2021.100197. Epub 2021 Oct 2. PMID: 34841375; PMCID: PMC8608397.

[11] T.B. Høeg, S. González-Dambrauskas, V. Prasad, The United States' decision to mask children as young as two for COVID-19 has been extended into 2023 and beyond: the implications of this policy, Paediatr. Respir. Rev. (2023 Apr 25), https://doi.org/10.1016/j.prrv.2023.04.004. S1526-0542(23)00019-2.

[12] J. Raifman, T. Green, Universal masking policies in schools and mitigating the inequitable costs of covid-19, N. Engl. J. Med. 387 (21) (2022 Nov 24) 1993–1994, https://doi.org/10.1056/NEJMe2213556. Epub 2022 Nov 9. PMID: 36351264; PMCID: PMC9730911.

[13] T.L. Cowger, E.J. Murray, J. Clarke, M.T. Bassett, B.O. Ojikutu, S.M. Sánchez, N. Linos, K.T. Hall, Lifting universal masking in schools - covid-19 incidence among students and staff, N. Engl. J. Med. 387 (21) (2022 Nov 24) 1935–1946, https://doi.org/10.1056/NEJMoa2211029. Epub 2022 Nov 9. PMID: 36351262; PMCID: PMC9743802.

[14] Johns Hopkins Center for Talented Youth. COVID-19 Updates. Updated 6/8/2023. Accessed July/28/2023. https://cty.jhu.edu/who-we-are/covid.

[15] Washington State Department of Health, Guidance to Prevent and Respond to COVID-19 in K-12 Schools and Child Cares, 2023. Updated May 30, https://doh.wa.gov/sites/default/files/2022-10/821165-K12SchoolsChildCare2022-2023.pdf. (Accessed 28 July 2023).

[16] T. Jefferson, C.B. Del Mar, L. Dooley, E. Ferroni, L.A. Al-Ansary, G.A. Bawazeer, M. L. van Driel, M.A. Jones, S. Thorning, E.M. Beller, J. Clark, T.C. Hoffmann, P. P. Glasziou, J.M. Conly, Physical interventions to interrupt or reduce the spread of respiratory viruses, Cochrane Database Syst. Rev. 11 (2020), CD006207, https://doi.org/10.1002/14651858.CD006207.pub5. (Accessed 28 July 2023).

[17] T. Jefferson, L. Dooley, E. Ferroni, L.A. Al-Ansary, M.L. van Driel, G.A. Bawazeer, M.A. Jones, T.C. Hoffmann, J. Clark, E.M. Beller, P.P. Glasziou, J.M. Conly, Physical interventions to interrupt or reduce the spread of respiratory viruses, Cochrane Database Syst. Rev. 1 (2023), CD006207, https://doi.org/10.1002/14651858.CD006207.pub6. (Accessed 28 July 2023).

[18] S.E. Budzyn, M.J. Panaggio, S.E. Parks, M. Papazian, J. Magid, M. Eng, L.C. Barrios, Pediatric COVID-19 cases in counties with and without school mask requirements - United States, july 1-september 4, 2021, MMWR Morb. Mortal. Wkly. Rep. 70 (39) (2021 Oct 1) 1377–1378, https://doi.org/10.15585/mmwr.mm7039e3. PMID: 34591829; PMCID: PMC8486393.

[19] M. Jehn, J.M. McCullough, A.P. Dale, M. Gue, B. Eller, T. Cullen, S.E. Scott, Association between K-12 school mask policies and school-associated COVID-19 outbreaks - maricopa and pima counties, Arizona, july-august 2021, MMWR Morb. Mortal. Wkly. Rep. 70 (39) (2021 Oct 1) 1372–1373, https://doi.org/10.15585/mmwr.mm7039e1. PMID: 34591830; PMCID: PMC8486387.

[20] A.E. Boutzoukas, K.O. Zimmerman, M. Inkelas, M.A. Brookhart, D.K. Benjamin, S. Butteris, S. Koval, G.P. DeMuri, V.G. Manuel, M.J. Smith, K.A. McGann, I. C. Kalu, D.J. Weber, A. Falk, A.L. Shane, J.E. Schuster, J.L. Goldman, J. Hickerson, V. Benjamin, L. Edwards, T.R. Erickson, D.K. Benjamin, School masking policies and secondary SARS-CoV-2 transmission, Pediatrics 149 (6) (2022 Jun 1), e2022056687, https://doi.org/10.1542/peds.2022-056687. PMID: 35260896; PMCID: PMC9647584.

[21] T.B. Høeg, V. Prasad, T. Porter, Contact tracing policy for masked students may be an important confounding variable, Pediatrics 150 (1) (2022 Jul 1), e2022057636A, https://doi.org/10.1542/peds.2022-057636A. PMID: 35765968.

[22] T.B. Høeg, A. Chandra, R. Duriseti, S. Ladhani, V. Prasad, Mask Mandates and COVID-19: A Reanalysis of the Boston Mask Study, July 22nd, 2023. arXiv: 2307.11974.

[23] M.J. Hendrix, C. Walde, K. Findley, R. Trotman, Absence of apparent transmission of SARS-CoV-2 from two stylists after exposure at a hair salon with a universal face covering policy - springfield, Missouri, may 2020, MMWR Morb. Mortal. Wkly. Rep. 69 (28) (2020 Jul 17) 930–932, https://doi.org/10.15585/mmwr.mm6928e2. PMID: 32673300.

[24] T. Lam-Hine, S.A. McCurdy, L. Santora, L. Duncan, R. Corbett-Detig, B. Kapusinszky, M. Willis, Outbreak associated with SARS-CoV-2 B.1.617.2 (delta) variant in an elementary school - marin county, California, may-june 2021, MMWR Morb. Mortal. Wkly. Rep. 70 (35) (2021 Sep 3) 1214–1219, https://doi.org/10.15585/mmwr.mm7035e2. PMID: 34473683; PMCID: PMC8422870.

[25] Høeg TB, Haslam A, Prasad. An analysis of studies pertaining to masks in Morbidity and Mortality Report: Characteristics and quality of all studies from 1978 to 2023. medRxiv 2023.07.07.23292338; doi: https://doi.org/10.1101/2023.07.07.23292338.

[26] A. Chandra, T.B. Høeg, Lack of correlation between school mask mandates and paediatric COVID-19 cases in a large cohort, J. Infect. 85 (6) (2022 Dec) 671–675, https://doi.org/10.1016/j.jinf.2022.09.019. Epub 2022 Sep 30. PMID: 36183909; PMCID: PMC9539411.

[27] E. Coma, M. Català, L. Méndez-Boo, S. Alonso, E. Hermosilla, E. Alvarez-Lacalle, D. Pino, M. Medina, L. Asso, A. Gatell, Q. Bassat, A. Mas, A. Soriano-Arandes, F. Fina Avilés, C. Prats, Unravelling the role of the mandatory use of face covering masks for the control of SARS-CoV-2 in schools: a quasi-experimental study nested in a population-based cohort in Catalonia (Spain), Arch. Dis. Child. 108 (2) (2023 Feb) 131–136, https://doi.org/10.1136/archdischild-2022-324172. Epub 2022 Aug 23. PMID: 35999036.

[28] A.A. Butt, S.R. Dargham, S. Loka, et al., Coronavirus Disease 2019 disease severity in children infected with the Omicron variant, Clin. Infect. Dis. 75 (1) (2022) e361–e3e7.

[29] E. Hani, M. Bertran, A. Powell, H. Williams, P. Birrell, D. DeAngelis, M.E. Ramsay, G. Oligbu, S.N. Ladhani, Significantly lower infection fatality rates associated with SARS-CoV-2 Omicron (B.1.1.529) infection in children and young people: active, prospective national surveillance, January-March 2022, England, J. Infect. 86 (4) (2023 Apr) 397–398, https://doi.org/10.1016/j.jinf.2023.01.032. Epub 2023 Jan 24. PMID: 36706963; PMCID: PMC9872565.

[30] A.M. Pezzullo, C. Axfors, D.G. Contopoulos-Ioannidis, A. Apostolatos, J.P. A. Ioannidis, Age-stratified infection fatality rate of COVID-19 in the non-elderly population, Environ. Res. 216 (Pt 3) (2023 Jan 1), 114655, https://doi.org/10.1016/j.envres.2022.114655. Epub 2022 Oct 28. PMID: 36341800; PMCID: PMC9613797.

[31] Espey, E. Positive COVID-19 cases at Silver Spring school prompt limited mask mandate. MOCO360. September 6, 2023.https://moco360.media/2023/09/06/positive-covid-19-cases-at-silver-spring-school-prompt-limited-mask-mandate/. (Accessed 8 September 2023).

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SPECIAL REPORT
No. 265 | JANUARY 30, 2023

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Robert E. Moffit, PhD, and Doug Badger

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SPECIAL REPORT

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CENTER FOR HEALTH AND WELFARE POLICY

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

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

> "For 75 years, CDC and public health have been preparing for COVID-19, and in our big moment, our performance did not reliably meet expectations."
>
> Dr. Rochelle Walensky, Director, Centers for Disease Control and Prevention, August 17, 2022[1]

Introduction

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

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

- On September 18, 2022, President Joe Biden declared that the "pandemic is over."[4]

- On October 13, 2022, the Biden Administration extended the national public health emergency declaration for another 90 days.[5] On January 11, 2023, the Administration extended it again.

- On November 15, 2022, despite the threat of a presidential veto, the United States Senate passed a resolution to end the national medical emergency by a vote of 62 to 36.[6] (The House of Representatives has taken no action.)

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

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

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

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

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

As attorney Mark Pulliam has observed:

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

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

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

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

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

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

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

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

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

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

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

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

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

The Federal Response: 2020

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

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

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

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

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

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

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

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

- The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, (Public Law 116-123)[31] codified the authority of the Secretary of HHS to waive or modify certain Medicare rules governing telehealth, expanding telehealth services beyond rural areas, allowing beneficiaries to get telehealth services in their homes, and expanding the number of services that can be delivered through telehealth.

- The Families First Coronavirus Response Act (Public Law 116-127)[32] eliminated Medicare beneficiary cost-sharing for diagnostic tests for COVID under both traditional Medicare and Medicare Advantage plans and further expanded telehealth services for Medicare beneficiaries.

- The Coronavirus Aid, Relief and Economic Security (CARES) Act (Public Law 116-136)[33] was the most ambitious and far-reaching of the three. Among its key provisions, Congress expanded the Accelerated and Advance Payments (AAP) Program for Medicare hospital reimbursements during the national medical emergency while significantly increasing the payment amounts and extending the deadline for hospitals and other medical facilities to repay the government. The law further expanded telehealth and the scope of practice for non-physician practitioners, including nurse practitioners, physician assistants, and clinical nurse specialists, in treating Medicare patients; increased Medicare hospital payment by 20 percent for patients diagnosed with COVID-19; allowed beneficiaries to get a 90-day supply for prescription refills; and required Medicare and Medicare Advantage to cover anticipated COVID-19 vaccines with no beneficiary cost-sharing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Federal Response: 2021

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

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

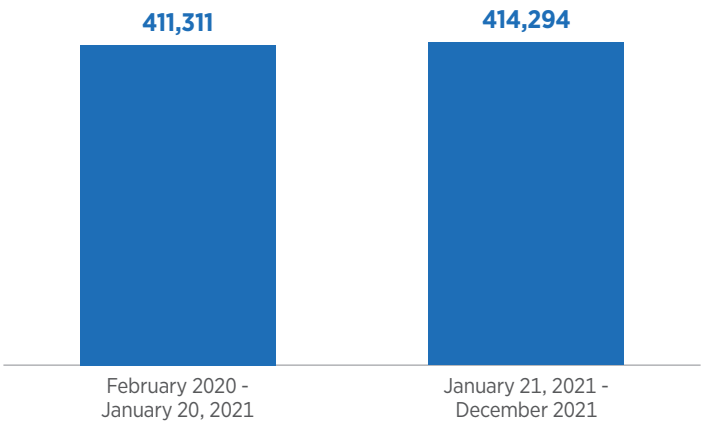
President Biden also asked for congressional action on another major COVID-19 relief bill. In March 2021, Congress enacted and Biden signed the American Rescue Plan Act of 2021 (P.L. 117-2),[50] which provided a total of $1.9 trillion in relief for individuals, businesses, and "various" public health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

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

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

CHART 1

Deaths with COVID-19



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

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

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

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

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

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

requirements."[59] And while the rapid development and deployment of COVID vaccines was a noteworthy exception to the federal government's lackluster performance in other areas, even the vaccines themselves were quickly politicized.

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

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

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

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

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

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

The Federal Response: Key Weaknesses

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Weakness No. 3: The Federal Bureaucracy's Testing Debacle.

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

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

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

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

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

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

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

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

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

As of August 2022, the SNS reported having:[97]

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

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

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

Weakness No. 5: Mass Confusion About Mask Mandates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As the authors of the Cato Institute review of published research on the efficacy of masking note, "ethical principles require that the strength of the evidence and best estimates of amount of benefit be truthfully communicated to the public."[117]

The CDC continually failed this test.

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

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

> In primary schools, the use of face masks is recommended for teachers and other adults when physical distancing cannot be guaranteed, but it is not recommended for students.
>
> In secondary schools, the use of face masks is recommended for both students and adults (i.e. masks for children older than 12 years) living in areas with community transmission of SARS-CoV-2.[121]

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

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

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

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

schools were not associated with lower SARS-CoV-2 incidence or transmission, suggesting that this intervention was not effective."[126]

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

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

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

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

Weakness No. 6: Costly School Closures.

