

## Written Testimony: Summary of lessons learned and the path forward

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### A. Executive Summary

Pandemic preparedness needs to be integrated into the standards and processes for improving the health of our Nation.

We will be better prepared for the next generation of pandemics if we unify clinical care, public health, and population health. That means combining our responses to existing population health issues – health disparities, obesity, diabetes, and cardiovascular disease and barriers to access – by using data, funding, and science for continuous programmatic improvement in outcomes.

These measures that will require legislative action and targeted funding would significantly improve the population health of the United States and ensure Americans can survive and thrive the current and future pandemics:

- Better real time data, analysis and use of data for decisions.
- Definitive laboratory diagnosis of all viral and respiratory diseases.
- Public health guidance that's transparent about the evidence behind it.
- Accountability for outcomes and impact of the spending of federal resources.
- Clear command and control when in times of crisis.
- Better responsiveness.
- Domestic manufacturing of essential medicines and protective equipment.
- Increased funding around critical knowledge and access gaps and for rural communities and Tribal Nations.
- A robust biotech industry that can rapidly develop new vaccines and viral and fungal treatments.
- A private sector that's all in on pandemic preparedness planning and response.
- Strong bidirectional communications channels between the White House and state and local leaders.

## A roadmap

To be ready for the next pandemic, we need to increase testing access across the country to obtain definitive diagnoses of all viral and bacterial diseases. This means investing in state-of-the-art equipment, trained technicians, and shared laboratory information systems ready to detect new infectious agents.

We must also continuously conduct behavioral research on the uptake of adult vaccines to address the structural and perception issues that limit them and show year-over-year progress.

To address the social determinants of health and the health disparities, we must work through trusted partnerships between community and federal, state, and local governments using real-time data to show improved outcomes and impact year over year, not just once or twice a decade.

We must stop observing the problems and start addressing them, issue by issue and location by location.

We must listen and work together in deep partnership with tribal nations, addressing the paternalistic and culturally insensitive manner of service delivery.

### **The underlying data problem that resulted in undetected spread, poor initial response and continues to cripple full impact**

But 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. These separate and partially overlapping systems often require duplicate data entry and lack sustainability when all the actual electronic versions of the needed data are available and could be easily anatomized and used at the local, state, and federal level to ensure a data-driven response to this and future pandemics.

This is not a resource issue, but a political will issue. No one agency should “own” critical surveillance data, but data should be available to all agencies, state and local governments and the communities.

Incomplete data pose a problem that is being addressed through modeling rather than comprehensive data acquisition and improvement: At issue were decisions CDC has made through the years to construct syndromic based suboptimal surveillance systems built and maintained by the U.S. Centers for Disease Control and Prevention. The CDC’s hospital and emergency room data were primarily modeled from incomplete sentinel reporting sites. Reporting was voluntary and sporadic, though funded with federal dollars. That means there was no continuous accountability around performance. Specific regions in the United States were either overrepresented or underrepresented, with inadequate visibility into all U.S. counties.

- The CDC didn’t want to upgrade or change their approach despite resources in 2020 as they were more committed to the concept and model rather than evolving with the need. Daily hospital admission data weren’t included in their data and the data that were available didn’t specify whether patients had confirmed or suspected COVID-19 — just general COVID. An absolute bed count of available ICU and

regular hospital beds was included, but, again, in a modelled methodology the majority of data missing critical demographics.

- Data are in siloed systems across the CDC without a single common data collection system, resulting in vast inefficiencies and significant duplication across diseases.

The solutions:

- Work with all 6,000 U.S. hospitals to establish routine, regular, and timely reporting that is modular, adaptable, flexible, and electronic, not paper based – reporting that transcends any specific infectious disease but can rapidly build out new data fields within 24-48 hours based on any specific pandemic need.
- Required regular reporting of already-collected codes for specific community-acquired infectious diseases with age bands, race, and ethnicity appropriately blurred at the county level, or combined counties to ensure HIPAA compliance.
- All data, including lab, hospitals, case, mortality, should be integrated at the community level and available internally and externally to government leaders but also the members for the community for empowerment and decision making.
- Use current technology and set up adaptive systems as technology innovates.

### **Definitive laboratory diagnosis**

We should obtain definitive laboratory diagnoses for all viral diseases and all significant respiratory diseases – something we currently don't do.

- Flu is and was tracked and diagnosed by a symptom complex rather than definitive laboratory testing with either nucleic acid testing or antigen testing.
- Many viral respiratory infections, including respiratory syncytial virus (RSV), parainfluenza, and adenovirus, are diagnosed via a process of elimination or assumptions based on the symptom complex, which are overlapping and never could be definitive.
- There was a lack of critical real time sequencing of SARS-CoV-2 and other respiratory viral infectious diseases at a level that is consistent with the depth of the pandemic with real-time data collection, reporting and visible to all Americans.

The solutions:

All respiratory diseases should be definitively diagnosed in the 21st century to drive local testing capacity, routine reporting, and development of enhanced antifungals and antivirals. There should be accountability to Congress, with regular reporting on testing and sequencing completed with full analysis.

- Work with all laboratories certified by CLIA, states, CAP and ISO, for routine anonymized reporting for all community circulating viral diseases
- Require that before doctors can prescribe any antivirals or code for specific respiratory infections for reimbursement, insurance companies, Medicaid, and Medicare should require that patients have a definitive laboratory diagnosis of the viral infection.

- This would incentivize physician's offices, urgent care centers, and all hospitals to have local lab platforms expanding diagnostic capability, thus driving up the number of facilities capable of making these diagnoses and report in a timely manner with inherent surge capacity.
- It would create a baseline of known viral disease so new infectious agents could be easily identified; create the critical laboratory capacity at all levels that would be useful between and for pandemics; and expand access to quality home rapid testing to empower every American with the knowledge they need to protect themselves and their families.

## CDC-specific issues

The COVID-19 pandemic highlighted specific issues with the CDC that still need to be addressed.

Guidance without implementation support and transparency of the underlying supporting data and science creates confusion and is ineffective. CDC personnel needed to be permanently in the field funding and supporting conducting behavioral research into flu vaccine uptake over the past decade to understand adult vaccine uptake by race, ethnicity, age, sex, and geography and develop clear strategies to increase vaccine uptake and show their efficacy. If this had occurred vaccine hesitancy could have been addressed year over year identifying the barriers to uptake and addressing them one by one county by county community by community.

For example, when the CDC recommended cloth masks in April 2020 – stating it was solely to ensure infected individuals weren't spreading the virus – it led to significant confusion across the country. Many Americans couldn't understand that cloth fabric only blocked droplets in one direction. Despite repeated requests for the CDC to conduct or commission these simple experiments, the CDC waited until Japan did the study in the fall of 2020 to brief on the bidirectional protection of cloth masks.

Additionally, continuous behavioral implementation research to improve and evolve messaging on vaccines should have been available to inform the initial vaccination strategies for counties with low vaccination rates.

The solutions:

The CDC must have mechanisms or internal capacity to investigate and provide the proof (the evidence base) of all the elements included in guidance in real time.

All guidance must include all the data, data analysis, and complete evidence base behind it. The CDC must ensure all guidance is accompanied by or linked to the evidence base or clearly state that the evidence base is being developed and guidance is perceptual rather than data driven.

The CDC or the National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA) must engage in all aspects of timely implementation science in partnership with states to ensure guidance is optimized for execution and has the mechanisms to evaluate both outcomes and the impacts of guidance and state-level public health funding. All Federally funded programs need continuous data collection for continuous program improvements defining what works and doesn't work and evolve programming.