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

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

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

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

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

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

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

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

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

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

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

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

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

- Researchers writing in *Health Affairs* found that "[i]n the absence of a statewide mask mandate, school districts in Iowa with higher teachers' unionization rates were more likely to adopt mask mandates, which the CDC strongly recommended."[138]

- Last year's CDC guidance on school reopenings raised significant questions among Members of Congress. On February 12, 2021, the agency issued its guidance on reopening schools, but it had previously shared its draft guidance with the American Federation of Teachers (AFT), one of the nation's two major teachers' unions. Such guidance is normally confidential. In breaking with past practice, the CDC permitted AFT officials to insert language into the guidance before its final release that would have the effect of extending the time that K–12 schools would remain closed. An Administration lawyer instructed a CDC official not to answer a question as to why the draft guidance was shared with the AFT.[139]

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

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

Weakness No. 7: The CDC Eviction Moratorium.

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

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

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

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

but, citing the CDC's pledge to "end the moratorium in only a few weeks," sided with Chief Justice John Roberts and Associate Justices Samuel Alito, Clarence Thomas, and Amy Coney Barrett and let the order stand.[146]

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

Weakness No. 8: Flawed Vaccine Policy.

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

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

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

The OSHA vaccine mandate was immediately challenged in the federal courts. OSHA claimed that its statutory authority to issue "emergency standards" justified the unprecedented mandate.[151] The Supreme Court disagreed, enjoining the mandate in January 2022.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Fraiman and his colleagues looked at people who had received two doses over a longer period of time (two months or more). The FDA's analysis included thousands of additional individuals, most of whom had received just one dose, with very little follow-up.

- The FDA compared the number of trial participants that had experienced serious adverse events, but the study's authors counted the number of such events. This is important because the study found that twice as many individuals in the vaccine group experienced multiple adverse events as experienced them in the placebo group. The FDA review of the safety and efficacy data did not account for that.

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

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

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

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

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

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

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

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

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

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

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

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

Weakness No. 9: Ignoring and Downplaying Natural Immunity.

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

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

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

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

protective effect observed 7 months following primary infection" and that "previous infection...induces effective immunity to future infections in most individuals."[179] The CDC simply ignored this major *Lancet* study.[180]

- Writing in the June 2022 edition of *The Lancet Child & Adolescent Health*, a team of British medical researchers found that COVID-19 reinfection is "uncommon" in adults but even more uncommon in children. The researchers found that in England between January 2020 and July 2021, there were 688,419 primary infections in children 16 years or younger and just 2,343 reinfections. Of the 109 children hospitalized with the reinfection, 78 (72 percent) had comorbidities. Of the entire cohort, there were 44 deaths among children testing positive for the coronavirus. All childhood deaths occurred among children with a primary infection; none occurred after reinfection. And of the four children admitted to an intensive care unit (ICU) following a COVID-19 reinfection, all four "had multiple and severe multisystem comorbidities and, despite detailed case note review, ascertaining the contribution of SARS-CoV-2 infection to the illness that eventually led to the intensive care admission was not possible."[181]

- In March 2021, a team of Israeli researchers who had conducted a large study of people that had recovered from COVID in order to determine their level of reinfection reported that "[o]ut of 149,735 individuals with a documented positive PCR [polymerase chain reaction] test between March 2020 and January 2021, 154 had two positive tests at least 10 days apart, reflecting a reinfection proportion of 1 per 1000."[182]

- With the emergence of the Delta variant of COVID-19, another team of Israeli researchers examined the comparative strengths of vaccine-induced immunity and natural immunity in an exceptionally large population study. They concluded that natural immunity was much stronger:

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

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

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

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

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

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

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

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

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

Weakness No. 10: Imposing Lockdowns.

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

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

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

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

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

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

  > An analysis of each of these three groups support[s] the conclusion that lockdowns have had little to no effect on COVID-19 mortality. More specifically, stringency index studies find that lockdowns in Europe and the United States only reduced COVID-19 mortality by 0.2% on average. SIPOs were also ineffective, only reducing COVID mortality by 2.9% on average. Specific NPI studies also find no broad-based evidence of noticeable effects on COVID-19 mortality.
  >
  > While this meta-analysis concludes that lockdowns have had little to no public health effects, they have imposed enormous economic and social costs where they have been adopted. In consequence, lockdown policies are ill-founded and should be rejected as a pandemic policy instrument.[190]

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

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

- In *Roman Catholic Diocese of Brooklyn v. Cuomo*, the Court granted emergency relief from New York State's restrictions on worship services, holding that those restrictions "violate[d] 'the 'minimum requirement of neutrality' to religion."[193]

- In *Tandon v. Newsom*, the Court invalidated a California restriction on religious gatherings because it "treat[ed] some comparable secular activities more favorably than at-home religious exercise, permitting hair salons, retail stores, personal care services, movie theaters, private suites at sporting events and concerts, and indoor restaurants to bring together more than three households at a time."[194]

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

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

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

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

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

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

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

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

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

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

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

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

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

Weakness No. 12: Suppressing Scientific Dissent.

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

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

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

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

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

> As immunity builds in the population, the risk of infection to all—including the vulnerable—falls. We know that all populations will eventually reach herd immunity—i.e. the point at which the rate of new infections is stable—and this can be assisted by (but is not dependent upon) a vaccine. Our goal should therefore be to minimize mortality and social harm until we reach herd immunity.
>
> The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at higher risk. We call this Focused Protection.
>
> Adopting measures to protect the vulnerable should be the central aim of public health responses to COVID-19....[206]

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

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

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

Addressing the Great Barrington Declaration's case for "herd immunity," the John Snow authors declared:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Peter Daszak, president of the EcoHealth Alliance of New York, "organized and drafted" and signed the letter that appeared in the March 7, 2020, issue of *The Lancet*, declaring that he had no conflict of interest even though his organization had received substantial NIH funding for coronavirus research at the Wuhan Institute of Virology.[223]

- Dr. Kristian Anderson of the Scripps Research Institute and five virologists published a peer-reviewed paper in the March 17, 2020, issue of *Nature Medicine* in which they declared definitively that the novel coronavirus was not a "laboratory construct."[224]

- Then, on March 26, 2020, Collins followed up these two publications with an NIH blog hammering home the same point: "Some folks are even making outrageous claims that the new coronavirus causing the pandemic was engineered in a lab and deliberately released to make people sick. A new study debunks such claims by providing scientific evidence that this novel coronavirus arose naturally."[225]

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

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

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

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

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

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

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

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

- "The most logical place to investigate the virus origin has been completely sealed off from outside inquiry by the CCP [Chinese Communist Party]. A gag order to both places was issued on 1/01/2020, and a Major General from the PLA [Peoples' Liberation Army] took over the WIV [Wuhan Institute of Virology] since early Jan. Of the five possible theories, the WCDC and WIV are most likely yet least investigated. All other proposed theories are likely to be a decoy to prevent inquiry to WCDC and WIV."

- "WIV has failed to convince the world of the whereabouts of its former employee Huang Yanlin, rumored to be Patient Zero. Huang worked at WIV but she is the only WIV employee who[se] bio, profile and picture have been deleted by WIV, fueling speculation of foul-play. WIV issued vigorous denial about Huang being infected claiming she has left WIV to another unnamed province to work and is currently healthy and fine. But Huang herself has never appeared in public and she has since 'disappeared.'"[231]

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

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

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

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

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

> To construct synthetic variants of natural coronaviruses in the lab, researchers often use a method called *in vitro* genome assembly. This method uses special enzymes called restriction enzymes to generate DNA building blocks that then can be "stitched" together in the correct order of the viral genome. To make a virus in the lab, researchers usually engineer the viral genome to add and remove stitching sites, called restriction sites. The ways researchers modify these sites can serve as fingerprints of *in vitro* genome assembly.
>
> We found that SARS-CoV-2 has the restriction site fingerprint that is typical for synthetic viruses. The synthetic fingerprint of SARS-CoV-2 is anomalous in wild coronaviruses, and common in lab-assembled viruses. The type of mutations (synonymous or silent mutations) that differentiate the restriction sites in SARS-CoV-2 are characteristic of engineering, and the concentration of these silent mutations in the restriction sites is extremely unlikely to have arisen by random evolution. Both the restriction site fingerprint and the pattern of mutations generating them are extremely unlikely in wild coronaviruses and nearly universal in synthetic viruses. Our finding strongly suggest a synthetic origin of SARS-CoV-2.[238]

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

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

conclusion is not intended to be dispositive.[239]

The report, however, further observes that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- **How should the federal government best coordinate responses to public health crises?** Congress has established several loci of authority during public health crises, including the HHS Office of Preparedness and Response, the CDC, FEMA, and various White House offices, including the National Security Council and the Domestic Policy Council. Lines of authority were confused, impairing the federal government's response. Congress should examine these failures in detail and consider stipulating in legislation which agency should coordinate these responses.

- **Why has the CDC failed to provide for the collection and dissemination of real-time public health data?** The CDC's failure to collect and disseminate data necessary for effective response is discussed at some length in this paper. Instead of holding the CDC directly accountable for its deficiencies in responding to the pandemic, in December 2022, Congress enacted and the President signed the Consolidated Appropriations Act, 2023, and provided the agency with a hefty infusion of new cash, allocating $9.2 billion for FY 2023, amounting to an increase of 42 percent since 2019.[255] As noted previously, that includes $175 million for public health data modernization. Given the importance of these efforts and the agency's chronic inertia, Congress should conduct aggressive oversight of the agency's handling of these additional resources to ensure that this time, the CDC is spending it efficiently and effectively.

- **How can the testing debacle that marred Washington's initial response to the pandemic be avoided in the future?** As discussed earlier, the federal government's blunders in making accurate and timely COVID-19 tests available contributed to the pathogen's silent spread during the pandemic's critical early weeks and months. Congress should closely examine what went wrong and consider enacting legislation directing the FDA, CDC, and CMS to establish procedures to ensure rapid development, production, and distribution of tests during future public health crises.

- **What is the proper role of the Strategic National Stockpile, and is it prepared for the next crisis?** As noted previously, frontline medical workers confronted a shortage of personal protective

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

- **What does science tell us about mask efficacy, and how did the CDC formulate its recommendations?** Between February and April 2020, federal officials reversed policy. Thereafter, the CDC recommended masking without firm scientific support for its efficacy. Previous scientific research was apparently ignored. Studies published in the CDC's *Morbidity and Mortality Weekly Reports* that support masking have proven to be both tendentious and flawed. While some have argued that the CDC's emphasis on scientific inquiry and peer review hampered its response to the pandemic, much of the scientific literature it produced in support of its recommendations did not attain the highest standards of scholarship. Congress should closely examine how the CDC came to publish studies with dubious findings that supported its public health recommendations and determine the extent to which the agency rushed these studies to print in response to political and bureaucratic pressure.

- **What was the scientific basis, particularly in peer-reviewed studies, for recommending mask mandates on school children?** Among the flawed studies published by the CDC were several that the CDC used to support its recommendation to mask schoolchildren. As noted, the CDC remains the only national or international public health agency that recommends masking two-year-old children. Congress should demand a detailed account of why the CDC published and promoted the results of these substandard studies and learn the extent to which political and bureaucratic pressures may have contributed to a rushed and inadequate peer review process.

- **How has federal policy, particularly on school closures and masking, affected children, and how can the CDC best avoid similar policy blunders in the future?** Although it was clear from the pandemic's earliest days that COVID-related hospitalizations and deaths were exceedingly rare among children, the CDC promoted

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

- **Why did the federal government impose vaccine mandates when the science did not establish that vaccines prevented infection and transmission of the disease?** Vaccine mandates were premised on the view that the government could require people to be immunized not to protect themselves against the disease but to protect others. President Biden, for example, said that the OSHA vaccine mandate was necessary to "protect the vaccinated" against infection from their unvaccinated coworkers.[256] Unvaccinated workers risked termination of employment unless they tested frequently and wore masks in the workplace. But the clinical trials on which the FDA relied to authorize the COVID-19 vaccines were not designed to determine whether they prevented transmission. In its December 2020 announcement of the emergency use authorization for the Pfizer mRNA vaccine, the FDA wrote that the trials had not adduced "evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person."[257] The mandates thus rested on a false premise, as did the government's refusal to distinguish between unvaccinated people who had never contracted the disease and those who had acquired natural immunity by recovering from it.

- **What are the risks and benefits of coronavirus vaccines relative to age and medical condition, and should the CDC modify its recommendations with respect to COVID vaccines?** Early development, production, distribution, and administration of COVID-19 vaccines during a national medical emergency were among the government's most significant pandemic policy successes, but the value of those vaccines, like the risk of COVID-related mortality and severe morbidity, is highly dependent on age and medical condition. Even after it became apparent that the vaccines did not prevent the transmission of the disease, the CDC continued to require that children and young adults be vaccinated. Congress should require the CDC to explain how it derived its risk/benefit analysis for vaccination schedules and why it has not revised those recommendations despite changing science.

- **Why did the CDC take so long to acknowledge the value of natural immunity when the supporting science is so clear?** The value of natural immunity is well-established in science. Public health authorities in other developed countries acknowledged its importance early on. For example, Italy issued vaccine passports to people who had received shots and those who had recovered from COVID-19 over the previous six months. The CDC should explain why it was an outlier in not conceding the efficacy of natural immunity until nearly two years after the pandemic began. This is critical because it goes to the heart of the CDC's credibility, which is crucial during public health emergencies. If the CDC refused to acknowledge the value of natural immunity because it thought doing so would conflict with its promotion of vaccines, then public health officials deliberately misled Americans about their risk of contracting the disease.

- **Why should the CDC administer the Vaccine Adverse Event Reporting System (VAERS) when the FDA is responsible for monitoring adverse effects associated with every other drug and all medical devices?** In addition to determining whether drugs and devices are safe and effective, the FDA has lead responsibility for monitoring adverse events once a product enters the market. The agency's surveillance system is well-established, and clinicians are well acquainted with reporting procedures. Federal law, however, makes the CDC the lead agency in monitoring the safety and efficacy of vaccines. The VAERS system, based on self-reporting, has proven to be deeply inadequate throughout the pandemic, depriving doctors and patients alike of accurate, age-related information about the risks and benefits of vaccines. Congress should examine these failures in detail and consider shifting lead responsibility for assessing vaccine safety to the FDA. Congress must improve the nation's system of vaccine surveillance to ensure public safety.

- **What were the lockdowns' measurable effects on population health, including mental health? What were the social and economic impact of the federally recommended lockdowns? What were their positive effects?** The value of government-imposed nonpharmaceutical interventions, especially lockdowns, is a matter that requires further inquiry. Whether and to what extent they slowed the spread of disease is a matter that requires additional attention. In addition to gathering evidence on the public health benefits of lockdowns,

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

- **How and why did federal agencies fail frontline clinicians, and what reforms are necessary to serve them more effectively during future crises?** During the early stages of the pandemic, the CDC recommended aggressive use of ventilators on patients who manifested respiratory symptoms linked to COVID-19. Its recommendation proved to be disastrous, but the agency was slow to adapt. In particular, it failed to convene physicians—something eminently feasible in an age when remote meetings have become commonplace—to share their clinical experiences with other clinicians. This was crucial during the early months of the pandemic when overburdened doctors and nurses sought more effective interventions for their severely ill patients. Congress should examine this failure in detail and consider legislation requiring the CDC or some other federal entity to establish a strategy for facilitating real-time communication with and between clinicians during public health emergencies.

- **Why did the federal government repeatedly garble its messaging?** CDC and other public health officials have sometimes acknowledged that their messaging has been inconsistent and confusing. This failure significantly diminished the credibility of public health officials to the detriment of the public. What remains unclear is why these repeated messaging failures occurred. Did officials make pronouncements without adequately establishing their scientific basis? Did political or bureaucratic pressures prompt mistaken declarations or prevent the agency from withdrawing or modifying erroneous guidance? Understanding the reasons for these failures is crucial to assuring that the federal public health bureaucracy is better prepared for future public health emergencies.

- **What can Congress do to prevent NIH and other federal officials from suppressing legitimate dissent, particularly in the scientific community?** It is important that federal officials protect the integrity of scientific research. Open and civil debate is essential to scientific inquiry, but NIH officials tried to discredit dissenting views among members of the scientific community who argued that the coronavirus likely emerged from a Chinese lab. They also tried to discredit prominent medical scientists who subscribed to a targeted

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

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

- **Did NIH officials inappropriately seek to suppress inconvenient hypotheses about the origins of COVID-19?** The origins of SARS-CoV-2 remain shrouded in uncertainty and (given the Chinese Communist Party's suppression of evidence) may well remain so. NIH officials especially sought to marginalize the hypothesis that the pathogen may have originated in a Wuhan laboratory. Congress should determine why certain government officials tried very hard to dismiss the possibility of a lab-engineered coronavirus during the early stages of a national medical emergency. If it finds evidence that these officials testified falsely under oath during congressional hearings, , it should consider making criminal referrals to the Department of Justice. Only vigorous prosecution of unlawful behavior will deter it in the future.

- **What controls should Congress impose on NIH funding for biomedical research that poses a potentially grave danger to public health? Should government stop funding gain-of-function research overseas?** Whether or not SARS-CoV-2 escaped from a laboratory conducting gain-of-function research, the global

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

Restoring Public Trust

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

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

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

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

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

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

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

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

- Failing to establish and maintain an experienced and well-staffed "center of command," with clear authority and reporting directly to the President, to coordinate the federal government's response;

- Failing to improve and modernize the CDC's data collection and dissemination;

- Failing to develop and deploy diagnostic testing expeditiously for surveillance and defense against COVID;

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

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

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

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

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

Endnotes

1. Cited in Krista Mahr, "CDC Director Orders Agency Overhaul, Admitting Flawed Covid-19 Response," *Politico*, August 17, 2022, https://www.politico.com/news/2022/08/17/cdc-agency-overhaul-covid-19-response-00052384 (accessed December 19, 2022).
2. Chart, "Cumulative Confirmed COVID-19 Cases," in Edouard Mathieu, Hannah Ritchie, Lucas Rodes-Guirao, Cameron Appel, Daniel Gavrilov, Charlie Giattino, Joe Hassel, Bobbie Macdonald, Saloni Dattani, Diana Beltekian, Esteban Ortiz-Ospina, and Max Roser, "Coronavirus (COVID-19) Cases," Global Change Data Lab, *Our World in Data*, https://ourworldindata.org/covid-cases (accessed December 20, 2022).
3. Chart, "Cumulative Confirmed COVID-19 Deaths," in Edouard Mathieu, Hannah Ritchie, Lucas Rodes-Guirao, Cameron Appel, Daniel Gavrilov, Charlie Giattino, Joe Hassel, Bobbie Macdonald, Saloni Dattani, Diana Beltekian, Esteban Ortiz-Ospina, and Max Roser, "Coronavirus (COVID-19) Deaths," Global Change Data Lab, *Our World in Data*, https://ourworldindata.org/covid-deaths (accessed December 20, 2022).
4. As with other presidential declarations, top Biden Administration officials were compelled to walk this one back, and the national public health emergency, justifying everything from the vaccine mandates to the President's massive $426 billion student loan forgiveness initiative, remains in force. Dylan Housman, "Biden Declaring the Pandemic 'Over' Stunned White House Officials: Report," *The Daily Caller*, September 19. 2022, https://dailycaller.com/2022/09/19/joe-biden-covid-coronavirus-pandemic-over-60-minutes/ (accessed December 19, 2022).
5. Xavier Becerra, Secretary, U.S. Department of Health and Human Services, "Renewal of Determination that a Public Health Emergency Exists," U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, October 13, 2022, https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx (accessed December 19, 2022).
6. Richard Payerchin, "COVID-19 Public Health Emergency to Continue; Senators Want End of National Emergency," *Medical Economics*, November 17, 2022, https://www.medicaleconomics.com/view/covid-19-public-health-emergency-to-continue-but-senators-vote-to-end-it (accessed December 19, 2022).
7. For an excellent summary of the contribution of obesity to pandemic mortality, see Sandro Galea and Michael Stein, "A Hard Weight," Public Health Post, "The Turning Point," November 11, 2021, https://www.facebook.com/publichealthpost/videos/306152561076840 3/ (accessed December 22, 2022). Their column appears regularly in "The Turning Point," a newsletter of the Boston University School of Public Health. See Boston University School of Public Health, "Public Health Post: About Us: The Turning Point," https://www.publichealthpost.org/the-turning-point/ (accessed December 22, 2022).
8. CDC data through June 29, 2022, estimate a total of just over one million deaths associated with COVID-19. Of these, only 1,063 were children under the age of 18. U.S. Department of Health and Human Development, Centers for Disease Control and Prevention, National Center for Health Statistics, "Weekly Updates by Select Demographic and Geographic Characteristics," https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAge (accessed December 19, 2022).
9. Committee for Economic Development of The Conference Board, "Preparing for the Next Public Health Crisis: Lessons from the Pandemic," Solutions Brief, May 2022, https://www.conference-board.org/pdfdownload.cfm?masterProductID=39333 (accessed December 19, 2022).
10. Ibid.
11. Dan Goldhaber, Thomas J. Kane, Andrew McEachin, Emily Morton, Tyler Patterson, and Douglas O. Staiger, "The Consequences of Remote and Hybrid Instruction During the Pandemic," Harvard University, Center for Education Policy Research, *Research Report*, May 2022, p. 21, https://cepr.harvard.edu/files/cepr/files/5-4.pdf?m=1651690491 (accessed December 19, 2022).
12. U.S. Department of Education, Institute of Education Sciences, National Center for Education Statistics, National Assessment of Educational Progress, "The Nation's Report Card," 2022, https://www.nationsreportcard.gov/ (accessed December 19, 2022).
13. Mark Pulliam, "Unmasking the Nanny State," RealClearPolicy, February 25, 2022, https://www.realclearpolicy.com/2022/02/25/unmasking_the_nanny_state_818603.html (accessed December 19, 2022).
14. Gaby Galvin, "Lack of Institutional Trust and Polarization Aren't Just US Problems. That Could Hamper the Global Pandemic Response," Morning Consult, March 22, 2022, https://morningconsult.com/2022/03/22/global-covid-perceptions-survey/ (accessed December 19, 2022).
15. Charles Silver and David A. Hyman, "COVID-19: A Case Study of Government Failure," Cato Institute, *Pandemics and Policy Series*, September 15, 2020, https://www.cato.org/pandemics-policy/covid-19-case-study-government-failure (accessed December 19, 2022). The authors further note that European states also experienced "shortages of tests, hospital beds, doctors and nurses, personal protective equipment, and ventilators. Needing to conserve scarce resources, some European countries released triage guidelines recommending prioritization of treatment for patients who were determined to have a higher likelihood of survival. Canada ran short of drugs. Australia was forced to ration masks and other personal protective equipment. In Japan, clinics turned away patients. Like the United States, countries with national health care systems also sought to 'flatten the curve' so that their systems could manage the spike in demand for treatments."
16. Cited in Sharon LaFraniere and Noah Weiland, "Walensky, Citing Botched Pandemic Response, Calls for CDC Reorganization," *The New York Times*, August 17, 2022, https://www.nytimes.com/2022/08/17/us/politics/cdc-rochelle-walensky-covid.html (accessed December 19, 2022).
17. Although an evaluation of state policies is beyond the scope of this paper, citizens should expect their state legislators to form select committees to inquire into the performance of their governors and state agencies.

18. This is hardly an exhaustive list. Other federal agencies, to some degree, had a role in the pandemic response.
19. @WHO (World Health Organization), "Preliminary investigations conducted by the Chinese authorities have found no clear evidence of human-to-human transmission of the novel #coronavirus (2019-nCoV) identified in #Wuhan, #China," Twitter, January 14, 2020, 6:48 AM, January 14, 2020, https://twitter.com/who/status/1217043229427761152 (accessed December 20, 2022).
20. Alex M. Azar II, Secretary of Health and Human Services, "Determination that a Public Health Emergency Exists," U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, January 31, 2020, https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx (accessed December 20, 2022). See also Jennifer Kates, Josh Michaud, Larry Levitt, Karen Pollitz, Tricia Neuman, Michelle Long, Robin Rudowitz, Mary Beth Musumeci, Meredith Freed, and Juliette Cubanski, "Comparing Trump and Biden on COVID-19," Kaiser Family Foundation *Issue Brief*, September 11, 2020, https://www.kff.org/coronavirus-covid-19/issue-brief/comparing-trump-and-biden-on-covid-19/ (accessed December 20, 2022).
21. Lev Facher, "U.S. Declares Public Health Emergency over Coronavirus, Bans Travel from China by Foreign Nationals," *STAT*, January 31, 2020, https://www.statnews.com/2020/01/31/u-s-declares-public-health-emergency-over-coronavirus-bans-travel-from-china-by-foreign-nationals/ (accessed December 20, 2022). The ban took effect on February 2, 2020.
22. See, for example, Editorial Board, "Trump's Xenophobic Travel Ban Punishes Americans Above All," *The Boston Globe*, updated February 17, 2020, https://www.bostonglobe.com/2020/02/17/opinion/trumps-xenophobic-travel-ban-punishes-americans-above-all/ (accessed December 20, 2022). Biden soon backtracked: "Two months later Mr. Biden grudgingly acknowledged that the China ban was good policy after all." Allan H. Ryskind, "Confessions of an 'Ever Trumper,'" *The Washington Times*, February 2, 2021, https://www.washingtontimes.com/news/2021/feb/2/confessions-of-an-ever-trumper/ (accessed December 20, 2022). In 2021, when the Omicron variant was identified in South Africa and determined to be highly contagious, President Biden blocked travel from several African nations to contain the latest viral contagion.
23. Kates et al., "Comparing Trump and Biden on COVID-19."
24. Rabail Chaudhry, George Dranitsaris, Talha Mubashir, Justyna Bartoszko, and Sheila Riazi, "A Country Level Analysis Measuring the Impact of Government Actions, Country Preparedness and Socioeconomic Factors on COVID-19 Mortality and Related Health Outcomes," *eClinicalMedicine*, Vol. 25 (August 2020), https://www.thelancet.com/pdfs/journals/eclinm/PIIS2589-5370(20)30208-X.pdf (accessed December 20, 2022).
25. President Donald J. Trump, Proclamation 9994, "Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak," March 13, 2020, in *Federal Register*, Vol. 85, No. 53 (March 18, 2020), pp. 15337–15338, https://www.govinfo.gov/content/pkg/FR-2020-03-18/pdf/2020-05794.pdf (accessed December 20, 2022). See also Kates et al., "Comparing Trump and Biden on COVID-19." The Obama Administration was the first to declare a national *public health* emergency. In April 2009, HHS issued a PHE declaration in response to the H1N1 flu. U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, "Declarations of a Public Health Emergency," https://aspr.hhs.gov/legal/PHE/Pages/default.aspx (accessed December 20, 2022).
26. John Kincaid and J. Wesley Leckrone, "In US COVID-19 Responses, Party Polarization Has Trumped Cooperative Federalism," London School of Economics and Political Science, United States Politics and Policy Blog, December 1, 2021, https://blogs.lse.ac.uk/usappblog/2021/12/01/in-us-covid-19-responses-party-polarization-has-trumped-cooperative-federalism/ (accessed December 20, 2022).
27. Dan Mangan, "Trump Issues 'Coronavirus Guidelines' for Next 15 Days to Slow Pandemic," CNBC, March 16, 2020, https://www.cnbc.com/2020/03/16/trumps-coronavirus-guidelines-for-next-15-days-to-slow-pandemic.html (accessed December 20, 2022).
28. Beth Duff-Brown, "Federalism Meets the COVID-19 Pandemic: Thinking Globally, Acting Locally," Stanford University, Stanford Law School, Legal Aggregate Blog, April 6, 2020, https://law.stanford.edu/2020/04/06/federalism-meets-the-covid-19-pandemic-thinking-globally-acting-locally/ (accessed December 20, 2022). Though academic and media critics often accused the President of refusing to "follow the science," Trump's initial actions in 2020 were based on the recommendations of his medical experts, including Dr. Fauci: "Dr. Fauci heatedly insists that the president has never, ever overridden the advice on the science offered by his advisors." Allan H. Ryskind, "President Trump vs Joe Biden on the Coronavirus Crisis," *The Washington Times*, March 30, 2020.
29. Kincaid and Leckrone, "In US COVID-19 Responses, Party Polarization Has Trumped Cooperative Federalism."
30. For a useful summary of these legislative actions, see the *2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, Communication from the Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, Transmitting the 2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds, letter of transmittal dated August 31, 2021, pp. 172–176, https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf (accessed December 20, 2022).
31. H.R. 6074, Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Public Law 116-123, 116th Cong., March 6, 2020, https://www.congress.gov/116/plaws/publ123/PLAW-116publ123.pdf (accessed December 22, 2022).
32. H.R. 6201, Families First Coronavirus Response Act, Public Law 116-127, 116th Cong., March 18, 2020, https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf (accessed December 22, 2022).
33. H.R. 748, Coronavirus Aid, Relief, and Economic Security Act, Public Law No. 116-136, 116th Cong., March 27, 2020, https://www.congress.gov/bill/116th-congress/house-bill/748 (accessed December 19, 2022).
34. H.R. 266, Paycheck Protection Program and Health Care Enhancement Act, Public Law 116-139, 116th Cong., April 24, 2020, https://www.congress.gov/116/plaws/publ139/PLAW-116publ139.pdf (accessed December 22, 2022).