CDC must support states and localities with a permanent staffing presence: 90%-95% of CDC domestic staff are in Atlanta and not in the field where the information dissemination and program implementation is occurring in real time. Public health involves the public, and the CDC's customers are the states and the Americans in those states. The CDC must evolve into a decentralized in-state presence with continuous feedback loops between the in-state personnel and headquarters to ensure timely development and modification of guidance based on the reality on the ground.

CDC must increase the speed of published data to support the evolution of policies in the Morbidity and Mortality Weekly Report (MMWR). Two examples:

- Information on the spread of SARS-CoV-2 in Marin County, California, schools was critical for school boards across the country for decision making, but the incident that occurred in May 2021 wasn't published until the end of August 2021, long after the Southern schools had made decisions and the students were fully back in school.
- The deaths from the Delta and Omicron variant surges and vaccinations that occurred in December 2021 and January and February 2022 weren't reported in real time when Americans with the warning could have enhanced protections for their loved ones. The primary analysis was done by the *Washington Post*, not the CDC, well after the surge was over, at the end of April. Vaccines are an important prevention tool, but they aren't 100%, and they aren't the only tool, so Americans should have been warned about susceptibility and the risk of severe disease despite vaccination so they could have taken precautions to protect their vulnerable family members.

## Accountability

There is no accountability connecting federal dollars spent to policies, outcomes, and impacts at the federal or state level. Investment and funding also aren't based on performance and health improvements.

- The CDC doesn't have specific annual performance milestones for itself or the states that receive grant monies. There are no annual granular county- and state-level assessments of the health of the country, particularly among major public health issues facing America.
- The CDC frequently follows a three- to five-year timeframe for reporting and publication that doesn't align with annual funding allocations to ensure continuous public health improvement.

The solutions:

CDC must develop timely reporting, implementation results, and outcomes linked to the major public health issues of the country that are translated down to each and every state. This should include timely data and reporting to ensure continuous program improvement for obesity, hypertension, diabetes mellitus, and community-acquired infections in partnership with states and territories, tribal nations, and communities to ensure culturally appropriate and highly impactful programming for dollars invested that looks at incremental improvements through annual reporting and trend lines.

## Command and control in a pandemic

The addition of Office of the Assistant Secretary for Preparedness & Response (ASPR) to the Department of Health and Human Services (HHS) has caused confusion about the division of labor and roles and responsibilities. There needs to be clarity on the specific roles of the CDC and the ASPR. This separation of responsibilities between ASPR and CDC has caused more coordination work and some confusion for the states.

### Increased responsiveness

We need to do a deep dive at the Food and Drug Administration (FDA) and the NIH into what actually increased responsiveness and what held us back from a rapid response to the pandemic.

#### Testing

**Good:** approval of laboratory designed assays (LDA), emergency use authorization (EUA)

**Bad:** Limiting EUA approvals and therefore testing to symptomatic disease until June 2021 inhibited the aggressive asymptomatic testing needed to prevent community spread and willingness to try new ways of reporting from the new devices and tests.

#### Treatment:

**Good :** Expanded compassion use, rapid review, and EUA further streamlined regular processes.

**Needs improvement :** Lack of pre-institutional review board (IRB) approved generic protocols for early stage hospitalized and late-stage patients. Lack of access to these critical study agents with controlled trials at all hospitals across the United States, including community hospitals, rather than just the currently established research hospitals. There should have been a national clinical research organizations CRO that would surge to states and territories when we first saw an increase in test positivity to ensure all hospitals had access to controlled trial agents for immediate testing, and we would have gotten the answers in days to weeks – not months later. This would have also facilitated the objective trial of agents that some proposed, from hydroxychloroquine to ivermectin, in the regions where they were interested in studying efficacy. Community hospitals and rural hospitals must be eligible for research activities. When research is done locally and community advisory boards are engaged there is a dramatic increase in community knowledge and trust in the research and results.

#### Vaccine development:

**Good:** the rapid movement from Phase I to Phase III trials as warranted, adding community-based research sites, parallel (prior to full efficacy) good manufacturing process (GMP) production to ensure immediate access to new and effective antivirals, additional therapeutics, and next generation vaccines.

**Needs improvement:** Inadequate education during the summer of 2020 to continually update the American people on the vaccines being developed with town halls, children's books for all households, a chat line to answer questions about the science proactively, education at all levels from K-12, higher education, adults through community centers and churches.

**We still need next generation COVID vaccines with enhanced vaccine protection and durability against infection and disease** — increased vaccine induced durability of protection against infection; potential for cross variant vaccine boosting and intranasal vaccines for durable IgA mucosal immunity.

**Bring essential medicines and PPE manufacturing back to the United States.**

The United States ran out of not only protective equipment but almost ran out of essential medication, devices, and diagnostic. This is an emergency and needs to be addressed.

### **Critical knowledge gaps**

Require NIH, CDC, and/or HRSA funding for behavioral science and implementation science around critical knowledge gaps.

### **Rural communities**

Require 20% of all NIH, HRSA, Substance Abuse and Mental Health Services Administration (SAMHSA), and CDC research funds go to biomedical, behavioral and implementation research in rural communities. That's equivalent to the number of Americans that reside in rural America.

### **Biotech**

Ensure a robust biotech industry for rapid development of new vaccines and viral and fungal treatments.

### **Private sector**

Ensure the private sector is at the table for all pandemic preparedness planning and response so that they can move faster and take risks the federal/state governments won't.

### **Communication**

Ensure the state and local leaders are in constant communication with the White House and federal agencies so that their lesson learned can be immediately highlighted to all the states. Solutions to many of these issues exist at the state level, and we all need to learn from them.

## **B. Overview**

**What went right: What went wrong: What we need to do to ensure every American survives COVID and every American can thrive despite COVID.**

**Survive:** treat every hospitalization and death from COVID as a program implementation failure and fill the gaps and address knowledge and implementation barriers.

**Thrive:** define the impact of vaccines and boosters on the incidence and severity of long COVID; the adult and child impact of COVID on the brain and cardiovascular system and glucose regulation so parents and families can make decisions on vaccination and boosting and critically mitigating infection prevention modalities.