35. H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116-260, 116th Cong., December 27, 2020, https://www.congress.gov/116/plaws/publ260/PLAW-116publ260.pdf (accessed December 22, 2022).
36. William L. Painter, "Tallying Federal Funding for COVID-19: In Brief," Congressional Research Service *Report for Members and Committees of Congress* No. R46449, updated October 15, 2021, p. 13, https://crsreports.congress.gov/product/pdf/R/R46449 (accessed December 20, 2022).
37. Committee for Economic Development of The Conference Board, "Preparing for the Next Public Health Crisis: Lessons from the Pandemic."
38. Jason Semprini, "Federalism and the Value of Institutional Experience During National Disaster: Identifying Determinants of Rapid Emergency Medicaid Waiver Adoption During the Covid-19 Pandemic," *Inquiries Journal*, Vol. 14, No. 1 (2022), http://www.inquiriesjournal.com/articles/1931/federalism-and-the-value-of-institutional-experience-during-a-national-disaster-identifying-determinants-of-rapid-emergency-medicaid-waiver-adoption-during-the-covid-19-pandemic (accessed December 20, 2022).
39. See H.R. 3103, Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, 104th Cong., August 21, 1996, https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf (accessed December 22, 2022).
40. Press release, "Trump Administration Unveils Enhanced Enforcement Actions Based on Nursing Home COV ID-199 Data and Inspections Results," U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, June 1, 2020, https://www.cms.gov/newsroom/press-releases/trump-administration-unveils-enhanced-enforcement-actions-based-nursing-home-covid-19-data-and (accessed December 20, 2022).
41. Priscilla Alvarez, Lauren Fox, and Paul LeBlanc, "What Is the Defense Production Act?" CNN, March 24, 2020, https://www.cnn.com/2020/03/24/politics/defense-production-act-coronavirus/index.html (accessed December 20, 2022).
42. Yelena Dzhanova, "Trump Compelled These Companies to Make Critical Supplies, But Most of Them Were Already Doling It," CNBC, updated April 4, 2020, https://www.cnbc.com/2020/04/03/coronavirus-trump-used-defense-production-act-on-these-companies-so-far.html (accessed December 20, 2022).
43. Committee for Economic Development of The Conference Board, "Preparing for the Next Public Health Crisis: Lessons from the Pandemic."
44. Paul Mango, "Operation Warp Speed Was a Tremendous Success. Here's Why It Won't Be Replicated Under Biden," *The Hill*, June 9, 2022, https://thehill.com/opinion/healthcare/3517236-operation-warp-speed-was-a-tremendous-success-heres-why-it-wont-be-replicated-under-biden/ (accessed December 20, 2022).
45. Maegan Vazquez and Nikki Carvajal, "Biden Offers Rare Praise for Trump During Covid Speech," CNN, updated December 22, 2021, https://www.cnn.com/2021/12/21/politics/biden-trump-covid-vaccine-booster/index.html (accessed December 20, 2022).
46. Trish Riley, "Restoring Federalism to Win the War Against COVID-19," National Academy for State Health Policy, COVID-19 State Action Center, January 26, 2021, https://www.nashp.org/restoring-federalism-to-win-the-war-against-covid-19 (accessed December 20, 2022).
47. Biden–Harris Democrats, "Joe Biden's Plan to Beat COVID-19," https://joebiden.com/beat-covid19/ (accessed December 20, 2022).
48. Ibid.
49. Ibid.
50. H.R. 1319, American Rescue Plan Act of 2021, Public Law 117-2, 117th Cong., March 11, 2021, https://www.congress.gov/117/plaws/publ2/PLAW-117publ2.pdf (accessed December 22, 2022).
51. Painter, "Tallying Federal Funding for COVID-19: In Brief," p. 13.
52. Agence France-Presse, "Biden: Anyone Responsible for So Many COVID Deaths 'Should Not' Be President," *Barron's*, October 22, 2020, https://www.barrons.com/news/biden-anyone-responsible-for-so-many-covid-deaths-should-not-be-president-01603416304 (accessed December 20, 2022).
53. Authors' calculations using a database downloaded from Mathieu et al., "Coronavirus (COVID-19) Deaths." According to that database, the first COVID-related death in the U.S. occurred on February 29, 2020. Through January 20, 2021, 411,311 deaths had been recorded. As of December 31, 2021, that number had risen to 825,605. Subtracting the 411,311 deaths through the last day of the Trump presidency from that number yields 414,294 such deaths through the first 11 months of the Biden presidency.
54. Ibid.
55. Ibid.
56. Chart, "Cumulative Confirmed COVID-19 Deaths."
57. President Joseph R. Biden Jr., Executive Order 14043, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees," September 9, 2021, in *Federal Register*, Vol. 86, No. 175 (September 14, 2021, pp. 50989–50990, https://www.govinfo.gov/content/pkg/FR-2021-09-14/pdf/2021-19927.pdf (accessed December 22, 2022). See also "Remarks by President Biden on Fighting the COVID-19 Pandemic," The White House, September 9, 2021, https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ (accessed December 20, 2022).
58. BBC News, "Coronavirus: Trump Feuds with Governors over Authority," April 14, 2020, https://www.bbc.com/news/world-us-canada-52274969 (accessed December 20, 2022).
59. Nandita Bose, "Biden Says Republican Governors Are Undermining COVID Safety Response," Reuters, September 16, 2021, https://www.reuters.com/world/us/biden-says-republican-governors-are-undermining-covid-safety-response-2021-09-16/ (accessed December 20, 2022).

60. Liz Szabo and JoNel Aleccia, "Some States Plan to Vet Covid-19 Vaccines Themselves. Bad Idea, Experts Say," NBC News, October 7, 2020, https://www.nbcnews.com/health/health-news/some-states-plan-vet-covid-19-vaccines-themselves-bad-idea-n1242355 (accessed December 20, 2022).
61. Liz Hamel, Lunna Lopes, Grace Sparks, Ashley Kirzinger, Audrey Kearney, Mellisha Stokes, and Mollyann Brodie, "KFF COVID-19 Vaccine Monitor: January 2022," Kaiser Family Foundation, published January 28, 2022, https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-january-2022/ (accessed December 20, 2022).
62. Norbert J. Michel, Paul Winfree, and Doug Badger, "Potential Long-Term Economic Consequences of the Federal Response to the COVID-19 Lockdowns," Heritage Foundation *Backgrounder* No. 3498, June 4, 2020, https://www.heritage.org/markets-and-finance/report/potential-long-term-economic-consequences-the-federal-response-the-covid.
63. See, for example, Beverly A. Cigler, "Fighting COVID-19 in the United States with Federalism and Other Constitutional and Statutory Authority," *Publius: The Journal of Federalism*, Vol. 51, Issue 4 (Fall 2021), pp. 673–692, https://academic.oup.com/publius/article/51/4/673/6333392?login=true (accessed December 20, 2022). See also Emily Berman, "The Roles of the State and Federal Governments in a Pandemic," *Journal of National Security Law & Policy*, Vol. 11, No. 1, Special COVID-19 Issue (2020), pp. 61–82, https://jnslp.com/wp-content/uploads/2020/12/The-Roles-of-the-State-and-Federal-Governments-in-a-Pandemic_2.pdf (accessed December 20, 2022); Ross K. Baker, "Donald Trump's Laissez Faire Federalism Is as Toxic as COVID-19," *USA Today*, July 14, 2020, https://www.usatoday.com/story/opinion/2020/07/14/donald-trump-federalism-coronavirus-covid-19-response-column/5424862002/ (accessed December 20, 2022); Sheryl Gay Stolberg and Noah Welland, "Study Finds 'Single Largest Driver' of Coronavirus Misinformation: Trump," *The New York Times*, updated October 6, 2021, https://www.nytimes.com/2020/10/01/us/elections/a-study-found-the-single-largest-driver-of-coronavirus-misinformation-it-was-the-president.html (accessed December 20, 2022).
64. National Coronavirus Recovery Commission, *Saving Lives and Livelihoods: Recommendations for Recovery*, June 15, 2020, p. 90, https://thf_media.s3.amazonaws.com/2020/NCRC_FINAL.pdf.
65. Gail R. Wilensky, "Policy Lessons from Our COVID Experience," *The New England Journal of Medicine*, Vol. 383, No. 17 (October 22, 2020), https://www.nejm.org/doi/full/10.1056/NEJMp2023204 (accessed December 20, 2022).
66. Louis Jacobson, "Biden Restores White House Office for Global Health Security," Poynter Institute, PolitiFact, January 21, 2021, https://www.politifact.com/truth-o-meter/promises/biden-promise-tracker/promise/1574/restore-white-house-directorate-global-health-secu/ (accessed December 20, 2022).
67. See U.S. Government Accountability Office, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Agencies*, GAO-22-105291, January 2022, https://www.gao.gov/assets/gao-22-105291.pdf (accessed December 20, 2022).
68. Ibid., p. 44.
69. Ibid., p. 10.
70. Ibid., p. 267.
71. Silver and Hyman, "COVID-19: A Case Study of Government Failure."
72. Dan Diamond, "Officials Reorganize HHS to Boost Pandemic Response," *The Washington Post*, July 20, 2022, https://www.washingtonpost.com/health/2022/07/20/biden-administration-aspr-independent-division/ (accessed December 20, 2022).
73. Deborah Birx, "Summary of Lessons Learned and the Path Forward," written testimony before the Select Subcommittee on the Coronavirus Crisis, Committee on Oversight and Reform, U.S. House of Representatives, June 23, 2022, p. 2, https://docs.house.gov/meetings/VC/VC00/20220623/114940/HHRG-117-VC00-Wstate-BirxD-20220623.pdf (accessed December 20, 2022).
74. U.S. Government Accountability Office, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, p. 193.
75. Ibid.
76. Birx, "Summary of Lessons Learned and the Path Forward," p. 3.
77. Zachary Stieber, "CDC Responds After Reporting Fewer COVID-19 Pediatric Deaths," *The Epoch Times*, March 19, 2022, https://www.theepochtimes.com/cdc-responds-after-reporting-fewer-covid-19-pediatric-deaths_4348279.html (accessed December 20, 2022).
78. Joseph Mercola, "The Truth Is Coming Out About COVID Deaths," *The Epoch Times*, March 1, 2022, https://www.theepochtimes.com/the-truth-is-coming-out-about-covid-deaths_4309806.html (accessed December 20, 2022).
79. Committee for Economic Development of The Conference Board, "Preparing for the Next Public Health Crisis: Lessons from the Pandemic."
80. Doug Badger and Robert E. Moffit, "COVID-19 and Federalism: Public Officials' Accountability and Comparative Performance," Heritage Foundation *Backgrounder* No. 3638, July 26, 2021, pp. 7–9, https://www.heritage.org/sites/default/files/2021-07/BG3638.pdf.
81. Donald F. Kettl, "How American-Style Federalism Is Hazardous to Our Health," *Governing*, May 26, 2021, https://www.governing.com/now/how-american-style-federalism-is-dangerous-to-our-health (accessed December 20, 2022).
82. Editorial, "Biden's CDC Must Make COVID Data Public," *The Washington Examiner*, February 24, 2022, https://www.washingtonexaminer.com/opinion/editorials/bidens-cdc-must-make-covid-data-public (accessed December 20, 2022).

83. See Apoorva Mandavilli, "The CDC Isn't Publishing Large Portions of the COVID Data it Collects," *The New York Times*, updated February 22, 2022, https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html (accessed December 20, 2022).
84. See press release, "Sen. Johnson to CDC: The Biden Administration Favors Censorship Over Transparency," Office of Senator Ron Johnson, March 2, 2022, https://www.ronjohnson.senate.gov/2022/3/sen-johnson-to-cdc-the-biden-administration-favors-censorship-over-transparency (accessed December 20, 2022).
85. See Joel White and Doug Badger, "In Order to Defeat COVID-19, the Federal Government Must Modernize Its Public Health Data," Heritage Foundation *Backgrounder* No. 3527, September 3, 2020, https://www.heritage.org/sites/default/files/2020-09/BG3527_0.pdf.
86. Report 117-403, *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2023*, Committee on Appropriations, U.S. House of Representatives, 117th Cong., 2nd Sess., July 5, 2022, p. 85, https://www.congress.gov/117/crpt/hrpt403/CRPT-117hrpt403.pdf (accessed December 20, 2022).
87. "Explanatory Statement Submitted by Mr. Leahy, Chair of the Senate Committee on Appropriations, Regarding H.R. 2617, Consolidated Appropriations Act, 2023," in *Congressional Record*, Vol. 168, No. 198—Book II (December 20, 2022), p. S8879, https://www.congress.gov/117/crec/2022/12/20/168/198/CREC-2022-12-20-pt2-PgS8553-2.pdf (accessed January 5, 2023).
88. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Public Health Surveillance and Data: Data Modernization Initiative: Why Sustainable Funding Matters: CDC Data Modernization Funding Overview," last reviewed October 12, 2022, https://www.cdc.gov/surveillance/surveillance-data-strategies/dmi-investments.html (accessed January 5, 2023), and U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Data Modernization Initiative: DMI Basics: The Why, What, and How of Data Modernization," CS 319521-T, p. [9], https://www.cdc.gov/surveillance/pdfs/dmi_basics_external_audiences-march_2021.pdf (accessed January 5, 2023).
89. "Explanatory Statement Submitted by Mr. Leahy, Chair of the Senate Committee on Appropriations, Regarding H.R. 2617, Consolidated Appropriations Act, 2023."
90. "The CDC also distributed the few kits that it produced equally to labs across the country without regard to the size of the local populations. The result was a dramatic shortage of tests in populous areas, creating the false impression that the number of cases in the United States was low." Silver and Hyman, "COVID-19: A Case Study of Government failure."
91. For a detailed discussion of the problems that surfaced with respect to the federal government's regulatory regime governing testing, see Zachary B. Sluzala and Edmund F. Haislmaier, "Lessons from COVID-19: How Policymakers Should Reform the Regulation of Clinical Testing," Heritage Foundation *Backgrounder* No. 3696, March 28, 2022, https://www.heritage.org/sites/default/files/2022-03/BG3696.pdf.
92. U.S. Government Accountability Office, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, p. 197.
93. On January 14, 2022, the Administration announced plans to mail free at-home COVID tests to households. "Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID-19 Tests to Americans for Free," The White House, January 14, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/ (accessed December 20, 2022).
94. Birx, "Summary of Lessons Learned and the Path Forward," p. 7.
95. Silver and Hyman, "COVID-19: A Case Study of Government Failure."
96. U.S. Government Accountability Office, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, p. 193.
97. U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, "Strategic National Stockpile," https://www.phe.gov/about/sns/Pages/products.aspx (accessed December 20, 2022).
98. For an excellent discussion of the WHO mask guidance, see Aileen Lain-yam Chan, C.C. Leung, T.H. Lam, and K.K. Cheng, "To Wear or Not to Wear: WHO's Confusing Guidance on Masks in the Covid-19 Pandemic," *British Medical Journal*, TheBMJOpinion Blog, March 11, 2020, https://blogs.bmj.com/bmj/2020/03/11/whos-confusing-guidance-masks-covid-19-epidemic/ (accessed December 20, 2022).
99. For a summary and discussion of federal public health authorities original messaging on the value of masks, see Badger and Moffit, "Covid-19 and Federalism: Public Officials' Accountability and Comparative Performance," esp. pp.15–17.
100. Leah Asmelash, "The Surgeon General Wants Americans to Stop Buying Face Masks," CNN, March 2, 2020, https://www.cnn.com/2020/02/29/health/face-masks-coronavirus-surgeon-general-trnd/index.html (accessed December 20, 2022).
101. Ibid.
102. Ian T.T. Liu, Vinay Prasad, and Jonathan J. Darrow, "How Effective Are Cloth Face Masks," *Regulation*, Winter 2021–2022, pp. 32–36, https://www.cato.org/sites/cato.org/files/2022-01/reg-v44n4-1.pdf (accessed December 20, 2022).
103. The CDC claimed that as an "emergency order," the mandate was not subject to the notice and comment requirements of a formal administrative regulation. See Mark Pulliam, "Unmasking the Nanny State," Liberty Fund, *Law and Liberty*, February 23, 2022, https://lawliberty.org/unmasking-the-nanny-state/ (accessed December 20, 2022).

104. Mary Margaret Olohan, "10 Covid-19 'Truths' That Weren't True," The Daily Signal, February 1, 2022, https://www.dailysignal.com/2022/02/01/covid-19-pandemic-lies-biden-fauci/.
105. Berkely Lovelace Jr., "CDC Reverses Indoor Mask Policy, Saying Fully Vaccinated People and Kids Should Wear Them Indoors," CNBC, updated July 28, 2021, https://www.cnbc.com/2021/07/27/cdc-to-reverse-indoor-mask-policy-to-recommend-them-for-fully-vaccinated-people-in-covid-hot-spots.html (accessed December 20, 2022).
106. Scientific "contradictions" have been a challenge for public health officials. As Professors Sandro Galea and Michael Stein of the Boston University School of Public Health have noted, the deeper problem is that policy changes have "often gone without explanation. The paradigmatic example of this was the reversal of course early in the pandemic about the utility of mask wearing. Science is, of course, about learning and refutation of past findings, and about iteratively getting ever closer to the truth." Sandro Galea and Michael Stein, "Epistemic Humility During a Global Pandemic," Public Health Post, "The Turning Point," July 8, 2021, https://www.publichealthpost.org/the-turning-point/epistemic-humility/ (accessed December 22, 2022).
107. *Health Freedom Defense Fund, Inc., Ana Carolina Daza, and Sarah Pope v. Joseph R. Biden Jr.*, United States District Court, Middle District of Florida, Tampa Division, Case No. 8:21-cv-1693-KKM-AEP, https://reason.com/wp-content/uploads/2022/04/Health-Freedom-Defense-Fund-v-Biden-ruling-4-18-22.pdf (accessed December 20, 2022).
108. Marita Vlachou, "Anthony Fauci Criticizes Court Ruling Voiding Federal Mask Mandate for Travel," Huffington Post, April 22, 2022, https://www.huffpost.com/entry/anthony-fauci-cricizes-ruling-on-masks_n_6262a43ee4b0ea625c063f77 (accessed December 20, 2022).
109. Ed Browne, "Fauci Says End of Plane Mask Mandate 'Unfortunate,' Judge 'Superceded' CDC," *Newsweek*, April 21, 2022, https://www.newsweek.com/florida-judge-kathryn-kimball-mizelle-mask-mandate-travel-fauci-cdc-1699585 (accessed December 20, 2022).
110. Jingyi Xiao, Eunice Shiu, Huizhu Gao, Jessica Y. Wong, Min W. Fong, Sukhyun Ryu, and Benjamin J. Cowling, "Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures," *Emerging Infectious Diseases*, Vol. 26, No. 5 (May 2020), p. 970, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7181938/pdf/19-0994.pdf (accessed December 20, 2022).
111. Ibid., p. 972.
112. Ian T. Liu, Vinay Prasad, and Jonathan J. Darrow, "Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review," Cato Institute *Working Paper* No. 64, November 8, 2021, p. 1, https://www.cato.org/sites/cato.org/files/2021-11/working-paper-64.pdf (accessed December 20, 2022).
113. Henning Bundgaard, Johan Skov Bundgaard, Daniel Emil Tadeusz Raaschou-Pedersen, Christian von Buchwald, Tobias Todsen, Jakob Boesgaard Norsk, Mia M. Pries-Heje, Christoffer Rasmus Vissing, Pernille B. Nielsen, Ulrik C. Winsløw, Kamille Fogh, Rasmus Hasselbalch, Jonas H. Kristensen, Anna Ringgaard, Mikkel Porsborg Andersen, Nicole Bakkegård Goecke, Ramona Trebbien, Kerstin Skovgaard, Thomas Benfield, Henrik Ullum, Christian Torp-Pedersen, and Kasper Iversen, "Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial," *Annals of Internal Medicine*, Vol. 174, No. 3 (March 2021), pp. 335–343, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7707213/ (accessed December 20, 2022).
114. Michael Klompas, Charles A. Morris, Julia Sinclair, Madelyn Pearson, and Erica S. Shenoy, "Universal Masking in Hospitals in the Covid-19 Era," *The New England Journal of Medicine*, Vol. 382, No. 21 (May 21, 2020), https://www.nejm.org/doi/full/10.1056/nejmp2006372 (accessed December 20, 2022). Subsequently, in a June 3, 2020, letter to the editor, the authors emphasized that people should wear masks "when circumstances compel them to be within 6 feet of others for sustained periods." Ibid., Editor's Note.
115. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Use and Care of Masks," last updated September 9, 2022, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html (accessed December 20, 2022).
116. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Use and Care of Masks: When to Wear a Mask or Respirator," last updated September 9, 2022, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html#:~:text=When%20to%20Wear%20a%20Mask,protection%2C%20and%20comfort%20for%20you. (accessed December 24, 2022).
117. Liu, Prasad, and Darrow, "Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review," p. 1.
118. Cited in Isaac Schorr, "Eric Adams's Embarrassing and Unthinking Allegiance to Covid Theater," *National Review*, April 7, 2022, https://www.nationalreview.com/the-morning-jolt/eric-adamss-embarrassing-and-unthinking-allegiance-to-covid-theater/ (accessed December 20, 2022). In April 2022, New York City Mayor Eric Adams announced the citywide imposition of mask mandates on children *under* the age of five years, a measure almost unprecedented anywhere among the advanced countries of the world.
119. "Children ages 2 years and older can wear masks or respirators to protect themselves and others from COVID-19." U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Use and Care of Masks: Considerations for Specific Groups of People: Children," last updated September 9, 2022, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html (accessed January 5, 2022).
120. World Health Organization, "Coronavirus Disease (COVID-19): Children and Masks," March 7, 2022 | Q&A, https://www.who.int/news-room/questions-and-answers/item/q-a-children-and-masks-related-to-covid-19 (accessed December 21, 2022).
121. European Union, European Centre for Disease Prevention and Control, "Questions and Answers on COVID-19: Children Aged 1–18 Years and the Role of School Settings," last updated April 26, 2022, https://www.ecdc.europa.eu/en/covid-19/questions-answers/questions-answers-school-transmission (accessed December 21, 2022).

122. Ambarish Chandra and Tracy Beth Hoeg, "Revisiting Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1–October 20, 2021," Preprints with The Lancet, posted May 25, 2022, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4118566 (accessed December 21, 2022).
123. Ibid.
124. Ibid.
125. Samantha E. Budzyn, Mark J. Panaggio, Sharyn E. Parks, Marc Papazian, Jake Magid, and Lisa C. Barrios, "Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1–September 4, 2021," U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Reports*, Vol. 70, No. 39 (October 1, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039e3-H.pdf (accessed December 21, 2022).
126. Ermengol Coma, Martí Català, Leonardo Méndez-Boo, Sergio Alonso, Eduardo Hermosilla, Enric Alvarez-Lacalle, David Pino, Manuel Medina, Laia Asso, Anna Gatell, Quique Bassat, Ariadna Mas, Antoni Soriano-Arandes, Francesc Fina, and Clara Prats, "Unravelling the Role of the Mandatory Use of Face Covering Masks for the Control of SARS-CoV-2 in Schools: A Quasi-Experimental Study Nested in a Population-Based Cohort in Catalonia (Spain)," posted March 7, 2022, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4046809 (accessed December 21, 2022).
127. Nicole Saphier, "Americans Deserve Apology from CDC, Biden's Anti-Science Machine," Fox News, March 1, 2022, https://www.foxnews.com/opinion/covid-cdc-biden-mask-mandate-nicole-saphier (accessed December 21, 2022).
128. Marty Makary, "10 Biggest COVID Mistakes—Americans Deserve an Apology from the Medical Experts," Fox News, March 16, 2022, https://www.foxnews.com/opinion/10-biggest-covid-mistakes-americans-apology-dr-marty-makary (accessed December 21, 2022).
129. Joseph T. Wu, Shujiang Mei, Sihui Luo, Kathy Leung, Di Liu, Qiuying Lv, Jian Liu, Yuan Li, Kiesha Prem, Mark Jit, Jianping Weng, Tiejian Feng, Xueying Zheng, and Gabriel M. Leung, "A Global Assessment of the Impact of School Closure in Reducing COVID-19 Spread," *Philosophical Transactions of the Royal Society A*, Vol. 380, Issue 2214 (January 10, 2022), https://royalsocietypublishing.org/doi/10.1098/rsta.2021.0124 (accessed December 21, 2022).
130. United Nations Educational, Scientific and Cultural Organization, "Education: From Disruption to Recovery," last update April 21, 2022, https://www.unesco.org/en/covid-19/education-disruption-recovery (accessed December 21, 2022).
131. Sandro Galea and Michael Stein, "The Limits of Our Science," Public Health Post, "The Turning Point," July 15, 2021.
132. Sandro Galea and Michael Stein, "Why Did We Keep Our Schools Closed?," Public Health Post, October 14, 2021, https://www.publichealthpost.org/the-turning-point/why-did-we-keep-our-schools-closed/ (accessed December 22, 2022).
133. George Psacharopoulos, Harry Patrinos, Victoria Collis, and Emiliana Vegas, "The COVID-19 Cost of School Closures," Brookings Institution, Education Plus Development Blog, April 29, 2020, https://www.brookings.edu/blog/education-plus-development/2020/04/29/the-covid-19-cost-of-school-closures/#:~:text=In%20this%20model%2C%20the%20cost,this%20loss%20may%20well%20materialize (accessed December 21, 2022).
134. Eric A. Hanusheck and Ludger Woessmann, Foreword in "The Economic Impacts of Learning Losses," Organisation for Economic Co-operation and Development, September 2020, https://www.oecd.org/education/The-economic-impacts-of-coronavirus-covid-19-learning-losses.pdf (accessed December 21, 2022).
135. Derek Thompson, "School Closures Were a Failed Policy," *The Atlantic*, October 26, 2022, https://www.theatlantic.com/newsletters/archive/2022/10/pandemic-school-closures-americas-learning-loss/671868/ (accessed January 4, 2023).
136. Marta Bertran, Zahin Amin-Chowdhury, Hannah Davies, Hester Allen, Tom Clare, Chloe Davison, Mary Sinnathamby, Giulia Seghezzo, Meaghan Kall, Hannah Williams, Nick Gent, Mary E. Ramsay, Shamez N. Ladhani, and Godwin Oligbu, "COVID-19 Deaths in Children and Young People: Active Prospective National Surveillance, March 2020 to December 2021, England," posted June 20, 2022, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125501 (accessed December 21, 2022).
137. The *British Medical Journal* reported that "a former IT programmer from Atlanta" noted a discrepancy between two CDC databases reporting childhood deaths with COVID among. One reported that 1700 had died with COVID, while the other placed the figure at 900. The programmer and another observer had been writing the CDC about the discrepancy for over a month without a reply. The CDC then quietly corrected its figures, attributing the correction "to its own 'rigorous quality control measures.'" Jennifer Block, "COVID-19: US Tracker Overestimated Deaths Among Children," *British Medical Journal*, published online March 29, 2022, https://www.bmj.com/content/376/bmj.o831 (accessed December 21, 2022).
138. Adam Dean, Jamie McCallum, Simeon Kimmel, and Atheendar Venkataramani, "Iowa School Districts Were More Likely to Adopt COVID-19 Mask Mandates Where Teachers Were Unionized," *Health Affairs*, Vol. 40, No 8 (August 2021), pp. 1270–1276, https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.02518 (accessed December 21, 2022).
139. For a detailed discussion of this incident, see Staff Report, *Interim Findings: Union Officials Wrote Key Portions of the Biden Administration's School Reopening Guidance*, Committee on Oversight and Reform, Select Subcommittee on the Coronavirus Crisis | Minority, March 30, 2022, p. 5, https://www.republicanwhip.gov/wp-content/uploads/2022/03/AFT-CDC-Interference-Interim-Report-3-30-2022.pdf (accessed December 19, 2022).
140. For a fuller discussion of the eviction moratorium, see Paul J. Larkin, "The Sturm und Drang of the CDC's Home Eviction Moratorium," *Harvard Journal of Law and Public Policy*, forthcoming, posted December 1, 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3935416 (accessed December 19, 2022).