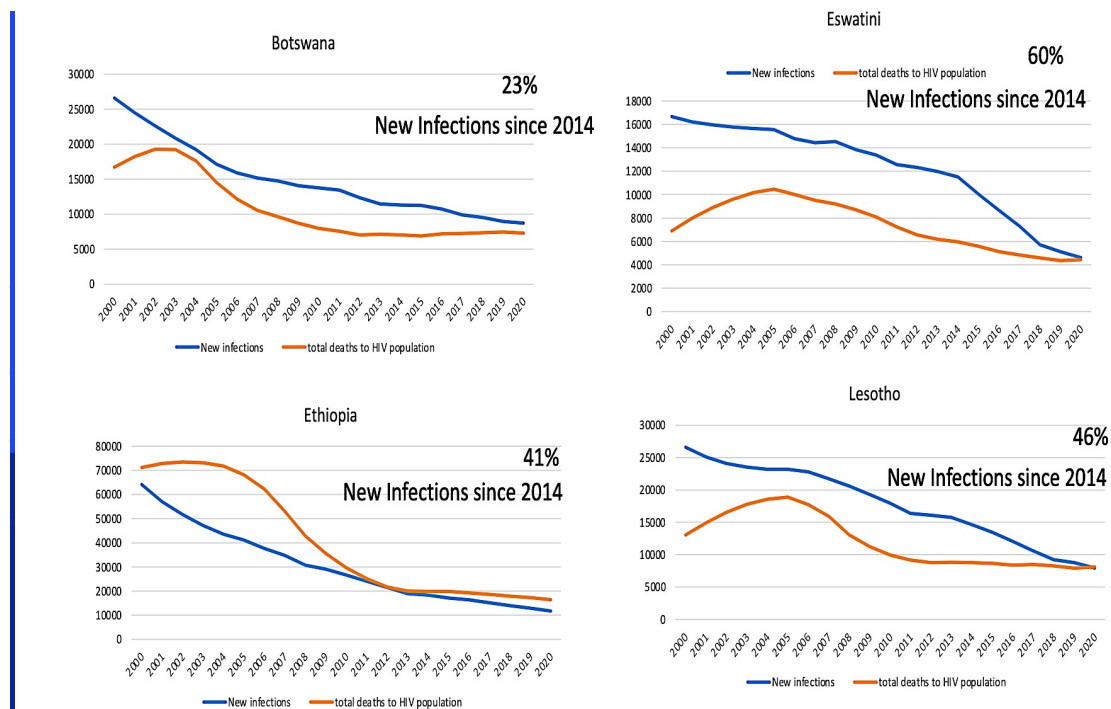
Building on what we know works from battling pandemics around the globe:

- Pandemics are always political
- New infectious pathogens always induce fear and desperation — leading to misinformation, stigma, and sensational but not effective therapies
- Effective pandemic response always requires local community engagement, not top-down paternalism
- Peer outreach is critical for communication and implementation

Americans have worked internationally for more than two decades effectively battling pandemics around the globe. Over the past two decades we have learned what works and what doesn't work on the ground by working with local partners implementing programs community by community, county by county, and country by country. We developed a clear effective roadmap to effective pandemic response – it started with continuous, real-time comprehensive data acquisition and analysis; using those analyses in real time to dialogue with communities about the specific risk and mitigation and ensuring access to the needed tools to prevent infection among the marginalized and the vulnerable, prevent hospitalizations, and prevent deaths. There are clear parallels that can be learned from these successes and applied to prevent infections in vulnerable Americans today, prevent hospitalization tomorrow, and prevent COVID deaths, and prevent the long-term consequences of COVID infections. We know it takes more than simply making concepts, guidance, and tools available. It takes constant program implementation improvements at the community level with peer-to-peer outreach for knowledge empowerment and addressing structural and access barriers.

The United States has been effectively battling pandemics across the globe for more than two decades through the Presidential Initiatives in HIV and Malaria and with long term bipartisan Congressional support and funding. From this global work, we have learned the critical lessons needed to control pandemics and have effectively implemented global programs. One program, The President's Emergency Plan for AIDS Relief (PEPFAR), dramatically lowered first the deaths from HIV and then new infections of HIV, changing the very course of the HIV pandemic country by country in Sub-Saharan Africa, where between 3-50 percent of all adults had acquired HIV. We learned that all pandemics are political, accompanied by continual misinformation about preventing, treating, and "curing" the disease and a consequent stigmatization of those infected and their families. We learned who was easy to reach and who wasn't. We learned that to reach the vulnerable and marginalized we had to constantly use data to "see" who we were missing and develop specific innovations and continuously change programming to improve outcomes. We learned that progress was directly dependent on putting the client, the patient, the person we were serving at the center. We learned we had to listen and partner with local leaders— government, faith, and community. We learned that every success exposed a new challenge. We learned that, with compressive and granular data for age, sex, and geography, combined with passion and commitment, each barrier, each obstacle could be overcome. We learned those hard lessons community by community and dramatically increased our positive outcomes and impact without new monies in a time of a flat budget. We learned to use data in real time to change the course of the HIV pandemic in many of the hardest hit countries.





We learned you need to move beyond the visible and the easy to reach to the truly at-risk and hard-to-reach populations and the vulnerable. We used age, sex, and deep granular data to understand who we were missing from needed prevention and treatment services. Using data, community-based surveys, geolocation coordinates, and, critically, implementation science, we identified who was at greatest risk and not being reached, identified the issues and barriers that needed to be addressed – some with policy changes, some with peer outreach, and we used data to ensure the interventions were working by continually measuring outcomes. Were we reaching young women, men, and key populations that were at increased risk of acquiring HIV? Were we reaching men, especially young men, who often aren't engaged with the health system? This work and this progress required getting on the ground and into the communities, battling misinformation with clear data and meeting people where they were with the empowering knowledge and effective tools they needed for decision-making person by person, community by community, county by county, and country by country.

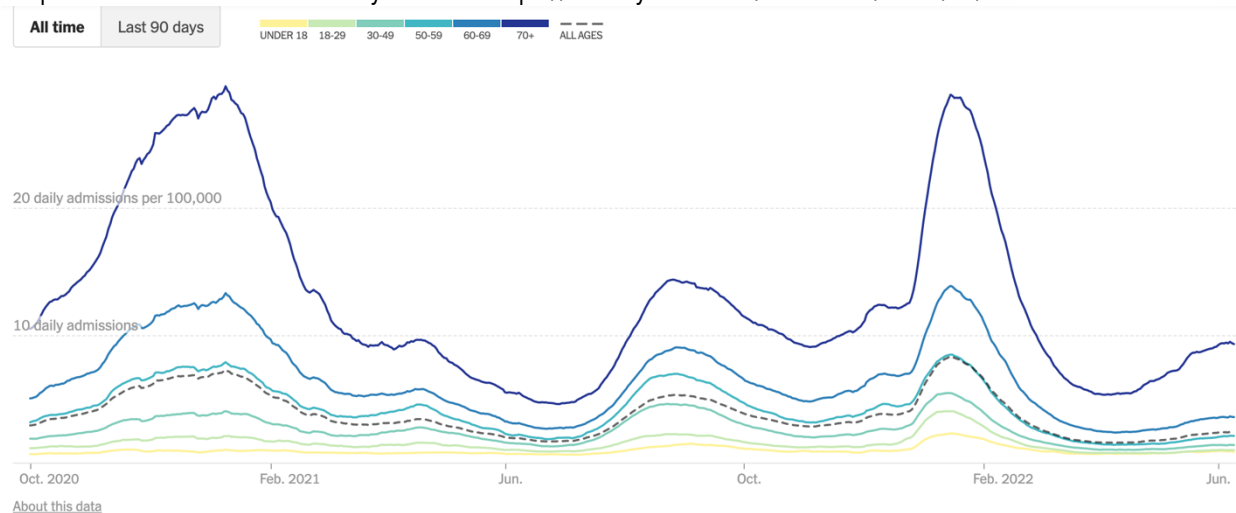
One size never fits all, and generic communication and generic guidance didn't fit at all. Generic guidance creates divides and the sense that “big government” doesn't understand or care to comprehend people's reality on the ground. Interventions that worked in one place with one age group have to be adapted and tailored to another, with constant attention to outcomes and impacts. The “secret sauce” was community-member input and intentional and funded peer outreach, input from those most at risk and the advocates and community and faith-based organizations that were embedded in their communities. Using these lessons, we tackled HIV in the highest-prevalence pandemic areas around the globe and we were successful. These essential lessons can be brought to the USA.