141. H.R. 748, Coronavirus Aid, Relief, and Economic Security Act, Section 4024.
142. President Donald J. Trump, Executive Order 13945, "Fighting the Spread of COVID-19 by Providing Assistance to Renters and Homeowners," August 8, 2020, in *Federal Register*, Vol. 85, No. 158 (August 14, 2020), pp. 49935–49937, https://www.govinfo.gov/content/pkg/FR-2020-08-14/pdf/2020-18015.pdf (accessed December 21, 2022).
143. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19," Agency Order, *Federal Register*, Vol. 85, No. 173 (September 4, 2020), pp. 55292–55297, https://www.govinfo.gov/content/pkg/FR-2020-09-04/pdf/2020-19654.pdf (accessed December 21, 2022).
144. Larkin, "The Sturm und Drang of the CDC's Home Eviction Moratorium,"
145. Ibid.
146. *Alabama Association of Realtors v. Department of Health and Human Services*, on application to vacate stay, 594 U.S. ____ (2021), https://www.supremecourt.gov/opinions/20pdf/20a169_4f15.pdf (accessed December 21, 2022).
147. *Alabama Association of Realtors v. Department of Health and Human Services*, 594 U.S. ____ (2021), https://www.supremecourt.gov/opinions/20pdf/21a23_ap6c.pdf (accessed December 21, 2022).
148. Cited in GianCarlo Canaparo and Frank Yang, "'15 Days' to 2 Years: How Power Corrupted Our Public Health Bureaucrats," The Daily Signal, March 23, 2022, https://www.dailysignal.com/2022/03/23/15-days-to-2-years-how-power-corrupted-our-public-health-bureaucrats/.
149. "Remarks by President Biden on Fighting the COVID-19 Pandemic."
150. For a discussion of the OSHA rule on the day of its issuance, see Doug Badger, The Honorable Ron Johnson, Paul J. Larkin, Martin Makary, and Robert E. Moffit, "What's Wrong With President Biden's COVID-19 Vaccine Mandate," Heritage Foundation *Lecture* No. 1327, November 19, 2021, delivered November 4, 2021, https://www.heritage.org/sites/default/files/2021-11/HL1327.pdf.
151. Paul J. Larkin and Doug Badger, "The First General Federal Vaccination Requirement: The OSHA Emergency Temporary Standard for COVID-19 Vaccinations," *Administrative Law Review Accord*, preprint, last revised January 10, 2022, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3935420 (accessed December 19, 2022).
152. *National Federation of Independent Business v. Department of Labor, Occupational Safety and Health Administration*, et al., 595 U.S. ____ (2022), https://www.supremecourt.gov/opinions/21pdf/21a244_hgci.pdf (accessed December 19, 2022).
153. *Biden v. Missouri and Becerra v. Louisiana*, 595 U.S. ____ (2022), https://www.supremecourt.gov/opinions/21pdf/21a240_d18e.pdf (accessed December 19, 2022).
154. Daniel Wiessner, "U.S. Court Split in Challenge to COVID Vaccine Mandate for Federal Workers," Reuters, November 2, 2022, https://www.reuters.com/legal/government/us-court-split-challenge-covid-vaccine-mandate-federal-workers-2022-11-02/ (accessed December 21, 2022; Emily M. Halliday, "Contractor Vaccine Mandate Still on Hold, for Now," Ogletree Deakins, October 25, 2022, https://ogletree.com/insights/contractor-vaccine-mandate-still-on-hold-for-now/#:~:text=At%20least%20for%20now%2C%20the,the%20contractor%20vaccine%20mandate%20nationwide (accessed December 21, 2022).
155. See "Statement by the President on H.R. 1776, the James N. Inhofe National Defense Authorization Act for Fiscal Year 2023," The White House, December 23, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/12/23/statement-by-the-president-on-h-r-7776-the-james-m-inhofe-national-defense-authorization-act-for-fiscal-year-2023/ (accessed December 24, 2022), and U.S. Senate, Committee on Armed Services, "Summary of the Fiscal Year 2023 National Defense Authorization Act," p. 3, https://www.armed-services.senate.gov/imo/media/doc/fy23_ndaa_agreement_summary.pdf (accessed December 24, 2022). See also Rules Committee Print 117-70, *Text of the House Amendment to the Senate Amendment to H.R. 7776*, James N. Inhofe National Defense Authorization Act for Fiscal Year 2023, December 6, 2022, Section 525, https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-117HR7776EAS-RCP117-70.pdf (accessed December 21, 2022).
156. According to Defense Department data, 3,717 Marines, 1,816 soldiers, and 2,064 sailors had been discharged for refusing to be vaccinated. Reuters, "White House Slams Congress for Move to Rescind Military's Vaccine Mandate," December 7, 2022, https://www.reuters.com/world/us/white-house-slams-congress-move-rescind-militarys-vaccine-mandate-2022-12-07/ (accessed December 21, 2022).
157. Courtney Kube, "Service Members Kicked Out of the U.S. Military for Refusing COVID Vaccine Could Be Allowed to Rejoin, Officials Say," NBC News, December 7, 2022, https://www.nbcnews.com/politics/congress/ndaa-military-vaccine-mandate-soldiers-sailors-rejoin-military-rcna60391 (accessed December 21, 2022).
158. Steve Beynon and Konstantin Toropin, "Pentagon Likely Rushed Denials of COVID-19 Vaccine Religious Exemption Requests, Watchdog Finds," Military.com, September 19, 2022, https://www.military.com/daily-news/2022/09/19/pentagon-likely-rushed-denials-of-covid-19-vaccine-religious-exemption-requests-watchdog-finds.html (accessed December 1, 2022).
159. Matthew Miller, "New York Gov. Hochul Tells Christian Worshippers: 'God Wants You to Be Vaccinated,'" Yahoo! News, September 27, 2021, https://www.washingtonexaminer.com/news/ny-governor-hochul-christians-god-wants-you-to-be-vaccinated (accessed December 21, 2022).
160. Reuters, "U.S. FDA Authorizes Bivalent COVID Shots for Kids as Young as Six Months Old," December 9, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-authorizes-moderna-pfizer-updated-covid-boosters-6-months-old-2022-12-08/ (accessed December 21, 2022).

161. U.S. Department of Health and Human Development, Centers for Disease Control and Prevention, "COVID-19 Primary Series Completion, Booster Dose Eligibility, and Booster Dose Receipt by Age, United States," updated December 16, 2022, https://data.cdc.gov/Vaccinations/COVID-19-Primary-Series-Completion-Booster-Dose-El/3pbe-qh9z (accessed December 21, 2022).

162. Chart, "Total COVID-19 Vaccine Doses Administered," Global Change Data Lab, *Our World in Data*, https://ourworldindata.org/grapher/cumulative-covid-vaccinations?country=~USA (accessed December 20, 2022).

163. Letter from Representatives Bill Posey, Louie Gohmert, Ralph Norman, Andy Biggs, Dan Bishop, Andrew Clyde, Warren Davidson, Diana Harshbarger, Vicky Hartzler, Mary Miller, Chip Roy, Lauren Boebert, Thomas Massie, Jeff Duncan, Matt Rosendale, and Bog Good and Senators Ted Cruz and Ron Johnson to the Honorable Robert M. Califf, M..D, Commissioner, U.S. Food and Drug Administration, June 7, 2022, p. 1, https://posey.house.gov/uploadedfiles/fdalettercovidvaxquestionsjune82022.pdf (accessed December 21, 202).

164. The clinical trials for vaccines that were granted authorization did not test whether they reduced transmission of the pathogen. For example, the FDA's December 2020 press release announcing that it had granted an emergency use authorization for Pfizer's COVID vaccine stated that "[d]ata are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person." News release, "FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine," U.S. Department of Health and Human Services, Food and Drug Administration, December 11, 2020, https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (accessed December 21, 2022).

165. Ria Lassauniere, Charlotta Polacek, Anders Frische, Lasse Boding, Susanne Gjørup Sækmose, Morten Rasmussen, and Anders Fomsgaard, "Neutralizing Antibodies Against the SARS-CoV-2 Omicron Variant (BA.1) 1 to 18 Weeks After the Second and Third Doses of the BNT162b2 mRNA Vaccine," *JAMA Network Open*, Vol. 5, No. 5 (May 2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792295 (accessed December 21, 2022).

166. *The Washington Post* cites an analysis by Cynthia Cox, the Kaiser Family Foundation's Vice President, who confirms that the vaccines have lost their potency and that the August 2022 deaths are still highly concentrated among the elderly. See McKenzie Beard, "Covid Is No Longer Mainly a Pandemic of the Unvaccinated. Here's Why," *The Washington Post*, November 23, 2022, https://www.washingtonpost.com/politics/2022/11/23/vaccinated-people-now-make-up-majority-covid-deaths/ (accessed January 4, 2023).

167. Joseph Fraiman, Juan Erviti, Mark Jones, Sander Greenland, Patrick Whelan, Robert M. Kaplan, and Peter Doshi, "Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials," posted June 23, 2022, last revised September 9, 2022, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239 (accessed December 21, 2022).

168. Ibid., p. 8.

169. Allison Krug, Josh Stevenson, and Tracy Beth Hoeg, "BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis," *European Journal of Clinical Investigation*, Vol. 52, No. 5 (May 2022), https://onlinelibrary.wiley.com/doi/10.1111/eci.13759 (accessed December 21, 2022).

170. Kevin Bardosh, Allison Krug, Euzebiusz Jamrozik, Trudo Lemmens, Salmaan Keshavjee, Vinay Prasad, Martin Makary, Stefan Baral, and Tracy Beth Hoeg, "Covid-19 Vaccine Boosters for Young Adults: A Risk Benefit Assessment and Five Ethical Arguments Against Mandates at Universities," posted September 12, 2022, last revised December 12, 2022, p. 31, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4206070 (accessed December 21, 2022). Punctuation and emphasis as in original.

171. U.S. Department of Health and Human Services, Health Resources and Services Administration, "Countermeasures Injury Compensation Program (CICP)," last reviewed November 2020, https://www.hrsa.gov/cicp (accessed December 21, 2022).

172. Table 1, "Comparison of Vaccine-Injury Compensation Programs: CICP v. VICP," in Kevin J. Hickey and Erin H. Ward, "Compensation Programs for Potential COVID-19 Vaccine Injuries," Congressional Research Service *Legal Sidebar* No. LSB10584, updated October 20, 2021, pp. 7–8, https://crsreports.congress.gov/product/pdf/LSB/LSB10584 (accessed December 21, 2022).

173. Ibid.

174. Table 1, "Alleged COVID-19 Countermeasure Claims Filed as of December 1, 2022," in U.S. Department of Health and Human Services, Health Resources and Services Administration, "," U.S. Department of Health and Human Services, "Countermeasures Injury Compensation Program (CICP) Data," last reviewed December 2022, https://www.hrsa.gov/cicp/cicp-data#table-1 (accessed December 21, 2022).

175. The agency has denied 55 countermeasure claims either because the standard of proof was not met or because a covered injury was not sustained. U.S. Department of Health and Human Services, Health Resources and Services Administration, Has the CICP Made Any Decisions Regarding COVID-19 Claims?" last reviewed December 2022, https://www.hrsa.gov/cicp/cicp-data#table-1 (accessed December 21, 2022).

176. Quoted in Michael Brendan Dougherty, "Republicans Need to Investigate the Pandemic Response," *National Review*, July 27, 2022, https://www.nationalreview.com/2022/07/republicans-need-to-investigate-the-pandemic-response/ (accessed December 19, 2022).

177. Marty Makary, MD, "The High Cost of Disparaging Natural Immunity to COVID," *The Wall Street Journal*, January 26, 2022, https://www.wsj.com/articles/the-high-cost-of-disparaging-natural-immunity-to-covid-vaccine-mandates-protests-fire-rehire-employment-11643214336 (accessed December 22, 2022). It is worth noting that Dr. Makary and his Johns Hopkins University colleagues conducted an independent study of their own and found that among 295 persons who contracted COVID-19 and had not been vaccinated, 99 percent of them had antibodies almost two years after they had been infected.