It is very clear today what has worked in the COVID response, what hasn't, and what gaps still exist today in the pandemic response. Rather than funding future generic pandemic preparedness, a laser focus on this current pandemic response – will create the systems – the data systems, the next-generation healthcare systems for rural and marginalized communities and Tribal Nations, the effective development and deployment of the needed prevention and treatment tools, and the peer outreach and communication to battle misinformation and ensure full

implementation of programs— to ensure all Americans can survive and, ultimately, thrive. Many will chalk our failure up to years of “neglect,” in terms of resources and personnel. It is not that simple — much of the blame lies with the choices made by Federal Departments and Agencies over the past two decades. Moving forward, we should be ensuring our Federal dollars are laser-focused, accountable to the American people through clear improvements in evidence-based outcomes and impact. The answer is about integrating the response creating a unified population health system, not creating parallel public-health and clinical-care systems. It is about needed reforms we must implement now, before the next unknown pathogen strikes. It is about effectiveness— measuring it, implementing it, and holding people and institutions accountable for it.

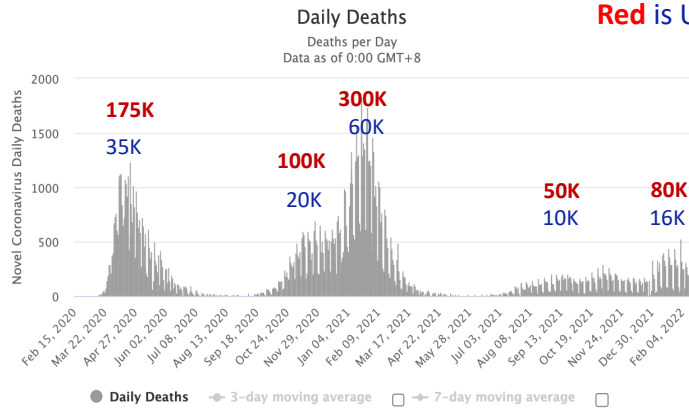
### C. What do we know about the virus, SARS-CoV2, in the United States, in broad brush strokes?

**We know who remains the most susceptible to severe disease, hospitalization, and deaths despite all of our improvements.** The most vulnerable were those over 70 years old. That remains a constant: the highest rate of hospitalization is in those over 70 years old. <https://www.nytimes.com/interactive/2021/us/covid-cases.html>



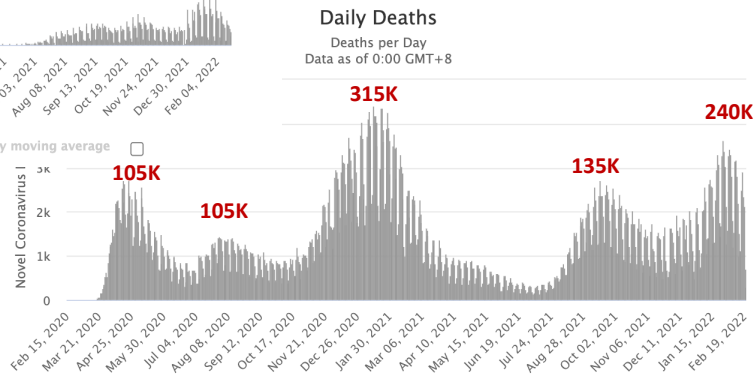
While other high-income countries have made significant strides in decreasing the deaths from COVID, especially among their vulnerable citizens, the United States continues to have high fatalities. In the last 11 months, the United Kingdom (UK) dramatically decreased its fatalities during the Delta and Omicron and the subvariant Omicron surges while the USA numbers have remained stubbornly highly. From 1 July 2021 to 4 June 2022, the USA experienced **409,380** recorded COVID deaths; in the same time period, the UK experienced 47,910 recorded COVID deaths. When the UK numbers are corrected for population, this would be the equivalent of **233,875** deaths in the United States population — over **40% less** than the United States actually experienced. (<https://www.worldometers.info/coronavirus/>)

## Daily New Deaths in the United Kingdom



**Blue** are the actual number of deaths in the UK  
**Red** is UK corrected to US population size

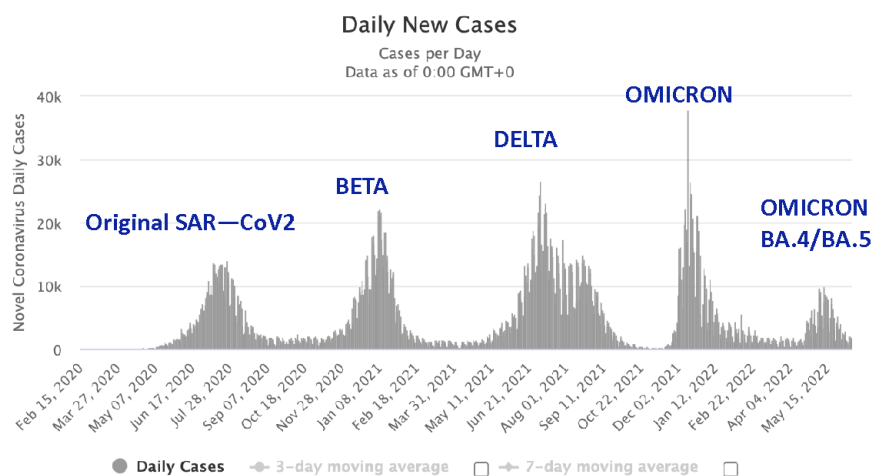
## United States



The UK is different in six areas: better real-time collection of data; better use of these data, with clear, consistent communication with the public and transparent access to accurate, empowering information; better primary vaccination and boosting rates; better access to free tests in both urban and rural areas; and access to quality health care in both urban and rural areas.

Surges and the regional aspects to surges are predictable as both natural immunity and vaccine-induced immunity wanes and reinfection occurs. This has been evident since December 2020, based on global and local data. Each surge will lead to improving partial immunity, but will not protect all. <https://www.worldometers.info/coronavirus/>

## Daily New Cases in South Africa



These surges in community transmissions will continue without a more durable vaccine, but we can effectively use the months between the surges to prepare using the last surge data to improve our COVID responses – by identifying and filling gaps and addressing disparities.

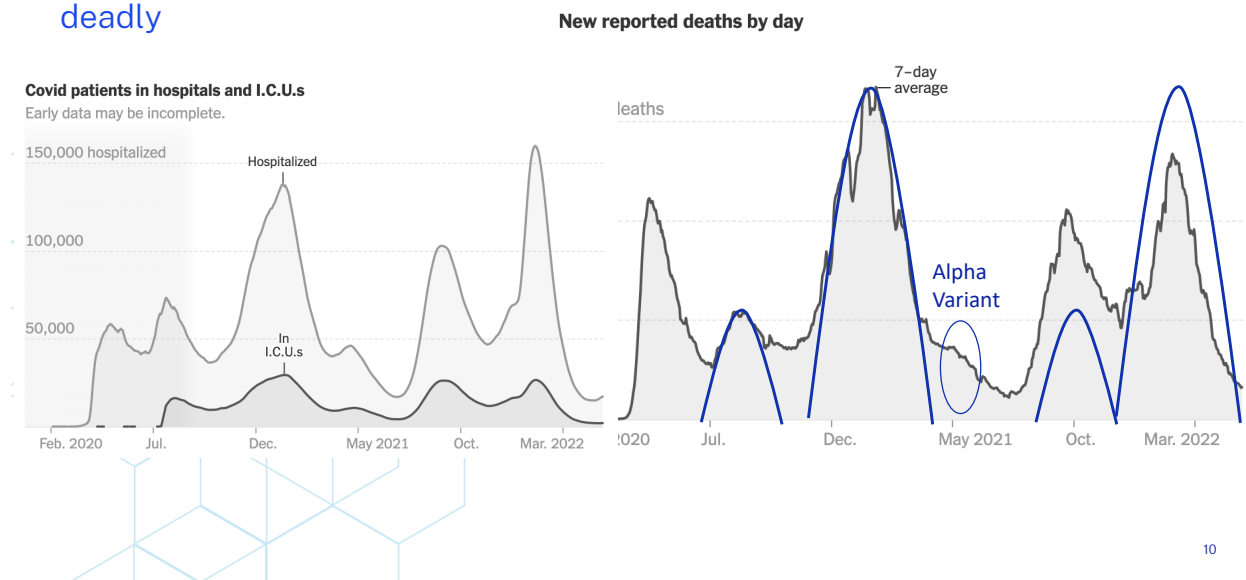
100 % of the European and the majority of global variants that have caused a surge in Europe have caused a surge here. When we see it there, we should prepare here – we must not wait.

**COVID variants were and are predictable** – all RNA viruses with this level of replication develop mutations in critical immune and antiviral epitopes of the virus. We need constantly to be investing in discovering and producing the next generation of vaccines, monoclonal antibodies, and combination antivirals to address the viral resistance that we know will come.

**Misinformation continues** – COVID was not like the “flu,” and Delta and Omicron were not “mild” in the United States. Terms like this imply the majority of susceptible Americans won’t die.

## Hospitalizations and death with each surge

Summer surge of 2021 was 40% more deadly and winter surge was 30% less deadly



Although we have no true idea how many Americans die from influenza each year, deaths from this SARS-CoV2 virus have never declined to even close to a flu season of fatalities. Misinformation festers and continues when the Federal government doesn’t present all the actual data, in real time, and when the science is NOT done but assumed, based on inaccurate models.

### D. What went right at the Federal, State, Local and Community level in 2020

- Development of comprehensive data streams to define the depth and breadth of community spread of the virus, and to drive equitable access to effective prevention and treatment tools across the country. (This should not have been needed, because the United States has the capacity today to create comprehensive fully electronic, real-time data streams).
- Long-term funding of the National Institutes of Health (NIH) and research on protein stabilization and antigen – antibody interactions that show the need for basic immunologic research independent of the specific pathogen.
- The process for granting Emergency-Use Authorizations (EUAs) at the Food and Drug Administration (FDA) – a new way to accelerate these reviews and the use of tools – a road map for a new, more effective approach to approving medical devices, diagnostics, therapies, and vaccines.

- Operation Warp Speed (OWS) – A whole-of-government response in partnership with the private sector, with the use of the Defense Production Act (DPA) to ensure the procurement of needed raw materials and equipment.
- Comprehensive partnership with the private sector to accelerate the production of tests, PPE, treatments, and vaccines.
- Increased use of (and insurance coverage of) telehealth and the required broadband expansion.
- Increased domestic production of N95 masks – a model for “reshoring” the manufacturing of our essential medicines, devices, and vaccines.
- Continuous program improvement based on ground-level experience, which started strong but has not been effectively continued.
- Continuous communication with local authorities and communities to enable the constant improvement of the Federal response, which also started strong but has not continued to the same degree.
- On-the-ground experience and “eyes on the ground” make a big difference.
- The active engagement of the private sector was key to our successes in 2020, from the development of COVID tests for use in hospitals to homes, the manufacturing of personal protective equipment (PPE) in the USA, therapeutics, vaccines, and the critical data stream.

What is needed now is to build on these lessons effectively. A laser focus on local implementation of all of the above at the State and local level is needed. Effective implementation requires knowledge of, and working daily with, State and local officials and ALL communities. This is what I learned from battling pandemics globally, and it was the reason we had weekly calls with governors and traveled to the States - not to talk, but to listen. We listened to Tribal Nations, communities, hospital personnel, and school officials – in dialogue. As a result, we were learning all the time and constantly changing our Federal support to meet the local needs. Through the weekly calls with governors and the constant visits, we were able to bring those implementation breakthroughs found to work in one area and take them across the country for immediate adaptation. We were learning from one another what was actually working on the ground – not following theories and generic guidance but specific and impactful interventions. We learned from hospitals in Florida about innovations in the rapid movement of stable patients to their homes, which became “hospitals without walls” because of unprecedented active monitoring, and we helped ensure the needed compensation for this program from the Center for Medicare and Medicaid Services (CMS). We learned about a comprehensive hospital dashboard all the area hospitals in Chicago were using to ensure that every patient had access to the technology and care that they needed – the hospitals abandoned competition for the good of every resident in the area. We learned the primary area of transmission from our astute Mayors of Miami and Miami-Dade in the Summer of 2020, which allowed us to alert the country that transmissions were occurring primarily in gatherings of friends and family, not in public places. We learned from universities like Clemson the importance of wastewater-monitoring, and from the Universities of Connecticut and South Carolina and Louisiana State University the invaluable role of rapid testing to identify asymptomatic students in prevent community spread. We learned about expanded mental health programs, the importance of keeping schools open, and the critical role of peer student support. We saw innovative support programs across colleges and universities that were creating a road map for effective whole-of-student approach. I am grateful to the University of New Hampshire, Plymouth State University, Boston University, and others for their continued weekly testing, as they were the same early group to demonstrate clearly in the Fall of 2021 that vaccines were not preventing infections even just two to three months after full vaccination. We learned from governors in Arizona, Texas, New Mexico, Louisiana, Mississippi, Alabama, and Florida about the data-driven adaptive mitigation they were using to decrease community spread while opening retail and outdoor dining and lifting other restrictions based on real-time numbers. We saw data-driven decision

making through the eyes of Tribal Chairmen, university presidents, governors, and mayors. We witnessed over-mitigation and under-mitigation. We saw that primary and secondary schools could open safely, and that outdoor dining was effective, yet not every State was willing to learn those lessons if they came from governors of the opposite party. On the other hand, we saw Democratic governors working effectively with Republican legislatures; we saw students working together to support each other, talk about mental health issues and their unique needs, and find solutions, from food banks to constant check-ins. I saw geriatric nurse assistants work around the clock to serve our elders in long-term care and step up lessons learned in real time to save lives.

We saw private-sector suppliers, from McKesson to Cardinal Health to Henry Schein, use our data to drive supplies, rather than profit margins. Our meeting on 4 March 2020 at which we requested diagnostic companies to supply PCR diagnostics and work on antigen tests made these tools available within weeks, not months. I saw the private sector work around the clock in a unique partnership with the Federal Government to bring PPE, high-throughput machines to enable home testing, new therapeutics, and vaccines to the American people in record time. We have many effective tools and the road map of what it takes to succeed, but we are still not ensuring access to real-time data and information to the American people so they can use the tools effectively. We are still not effectively communicating with ALL the American people and empowering them with the information they need to save themselves and their families; we are still not using data, not only to report on the gaps but to fix them and concentrate resources where they are needed the most.

Additional tools still are needed: improvements in the durability of vaccine protection; next-generation vaccines to ensure we are one step ahead of the virus, not always one step behind; the continued rapid development of next-generation antivirals to ensure we are ready for resistance; the use of data in real time; knowledge-sharing across communities and States; focused implementation science to improve our programming continuously.

#### **E. What went wrong in 2020 and what continues until today**

As I said 15 months ago, 30 to 40 percent of the deaths in 2020 were avoidable, and this holds true for 2021 and 2022 as well.

Several problems that contributed to these unfortunate outcomes deserve sustained attention from Congress and policy-makers”.