178. Paul Elias Alexander, "150 Research Studies Affirm Naturally Acquired Immunity to COVID-19: Documented, Linked, and Quoted," Brownstone Institute, October 17, 2021, https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/ (accessed December 22, 2022).

179. Victoria Jane Hall, Sarah Foulkes, Andre Charlett, Ana Atti, Edward J. M. Monk, Ruth Simmons, Edgar Wellington, Michelle J. Cole, Ayoub Saei, Blanche Oguti, Katie Munro, Sarah Wallace, Peter D. Kirwan, Madhumita Shrotri, Amoolya Vusirikala, Sakib Rokadiya, Meaghan Kall, Maria Zambon, Mary Ramsay, Tim Brooks, Colin S. Brown, Meera A. Chand, Susan Hopkins, and the SIREN Study Group, "SARS-CoV-2 Infection Rates of Antibody-Positive Compared to Antibody Negative Health Care Workers in England: A Large, Multicentre, Prospective Cohort Study (SIREN)," *The Lancet*, Vol. 397, Issue 10283 (April 17. 2021), pp. 1459–1469, https://www.icpcovid.com/sites/default/files/2021-08/Ep%20164-1%20B%20Victoria%20Jane%20Hall%20SIREN%20SARS-CoV-2%20in%20Ab%2B%20and%20AB-%20HCW%20in%20England%20Lancet%209%20April%202021.pdf (accessed December 22, 2022).

180. Saphier, "Americans Deserve Apology from CDC, Biden's Anti-Science Machine."

181. Anna A Mensah, Helen Campbell, Julia Stowe, Giulia Seghezzo, Ruth Simmons, Joanne Lacy, Antoaneta Bukasa, Shennae O'Boyle, Mary E. Ramsay, Kevin Brown, and Shamez N. Ladhani, "Risk of SARS-CoV-2 Reinfections in Children: A Prospective National Surveillance Study Between January, 2020, and July, 2021, in England," *The Lancet Child & Adolescent Health*, Vol. 6, No. 6 (June 2022), pp. 384–392, https://www.thelancet.com/action/showPdf?pii=S2352-4642%2822%2900059-1 (accessed December 22, 2022).

182. Galit Perez, Tamar Banon, Sivan Gazit, Shay Ben Moshe, Joshua Wortsman, Daniel Grupel, Asaf Peretz, Amir Ben Tov, Gabriel Chodick, Miri Mizrahi-Reuveni, and Tal Patalon, "A 1 to 1000 SARS-CoV-2 Reinfection Proportion in Members of a Large Healthcare Provider in Israel: A Preliminary Report," medRxiv, preprint, posted March 8, 2021, p. 2, https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1.full.pdf (accessed December 22, 2022).

183. Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, and Tal Patalon, "Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections," medRxiv, preprint, posted August 25, 2021, p. [3], https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf (accessed December 22, 2022).

184. Tomas M. Leon, Vajerra Dorabawila, Lauren Nelson, Emily Lutterloh, Ursula Bauer, Byron Backenson, Mary T. Bassett, Hannah Henry, Brooke Bregman, Claire M. Midgley, Jennifer F. Myers, Ian D. Plumb, Heather E. Reese, Rui Zhao, Melissa Briggs-Hagen, Dina Hoefer, James P. Watt, Benjamin J. Silk, Seema Jain, and Eli S. Rosenberg, "COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis—California and New York, May–November 2021," U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, Vol. 71, No. 4 (January 28, 2022), p. 130, https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7104e1-H.pdf (accessed December 22, 2022).

185. Ibid., p. 131.

186. Makary, "The High Cost of Disparaging Natural Immunity to Covid."

187. Tal Patalon, Yaki Saciukl, Hanit Ohayon Hada, Galit Perez, Asaf Peretz, Amir Ben-Tove, and Sivan Gazit, "Naturally Acquired Immunity Dynamics Against SARS-CoV-2 in Children and Adolescents," medRXiv, preprint, posted June 21, 2022, p. 3, https://www.medrxiv.org/content/10.1101/2022.06.20.22276650v1.full.pdf (accessed December 22, 2022). The study population ranged between 293,743 and 458,959 individuals from five to 18 years of age. This is a preprint study, which means that it has not been peer-reviewed and is not to be used for clinical guidance.

188. Zachary Stieber, "Growing Number of Experts Call on US Government to Recognize Natural Immunity," *The Epoch Times*, February 23, 2022, https://www.theepochtimes.com/mkt_app/growing-number-of-experts-call-on-us-government-to-recognize-natural-immunity_4295612.html (accessed December 21, 2022).

189. Chaudhry et al., "A Country Level Analysis Measuring the Impact of Government Actions, Country Preparedness and Socioeconomic Factors on COVID-19 Mortality and Related Health Outcomes."

190. Jonas Herby, Lars Jonung, and Steve H. Hanke, "A Literature Review and Meta-Analysis of the Effects of Lockdowns on COVID-19 Mortality," Johns Hopkins Institute for Applied Economics, Global Health and the Study of Business Enterprise, Studies in Applied Economics No. 200, January 2022, p. 2, https://sites.krieger.jhu.edu/iae/files/2022/01/A-Literature-Review-and-Meta-Analysis-of-the-Effects-of-Lockdowns-on-COVID-19-Mortality.pdf (accessed December 22, 2022). The researchers screened 18,590 studies in their review, settling on 24 studies that dealt with the specific issue of government lockdowns' effectiveness.

191. Kevin D. Dayaratna, Patrick Tyrrell, and Andrew Vanderplas, "A Comparative Analysis of Policy Approaches to COVID-19 Around the World, with Recommendations for U.S. Lawmakers," Heritage Foundation *Special Report* No. 234, July 20, 2020, https://www.heritage.org/public-health/report/comparative-analysis-policy-approaches-covid-19-around-the-world.

192. For a more complete discussion of these cases, see Mark Storslee, "The COVID-19 Church-Closure Cases and the Free Exercise of Religion," *Journal of Law and Religion*, Vol. 37, Issue 1 (January 2022), pp. 72–95, https://www.cambridge.org/core/services/aop-cambridge-core/content/view/8534D9FAC511DC0F3D78BB519744875B/S0748081421000813a.pdf/the-covid-19-church-closure-cases-and-the-free-exercise-of-religion.pdf (accessed December 22, 2022).

193. *Roman Catholic Diocese of Brooklyn, New York v. Andrew M. Cuomo, Governor of New York*, 592 U.S. ____, 2 (2020), https://www.supremecourt.gov/opinions/20pdf/20a87_4g15.pdf (accessed December 22, 2022).

194. *Ritesh Tandon et al. v. Gavin Newsom, Governor of California*, 593 U.S. ____, 3 (2021), https://www.supremecourt.gov/opinions/20pdf/20a151_4g15.pdf (accessed December 22, 2022).

195. Gene Falk, Paul D. Romero, Isaac A. Nicchitta, and Emma C. Nyhoff, "Unemployment Rates During the COVID-19 Pandemic," Congressional Research Service *Report for Members and Committees of Congress* No. R46554, updated August 20, 2021, p. 1, https://sgp.fas.org/crs/misc/R46554.pdf (accessed December 22, 2022).
196. Santiago Garcia and Timothy D. Henry, "The Hidden Costs of National Lockdowns," *The Lancet Regional Health—Europe*, Vol. 2 (March 2021), https://www.thelancet.com/pdfs/journals/lanepe/PIIS2666-7762(21)00012-0.pdf (accessed December 22, 2022).
197. Makary, "10 Biggest Covid Mistakes—Americans Deserve an Apology from the Medical Experts."
198. Sandro Galea and Michael Stein, "The Problem with Health Behavior," Public Health Post, "The Turning Point," July 22, 2021, https://www.publichealthpost.org/the-turning-point/the-problem-with-health-behavior/ (accessed December 22, 2022).
199. Ari R. Joffe, "COVID-19: Rethinking the Lockdown Groupthink," *Frontiers in Public Health*, Vol. 9 (February 26, 2021), https://www.frontiersin.org/articles/10.3389/fpubh.2021.625778/full (accessed December 22, 2022).
200. "Clinicians in hot spots treating patients are developing new understandings about how to treat the disease but are struggling to get the information out to other providers. A core useful role for public health officials would be to ensure that this information is regularly shared, allowing doctors to use it to inform clinical decisions." See National Coronavirus Recovery Commission, *Saving Lives and Livelihoods: Recommendations for Recovery*, p. 53.
201. Kevin Pham, "Under This Doctor's Care, Most COVID-19 Patients Are Recovering. Here's His Unusual Approach," The Daily Signal, May 4, 2020, https://www.dailysignal.com/2020/05/04/under-this-doctors-care-most-covid-19-patients-are-recovering/.
202. Press release, "NIH Begins Large Clinical Trial to Test Immune Modulators for Treatment of COVID-19," U.S. Department of Health and Human Services, National Institutes of Health, October 16, 2020, https://www.nih.gov/news-events/news-releases/nih-begins-large-clinical-trial-test-immune-modulators-treatment-covid-19 (accessed December 20, 2022).
203. News release, "Coronavirus (COVID-19) Update: FDA Authorizes Drug for Treatment of COVID-19," U.S. Department of Health and Human Services, Food and Drug Administration, June 24, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-treatment-covid-19 (accessed December 21, 2022).
204. Thomas Yadegar, MD, personal communication with the authors, April 29, 2020.
205. Martin Kulldorff, Sunetra Gupta, Bhattacharya, "The Great Barrington Declaration," October 4, 2020, https://gbdeclaration.org/ (accessed December 21, 2022). As of December 21, 2022, the Declaration's website claimed 934,094 signatures: 870,827 "concerned citizens," 15,989 "medical & public health scientists," and 47,278 "medical practitioners."
206. Ibid.
207. Zachary Stieber, "Exclusive: Dr. Collins Caught Off-Guard by First Questions on 'Takedown' Email," *The Epoch Times*, March 19, 2022, https://www.theepochtimes.com/mkt_morningbrief/exclusive-dr-collins-blindsided-by-first-questions-on-takedown-email_4348218.html (accessed December 21, 2022); and Zachary Stieber, "Exclusive: Fauci Said Great Barrington Declaration Reminded Him of AIDS Denialism," *The Epoch Times*, March 15, 2022, https://www.theepochtimes.com/health/exclusive-fauci-said-great-barrington-declaration-reminded-him-of-aids-denialism_4337628.html (accessed December 25, 2022); and email from Emma Wojtowicz. NIH/OD [Office of the Director], to Francis Collins, NIH/OD, December 17, 2021, https://www.documentcloud.org/documents/21451234-wojtowicz-to-collins (accessed December 25, 2022).
208. Professor Kristina Alexanderson et al., "The John Snow Memorandum," https://www.johnsnowmemo.com/john-snow-memo.html (accessed December 14, 2022).
209. Ibid.
210. John P. Ioannidis, "Citation Impact and Social Media Visibility of Great Barrington and John Snow Signatories for COVID-19 Strategy," *British Medical Journal Open*, Vol. 12, Issue 2 (2022), p. 2, https://bmjopen.bmj.com/content/12/2/e052891 https://bmjopen.bmj.com/content/12/2/e052891.info (accessed December 22, 2022).Ioannidis also reports that the Great Barrington Declaration, as of November 25, 2021, attracted the signatures of 15,019 medical and public health scientists and 44,541 medical practitioners. Both the Great Barrington Declaration and the John Snow Memorandum, Ioannidis adds, were signed by "many leading stellar scientists with very high citation impact in the scientific literature." Ibid., pp. 2 and 4.
211. Zachary Stieber and Jan Jekielek, " Fauci Comparison of Great Barrington Declaration Authors to AIDS Deniers 'Utterly Shocking': Bhattacharya," *The Epoch Times*, March 21, 2022, https://www.theepochtimes.com/fauci-comparison-of-great-barrington-declaration-authors-to-aids-deniers-utterly-shocking-bhattacharya_4351079.html (accessed December 21, 2022).
212. Galea and Stein, "Epistemic Humility During a Global Pandemic."
213. As Dr. Ioannidis observes, "GBD focuses more on the potential multifaceted collateral damage of lockdowns and on prioritizing quantitative assessment of risk (where children and young people have far lower risk than elderly, vulnerable people), while JSM depends more heavily on basic virology expertise. Given the magnitude of the COVID-19 crisis, it is important to ensure that scientific disciplines can collaborate dispassionately and that different views can be juxtaposed and integrated. GBD and JSCM may have more in common than it is often thought. Critical differences between them should be probed with rigorous science rather than defended on partisan grounds and with social media warfare." Ioannidis, "Citation Impact and Social Media Visibility of Great Barrington and John Snow Signatories for COVID-19 Strategy," p. 7.