##### **Continued Gaps in Data:**

- Pandemic surveillance based on symptoms, not definitive laboratory diagnosis;
- Pandemic responses based on partial information or incomplete;
- Lack of comprehensive data streams to understand the depth and breadth of community spread;
- Inadequate geographic representation to ensure representative rural and urban sampling; and
- Lack of the needed science, from implementation science to behavioral science; and
- Lack of consistent engagement with ALL communities

When I arrived at the White House, there were no comprehensive data streams on the pandemic. We had to come to you in Congress to legislate a requirement for laboratory reporting of all PCR COVID tests, which you did— a critical step. But what about the rest of the needed pandemic data? Over three months I kept asking the Centers for Disease Control (CDC) to collect definitive and presumptive new COVID admissions from all hospitals, along with ensuring 100-percent reporting of inpatient COVID cases and those in intensive-care units (ICUs). With the Remdesivir critical distribution pending, I had to go to the Vice President and ask him to task the U.S. Department of Health and Human Services (HHS) to collect these data. He did, and HHS did — we never “took” hospital reporting

data from the CDC — it refused to collect them. CDC also refused to collect information on PPE stock levels from hospitals so we could direct supplies to the facilities with clear, demonstrated needs.

I applaud the new research into long COVID, but this is late. We should know today whether vaccination and boosters protect against long COVID across age groups, protect against the inflammatory syndromes, protect against the late cardiovascular findings, the increased incidence of diabetes and the late brain findings.

Today, we are still not using data in real time strategically and equitably to save Americans— in time to really change the outcomes and impact of COVID-19. We are not addressing the gaps and the barriers that leave Americans vulnerable to severe COVID and death. We still are not using data in real time to decrease the hospitalizations and deaths that remain elevated in specific counties. We are not using data in real time to empower Americans with the information they need to protect themselves and their families.

#### **Continued Muddled, Confusing, and Inconsistent Communication:**

Beginning in 2020, consistent and factual communication from the President to the country was lacking. Beginning in 2021, the communication from the President was more consistent and fact-based, but Federal Agencies' communications were not: Agencies provided muddled and contradicting information — or partial information that implied we knew something we didn't, which they later had to correct, which accelerated the loss of respect and trust in the Federal Government. Lack of consistent communication on the state of the pandemic — overstating progress, based on hope, not data implying the next surge would be better, smaller, milder; and not preparing adequately for the next predictable deadly surge. Poor communication of the evidence used to support the guidance being issued by Federal agencies. Poor communication about the effectiveness of COVID vaccines — the difference between preventing *infection* and preventing *severe disease* and the rapid degree with which both wane after vaccination and booster. Finally, basing decisions about the pandemic response on polling, not data and science.

#### **Lack of Investment in the Right Science — Behavioral Research and Implementation Science**

We are not conducting the research — the behavioral science and implementation science— needed to change individual outcomes and the overall impact of COVID-19 in the United States. We remain mired in magical thinking that this surge will be different. We go on the airways and support media statements that this time we will have cases without hospitalizations or deaths. And, yes, while improvements in the fatality rates in urban areas have occurred, they are not uniform, and they are glaringly absent in rural areas. Access to life-saving testing and treatment have been addressed in urban areas. But misinformation needs to always be combated locally, resident by resident; nurses and family doctors play a key role, but not where primary care is scarce and people rely on emergency rooms. There is no one to battle misinformation in rural areas and to ensure the implementation lifesaving programs.

#### **Poor or Inadequate Implementation of the Pandemic Response: Slogans Do Not Make a Program**

Persistent magical thinking, rather than data-driven decision-making. Unclear command and control, accountability, and on-the-ground pandemic experience at Federal Agencies. No long-term State experience among CDC staff, and Few CDC experts embedded in State Health Departments. Inability of the CDC to support practical programmatic implementation. Lack of behavioral research into the structural drivers of vaccine hesitancy among adult Americans: No understanding of the issues with access to influenza vaccine (Why did we just chart the low uptake in rural areas and among specific race and ethnicity groups and not do the hard work to fix it by doing behavioral research on why these gaps exist? Are they structural lack of physical access, or related to a lack of clear information? Who are the trusted voices, trusted platforms in these areas?) Unwillingness to learn across political parties and counties;

Lack of access to health care in rural America and lack of coordination between rural health facilities. Lack of culturally appropriate support to Tribal Nations.

#### **F. Critical gaps in our rural health system that must be addressed**

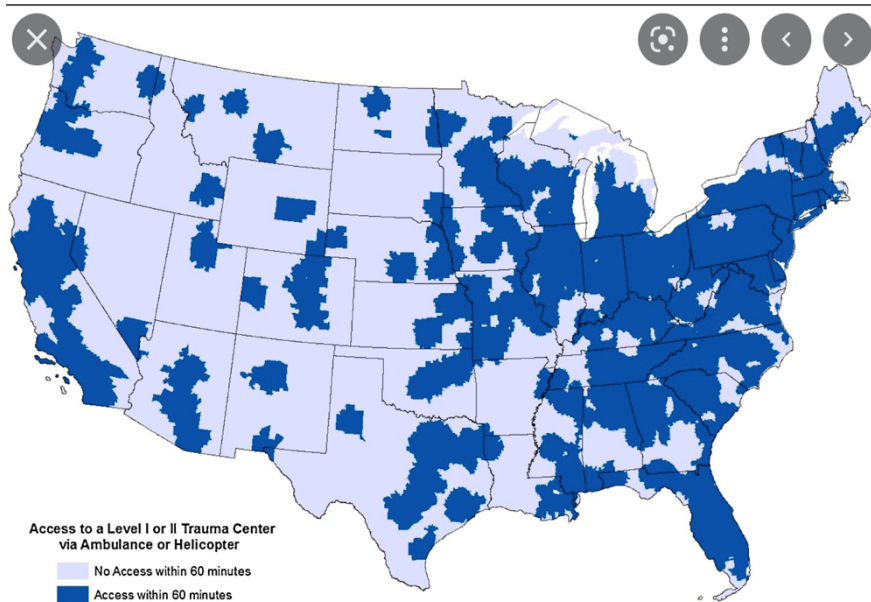
We continue to make excuses why one million Americans have died, more than 175,000 of whom we lost in just the last five months from January to May 2022. This is a failure. If we do not fix this failure, we will remain vulnerable to this virus and future pandemics. This is not about how people voted, but access to health care and information in our rural America. All pandemics are riddled with misinformation, and hucksters who take advantage of fear and confusion to promise miracles through unproven treatments. Remember during the early days of the HIV pandemic when people claimed infection could be prevented by showering, HIV could be cured by sleeping with a virgin, and herbal medicines were both a preventative and a treatment? We tackle these rumors and falsehoods with clear information and transparent data down at the community level, not from a podium or a computer in Atlanta, but in town halls, community centers, churches, and community-based organizations all across the country.

Yes, if you are privileged and live in an urban setting you can get high-quality masks, free tests, vaccines, and rapid access to antivirals, including Paxlovid. If you live in urban America, most likely your survival rates with COVID have remarkably improved. You and your family will not only survive, but thrive.

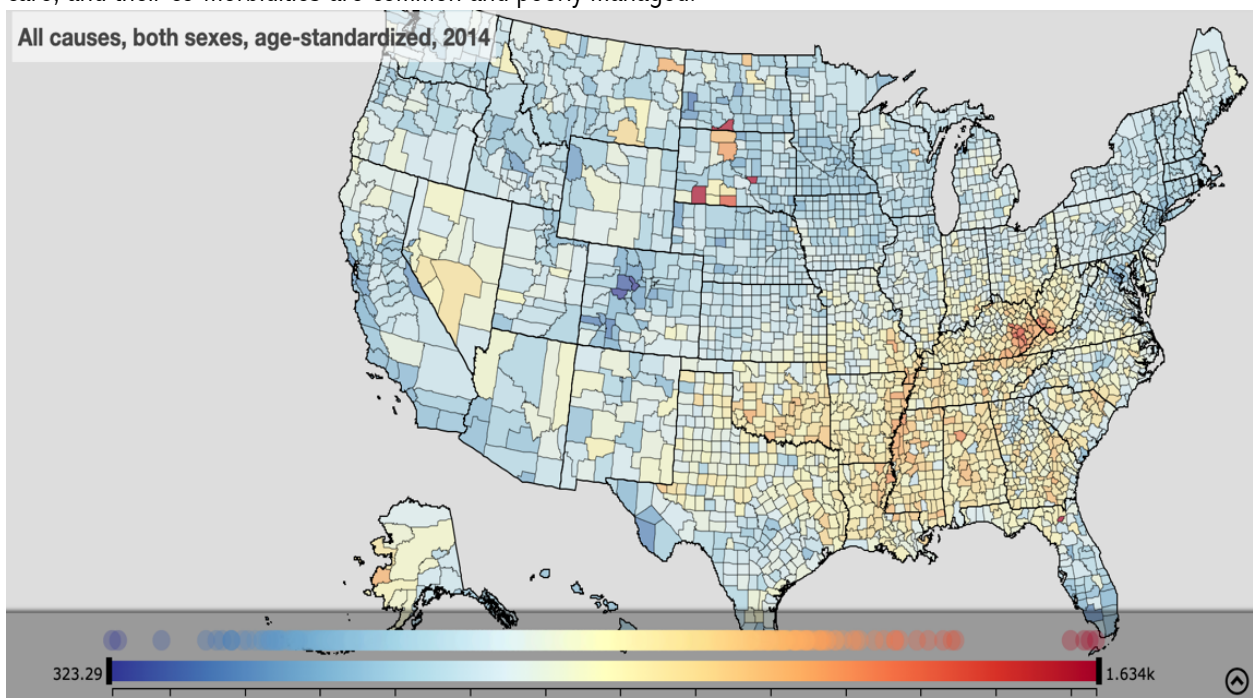
But this is not true for Americans in rural areas, where health care access has become more and more difficult as hospital systems have consolidated and local community hospitals have closed or been severely compromised. Let me give you an example. Being a Level 1 trauma center means a facility has technology and personnel to meet the highest level of trauma needs in the community. The designation is also an indication of NIH research funding and sophisticated medical equipment and medical subspecialists. These hospitals are where innovative research is done and where the life-saving critical severe COVID treatments are available including extracorporeal membrane oxygenation (ECMO) machines are. The New York City area has 22 such centers, Chicago 11, and Mississippi one. Indeed, as shown below, access to Level 1 trauma centers (or even the lower Level 2) by ambulance or helicopter within 60 minutes is available in urban areas, but not rural America. This is what is creating two realities in America: Geographic areas where you can and cannot access innovative healthcare.

This same pattern plays out in the Federal Government's research investments. Urban area hospitals receive NIH research dollars, not community hospitals where we need data and research on new implementation and behavioral science to understand and improve access in rural America, to understand behavioral choices and ensure access to critical prevention and treatment tools.





Rural Americans have been dying at higher rates for years – long before the COVID 19 pandemic. Rural America is older and often with more comorbidities. Look at the map below of all-cause fatalities from 2014: Americans were dying more frequently, even when matched for age, across the South, the rural Heartland, and up through Appalachia. This the reality in which millions of our fellow citizens live: they have less access to preventive health care, and their co-morbidities are common and poorly managed.



These data from 2014— all-cause mortality – don't they remind you of the graphics today of COVID-19 deaths in red counties? Why did we think COVID would be different? Did we develop Federal programs to change the underlying situation? Did we shift resources to better our chances of improving outcomes? Did we work to increase access to health care? Did we do the behavioral research to understand the drivers of people's health decisions? Or did we

just collect the data, observe the outcome of higher deaths, and simply write another article for publication? There is no one to sit with the residents and answer their questions and address their concerns. They were abandoned years ago — all of this was seen, recorded, analyzed, but not addressed. It doesn't help to have health insurance if there are no providers.

Some in the media and some public health officials continue to marginalize and stigmatize entire regions and populations without exploring the root causes and fixing them. Why do we keep talking about the “Fall and winter” surges and ignore the deadly Summer surges that killed 100,000 Americans in 2020 and 135,000 more in 2021? Why haven't we heavily invested in getting information and rural specific data to increase vaccine uptake? Why haven't we gotten on the ground and figured out other delivery and implementation options for rural areas? We know who is at the greatest risk — it's still Americans over 70. Why hasn't the Federal Government shipped 20 tests to every Medicare recipient with instructions on when to test proactively twice weekly prior to symptoms during a surge in their geographic area and open a hotline for direct telemedicine so that immediately on testing positive a senior can be overnighted or rapidly pick up from a pharmacy paxlovid?

This is how you ensure rural Americans survive. You don't do it by putting up a map and saying, “It's because they voted for Trump.” This is on us — all of us on public health, all of us in positions of power, voice and representation. We are not serving all Americans with the lifesaving actions and COVID tools we have today.

Critical changes are needed now in our pandemic preparedness and response. For decades the domestic side of the CDC used pandemic-preparedness monies to strengthen public health laboratories and develop sophisticated modeling to use partial data from less than 40 percent of clinical sites and less than 10 percent of the geography to predict and see deadly pandemics coming. CDC based its entire pandemic-preparedness plan on isolating and quarantining people because of their symptoms, not definitive laboratory diagnosis. Modelers believed they could see community spread through the eyes of those with symptoms. There was no planning for a primarily silent or asymptomatic-spreading virus that could only be seen early through testing. This left our country vulnerable.