214. According to John Barry, chief historian of the 1918 flu and author of *The Great Influenza*, "There were no general lockdowns, the way we have today. Most cities closed saloons, theaters, places of public gathering, but no general closing." Stephanie Soucheray, "'Great Influenza' Author Talks COVID-19, 1918 Flu," Cidrap [Center for Infectious Disease Research and Policy, University of Minnesota], April 10, 2020, https://www.cidrap.umn.edu/news-perspective/2020/04/great-influenza-author-talks-covid-19-1918-flu (accessed December 22, 2022).
215. Kevin Griffith and Samantha G. Auty, "A Surge in Overdose Deaths During COVID-19," Public Health Post *Databyte*, March 3, 2022, https://www.publichealthpost.org/databyte/surge-overdose-deaths-covid/ (accessed December 22, 2022).
216. Zachary Stieber, "Great Barrington Declaration Authors Join Lawsuit Against Alleged Government–Big Tech Collusion," *The Epoch Times*, August 3, 2022, https://www.theepochtimes.com/great-barrington-declaration-authors-join-lawsuit-against-alleged-government-big-tech-collusion_4640259.html (accessed December 22, 2022).
217. Kieran Corcoran, "Infamous WHO Tweet Saying There Was 'No Clear Evidence' COVID-19 Could Spread Between Humans Was Posted for 'Balance' to Reflect Findings from China," *Business Insider*, April 18, 2020, https://www.businessinsider.com/who-no-transmission-coronavirus-tweet-was-to-appease-china-guardian-2020-4 (accessed December 20, 2022).
218. Chart, "Daily and Total Confirmed COVID-19 Deaths, World," Global Change Data Lab, *Our World in Data*, https://ourworldindata.org/grapher/total-daily-covid-deaths (accessed December 20, 2022).
219. Olohan, "10 COVID 19 'Truths' That Weren't True."
220. Nicholas Wade, "The Origin of COVID: Did People or Nature Open Pandora's Box at Wuhan?" *Bulletin of the Atomic Scientists*, May 5, 2021, https://thebulletin.org/2021/05/the-origin-of-covid-did-people-or-nature-open-pandoras-box-at-wuhan/ (accessed December 19, 2022).
221. Jeff Carlson and Hans Mahncke, "Memo Reveals State Department Assessed in Early 2020 that Lab Leak Was Most Likely Origin of COVID-19," *The Epoch Times*, April 6, 2022, https://www.theepochtimes.com/memo-reveals-state-department-assessed-in-early-2020-lab-leak-was-most-likely-origin-of-covid-19_4387879.html (accessed December 20, 2022).
222. Ibid.
223. Wade, "The Origin of Covid: Did People or Nature Open Pandora's Box at Wuhan?" *The Lancet* letter, declaring "solidarity" with China's medical professionals, is a remarkable document, reading in part: "Conspiracy theories do nothing but create fear, rumours, and prejudice that jeopardize our global collaboration in the fight against this virus." See Charles Calisher, Dennis Carroll, Rita Colwell, Ronald B. Corley, Peter Daszak, Christian Drosten, Luis Enjuanes, Jeremy Farrar, Hume Field, Josie Golding, Alexander Gorbalenya, Bart Haagmans, James M Hughes, William B. Karesh, Gerald T. Keusch, Sai Kit Lam, Juan Lubroth, John S. Mackenzie, Larry Madoff, Jonna Mazet, Peter Palese, Stanley Perlman, Leo Poon, Bernard Roizman, Linda Saif, Kanta Subbarao, and Mike Turner, "Statement in Support of the Scientists, Public Health Professionals, and Medical Professionals of China Combatting COVID-19," *The Lancet*, Vol. 395 (March 7, 2020), Correspondence, pp. e42–e43, https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2930418-9 (accessed December 22, 2022).
224. Kristian G. Andersen, Andrew Rambaut, W. Ian Lipkin, Edward C. Holmes, and Robert F. Garry, "The Proximal Origin of SARS-CoV-2," *Nature Medicine*, Vol. 26, Issue 4 (April 2020), pp. 450–452, Correspondence, https://www.nature.com/articles/s41591-020-0820-9 (accessed December 21, 2022).
225. Francis Collins, "Genomic Study Points to Natural Origin of COVID-19," U.S. Department of Health and Human Services, National Institutes of Health, NIH Director's Blog, March 26, 2020, https://directorsblog.nih.gov/2020/03/26/genomic-research-points-to-natural-origin-of-covid-19/ (accessed December 21, 2022).
226. "The Daszak and Andersen letters were political, not scientific, statements, yet were amazingly effective. Articles in the mainstream press repeatedly stated that a consensus of experts had ruled lab escape out of the questions or extremely unlikely. Their authors relied for the most part on the Daszak and Anderson letters, failing to understand the yawning gaps in their arguments. Mainstream newspapers all have science journalists on their staff, as do major networks, and these specialist reporters are supposed to be able to question scientists and check their assertions. But the Daszak and Andersen assertions went largely unchallenged." Wade, "The Origin of COVID: Did People or Nature Open Pandora's Box at Wuhan?"
227. Carlson and Mahncke, "Memo Reveals State Department Assessed in Early 2020 that Lab Leak Was Most Likely Origin of COVID-19."
228. Jerry Dunleavey," "Fauci Shut Down Lab Leak Theory Despite Scientists Lending It Credence, Emails Show," *The Denver Gazette*, January 11, 2022, https://denvergazette.com/news/fauci-shut-down-lab-leak-theory-despite-scientists-lending-it-credence-emails-show/article_908df8b6-2161-5b7e-b7ed-003be942e341.html (accessed December 20, 2022).
229. Office of the Director of National Intelligence, "Unclassified Summary of Assessment on COVID-19 Origins," August 27, 2021, p. 1, https://www.dni.gov/files/ODNI/documents/assessments/Unclassified-Summary-of-Assessment-on-COVID-19-Origins.pdf (accessed December 19, 2022).
230. Memorandum, "An Analysis of Circumstantial Evidence for Wuhan Labs as the Source of the Coronavirus," U.S. Department of State, April 2020, p. 2, https://usrtk.org/wp-content/uploads/2022/03/State-Department-FOIA-An-Analysis-of-Circumstantial-Evidence-for-Wuhan-Labs-as-the-Source-of-the-Coronavirus.pdf (accessed December 19, 2022).
231. Ibid., pp. 2–5.
232. Wade, "The Origin of COVID: Did People or Nature Open Pandora's Box at Wuhan?" A biosafety level 2 (BLS2) is the safety level for labs that work with pathogens that pose a "moderate" health hazard. The highest safety level for a lab (BLS4) would be reserved for a highly dangerous pathogen that results in fatal disease for which there is no vaccine or cure.

233. For an excellent discussion of the controversy, see Amy Maxmen and Smriti Mallapaty, "The Covid Lab Leak Hypothesis: What Scientists Do and Don't Know," *Nature News Explainer*, June 8, 2021, https://www.nature.com/articles/d41586-021-01529-3 (accessed December 19, 2022).

234. Jonathan Pekar, Andrew Magee, Edyth Parker, Niema Moshiri, Katherine Izhikevich, Jennifer L. Havens, Karthik Gangavarapu, Lorena Mariana Malpica Serrano, Alexander Crits-Christoph, Nathaniel L. Matteson, Mark Zeller, Joshua I. Levy, Jade C. Wang, Scott Hughes, Jungmin Lee, Heedo Park, Man-Seong Park, Katherine Ching Zi Yan, Raymond Tzer Pin Lin, Mohd Noor Mat Isa, Yusuf Muhammad Noor, Tetyana I. Vasylyeva, Robert F. Garry, Edward C. Holmes, Andrew Rambaut, Marc A. Suchard, Kristian G. Andersen, Michael Worobey, and Joel O. Wertheim, "The Molecular Epidemiology of Multiple Zoonotic Origins of SARS-CoV-2," *Science*, Vol. 337, Issue 6609 (July 2022), pp. 960–966, https://www.science.org/doi/10.1126/science.abp8337 (accessed December 19, 2022).

235. Edward C. Holmes, Stephen A. Goldstein, Angela L. Rasmussen, David L. Robertson, Alexander Crits-Christoph, Joel O. Wertheim, Simon J. Anthony, Wendy S. Barclay, Maciej F. Boni, Peter C. Doherty, Jeremy Farrar, Jemma L. Geoghegan, Xiaowei Jiang, Julian L. Leibowitz, Stuart J.D. Neil, Tim Skern, Susan R. Weiss, Michael Worobey, Kristian G. Andersen, Robert F. Garry, and Andrew Rambaut, "The Origins of SARS-CoV-2: A Critical Review," *Cell*, Vol. 84, No. 19 (September 16, 2021), p. 4842, https://www.cell.com/cell/pdf/S0092-8674(21)00991-0.pdf (accessed December 19, 2022).

236. Ibid., p. 4853.

237. Valentin Bruttel, Alex Washburne, and Antonius VanDongen, "Endonuclease Fingerprint Indicates a Synthetic Origin of SARS-CoV-2," bioRxiv preprint, posted October 20, 2022, https://www.biorxiv.org/content/10.1101/2022.10.18.512756v1.full.pdf (accessed December 19, 2022).

238. Ibid.

239. Minority Oversight Staff, Committee on Health Education, Labor and Pensions, U.S. Senate, *An Analysis of the Origins of the COVID-19 Pandemic: Interim Report*, October 2022, p. 4, https://www.help.senate.gov/imo/media/doc/report_an_analysis_of_the_origins_of_covid-19_102722.pdf (accessed December 19, 2022).

240. Ibid.

241. "Statement by President Joe Biden on the Investigation into the Origins of COVID-19," The White House, August 27, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/27/statement-by-president-joe-biden-on-the-investigation-into-the-origins-of-covid-%E2%81%A019/ (accessed December 19, 2022).

242. Memorandum, "An Analysis of Circumstantial Evidence for Wuhan Labs as the Source of the Coronavirus," p. 4.

243. Ibid. p. 3.

244. Ibid., pp. 3–4.

245. Wade, "The Origin of COVID: Did People or Nature Open Pandora's Box at Wuhan?"

246. Paul Farrell, "Outcry as British Researcher Is Given Another US Grant to Investigate COVID—Despite Fears His Initial Work at Wuhan Lab Triggered Pandemic: Peter Daszak Is Paid $650,000 to Study Bat Coronaviruses—and 'Assess Their Ability to Infect Humans,'" *Daily Mail*, October 3, 2022, https://www.dailymail.co.uk/news/article-11273773/Outcry-British-researcher-given-grant-NIH-investigate-COVID.html (accessed December 20, 2022).

247. Wade, "The Origin of COVID: Did People or Nature Open Pandora's Box at Wuhan?" Remarkably, in 2018, Daszak and his team at EcoHealth Alliance proposed an even bolder project to the Defense Advanced Research Projects Agency (DARPA) for a review by the agency's Biological Technologies Office. The firm was seeking a $14.2 million grant for "Defusing the Threat of Bat-borne Coronaviruses." DARPA rejected the proposal because, among other things, it did not "mention or assess potential risks of Gain of Function (Gof) research," had no "risk mitigation plan," and "hardly addresses or discusses ethical, legal, and social issues." For DARPA's response, see "Rejection of Defuse Project Proposal," Proposal Identifier HR001118S0017-PREEMPT-FP-019, https://assets.ctfassets.net/syq3snmxclc9/5OjsrkkXHfuHps6Lek1MO0/5e7a0d86d5d67e8d153555400d9dcd17/defuse-project-rejection-by-darpa.pdf (accessed December 22, 2022). See also Farrell, "Outcry as British Researcher Is Given Another US Grant to Investigate COVID."

248. See Letter from Lawrence A. Tabak, Principal Deputy Director, National Institutes of Health, to The Honorable James Comer, Ranking Member, Committee on Oversight and Reform, U.S. House of Representatives, October 20, 2021, https://int.nyt.com/data/documenttools/nih-eco-health-alliance-letter/512f5ee70ce9c67c/full.pdf (accessed January 5, 2023). See also Olohan, "10 COVID-19 'Truths' that Weren't True."

249. Press release, "Dr. Paul, Rep. Comer Send Letter to Director of the NIH Requesting Information on the Removal of 'Gain of Function' from the NIH Website," Office of Senator Rand Paul, November 1, 2021, https://www.paul.senate.gov/news/dr-paul-rep-comer-send-letter-director-nih-requesting-information-removal-gain-function-nih (accessed December 19, 2022).

250. See, for example, their 2015 article in Nature Medicine: Vineet D. Menachery, Boyd L. Young Jr, Kari Debbink, Sudhakar Agnihothram, Lisa E. Gralinski, Jessica A. Plante, Rachel L. Graham, Trevor Scobey, Xing-Yi Ge, Eric F. Donaldson, Scott H. Randell, Antonio Lanzavecchia, Wayne A Marasco, Zhengli-Li Shi, and Ralph S. Baric, "A SARS-like Cluster of Circulating Bat Coronaviruses Shows Potential for Human Emergence," *Nature Medicine*, Vol. 21, No. 12 (December 2015), pp. 1508–1513, https://www.nature.com/articles/nm.3985 (accessed December 20, 2022).

251. Wade, "The Origin of COVID: Did People or Nature Open Pandora's Box at Wuhan?"

252. Rich Mendez, "'If Anybody Is Lying Here, Senator, It Is You,' Fauci Tells Sen. Paul in Heated Exchange," CNBC, July 20, 2021, https://www.cnbc.com/2021/07/20/if-anybody-is-lying-here-senator-it-is-you-fauci-tells-sen-paul-in-heated-exchange-at-senate-hearing.html (accessed December 19, 2022).

253. Fred Lucas, "Four Takeaways from Senate Panel's Hearing on Gain-of-Function Research, COVID-19," The Daily Signal, August 3, 2022, https://www.dailysignal.com//print?post_id=930762.
254. Office of the Director of National Intelligence, "Unclassified Summary of Assessment on COVID-19 Origins," p. 1.
255. See Richard Stern, "18 Absurdities of the McConnell–Schumer Omnibus Spending Bill," The Daily Signal, December 20, 2022, https://www.dailysignal.com/2022/12/20/18-absurdities-of-the-mcconnell-schumer-omnibus-spending-bill/.
256. "Remarks by President Biden on Fighting the COVID-19 Pandemic."
257. News release, "FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine.".
258. Greta Massetti, Brendan R. Jackson, John T. Brooks, Cria G. Perrine, Erica Reott, Aron J. Hall, Debra Lubar, Ian T. Williams, Matthew D. Ritchey, PT; Pragna Patel, Leandris C. Liburd, Barbara E. Mahon, "Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems—United States, August 2022," Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report*, Vol. 71, No. 33 (August 11, 2022), p. 1057, https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7133e1-H.pdf (accessed December 26, 2022).
259. Krista Mahr, "New CDC Guidance for Schools Aims for Normalcy," *Politico*, August 11, 2022, https://www.politico.com/news/2022/08/11/cdc-covid-testing-schools-00051209 (accessed December 19, 2022).
260. Silver and Hyman, "COVID-19: A Case Study of Government Failure."
261. Dougherty, "Republicans Need to Investigate the Pandemic Response."

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