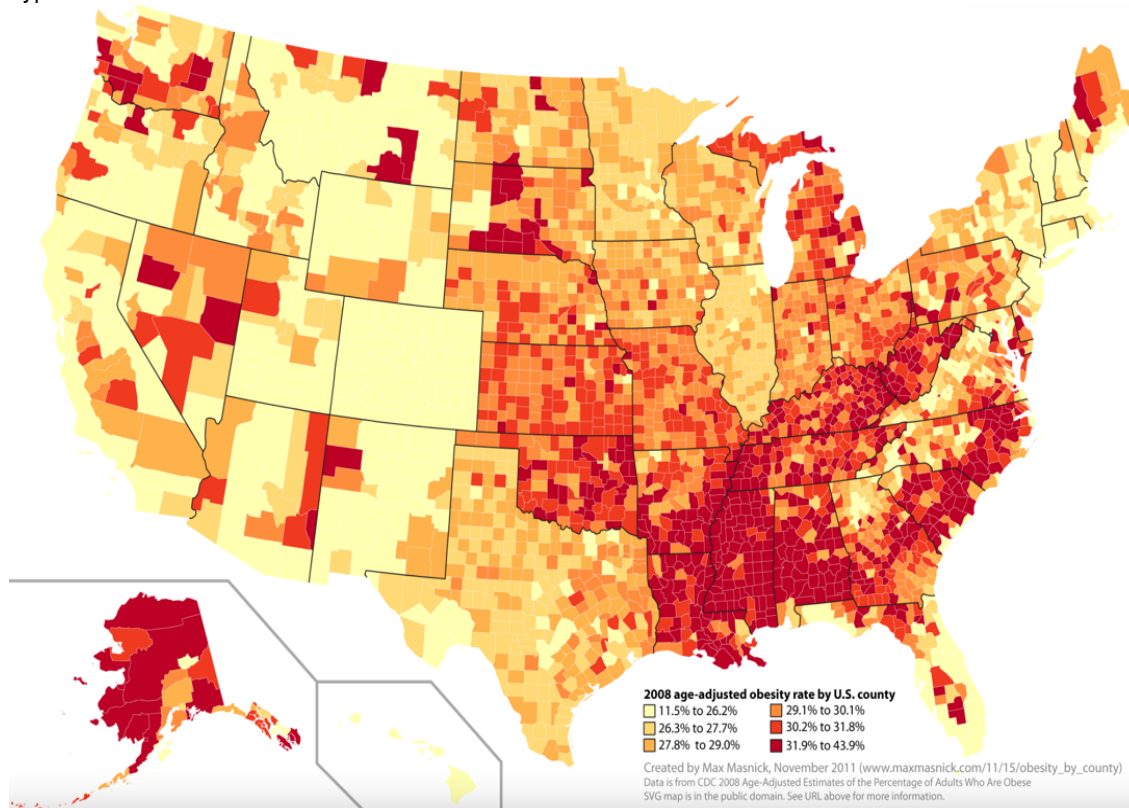
In comparison, around the globe in battling the pandemics of HIV, TB, and malaria we had moved to definitive diagnosis of these community infectious diseases more than a decade ago. No matter how rural a community is or how far down the end of the road, we support laboratory information systems so that new diagnoses can be visible in real time. With U.S. taxpayer dollars, we created physical infrastructure, developed health systems, and trained the personnel to man them. And we changed the course of three pandemics.

Yet here in the USA we remained mired in 20<sup>th</sup> century technology and old ideas and old thinking. We perfected models rather than building the data infrastructure that would have saved lives in 2020.

I hear many saying we have neglected to invest in public health, but the hard truth is that more money doing more of what precipitated and facilitated our poor response is not the answer. The issue is how we use the 10 billion dollars CDC receives each year. The deep neglect that is more fundamental is related to the slow erosion of rural health care - the consolidation of hospital systems and the creation of magnificent urban-based highly innovated and highly staffed hospitals that has left our rural areas and Tribal Nations without. I spent the last 20 years creating access to tiered, effective health care in resource-limited settings that is better than what I saw over the last two years in Tribal Nations and rural America.

Returning to the USA in March 2020, I found a country in which, for healthcare delivery, the stronger had gotten stronger and more sophisticated and the vulnerable, rural areas of Southern, Midwestern, and Northern Plain

States were left deserted. They have become impoverished regions with exploding rates of unaddressed obesity, hypertension, and diabetes.



Slogans like, “Get a test and get treatment,” don’t help. This is our wake-up call. This is not about pandemic preparedness, but access to knowledge and services. Stop justifying the ongoing crisis of COVID hospitalizations and deaths by implying these Americans are making data-informed decisions and choices – they are not. We are not doing the hard work to change their daily reality to address their issues to change the outcomes. Our Federal Agencies might be following the data, but they are not acting on them— not using them to drive investment and change.

I think back to just a decade ago when we had preexposure prophylaxis to prevent new HIV infections, or PrEP. I imagine what would have happened if we used to talk from microphones, put the drugs in pharmacies, and said, “Just test and if you are HIV-positive go to your pharmacy or doctor and get treatment, and if you are HIV-negative go to your pharmacy and get PrEP.” Ten to 20 percent of the more affluent gay men would have done that, but across the South of the USA and through the globe nothing would have happened – nothing would have changed. We didn’t do that – we went community by community, we invested in peer outreach and education through community- and faith-based organizations. We went to churches, community centers, we did the hard on the groundwork. We collected data in real time to see who we were reaching and who we weren’t. We worked with the private sector to do focus groups and deep dives with the best communicators and define the barriers and misinformation, and we battled lies and rumors on the ground, not from the capital.

## G. Conclusions:

Today we have the technology and capacity to collect all community acquired infection diseases data in real time, blur identities to ensure no individual can be identified, and use these data to save lives and ensure Americans not only survive but thrive. We did this in the PEPFAR program; can do it here in the United States. Instead of talking about preparing for the next pandemic, we should invest all our thinking, energy, and resources in altering the current pandemic's impact on the American people. Right now, we are failing.

**But if :**

**We require definitive diagnosis** of all viral and bacterial diseases increasing testing access across the country, state of the art equipment, trained technicians, and shared laboratory information systems ready to detect new infectious agents.

**We continuously conduct behavioral research on the uptake of adult vaccines** and year over year address the structural and perception issues that limit vaccine uptake and show year over year progress with programming.

**We work to address the social determinants of health and the health disparities** through trusted partnerships between community and federal, state, and local partners using real-time data to show improved outcomes and impact year over year, not just once or twice a decade. We stop just observing the problem and start addressing the problems issue by issue, location by location.

**We listen and work together in deep partnership with Tribal Nations** addressing the paternalistic and culturally insensitive manner of service delivery to our tribal nations.

**We can change the current rate of hospitalizations and deaths from COVID19 and be optimally prepared for the next pandemic or new variants of SARS-CoV2.**

ACTION IS NEEDED NOW. If EUA treatments and vaccines are going to be restricted to Federal purchase or Federally defined supply outlets, we need active programmatic support and continuous program improvement directly funded and supported by the Federal Government. Rural America does not have the same access to vaccines, pharmacies, or primary care personnel that urban areas do. We have to treat every hospitalization and death as a programmatic failure, investigate it, and define and correct the barriers that led to it. If we had not taken this approach in HIV, the pandemic would be raging and unchanged. You can't just put drugs in pharmacies or make tests available online and expect that to be a program. If you want every American to survive, you need to ensure that the rates of hospitalization in those over 70 years of age decline significantly and stay down. Those most susceptible as a population to death from COVID need to achieve rates of hospitalization equal to that among people 60-65 years of age, which would approach the experience with seasonal influenza. But we aren't close. To be clear, people over 70 are the most vaccinated and boosted segment of our population, yet they continue to be at the greatest risk to hospitalization and deaths. Also, remember that hospitalizations are not benign in Americans over 70 – just being admitted to the hospital can shorten their lifespan because of stress and exposure to nosocomial infections. I leave you with two additional concrete time sensitive recommendation. 1. require that CDC implement them right now: or move those funds to HRSA who knows program implementation and program improvements. Go back and define the geography, age, race, ethnicity, and vaccine status of 100% of the hospitalization and deaths from the Delta surge in the Summer of 2021 and the Omicron Surge of 2021-2022. 2. Investigate all the programmatic implementation issues in the counties with the majority of deaths. Get on the ground and find out what the access to testing, vaccination, and care in each place, and address them prior to the coming Summer surge.

Let's start with this goal – all Americans survive COVID-19 - and then use data to lay out our objectives clearly, design programs to achieve them, and ensure the transparency and accountability of all the dollars we invest to do so. We need to treat deaths as programmatic failures and implement corrective actions in real time, continuously, driven by data, in deep community partnership. If we ensure every American not only can survive but thrive despite

SARS-CoV2, and we sustain these initiatives, we will be prepared for the next pandemic at the community level, local level, State level, and Federal level. We have the technology and capacity to do this. We just need Federal leadership.