THE FEDERAL RESPONSE TO COVID-19

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

AND THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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C O N T E N T S

[1] Replies from the three witnesses and Dawn O'Connell, Assistant Secretary for Preparedness and Response, Department of Health and Human Services, have been retained in committee files and are available at https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=115351. Ms. O'Connell was invited to testify in person but was unable to attend.

THE FEDERAL RESPONSE TO COVID-19

WEDNESDAY, FEBRUARY 8, 2023

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
JOINT WITH THE
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittees met, pursuant to call, at 10:01 a.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Morgan Griffith (chairman of the Subcommittee on Oversight and Investigations) presiding.

Members present: Representatives Griffith, Guthrie (Subcommittee on Health chairman), Burgess, Latta, Bilirakis, Johnson, Bucshon, Hudson, Carter, Duncan, Palmer, Dunn, Lesko, Pence, Crenshaw, Joyce, Harshbarger, Miller-Meeks, Cammack, Obernolte, Rodgers (ex officio), Eshoo (Subcommittee on Health ranking member), Castor (Subcommittee on Oversight and Investigations ranking member), DeGette, Schakowsky, Sarbanes, Tonko, Cárdenas, Ruiz, Peters, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Craig, Schrier, Trahan, and Pallone (ex officio).

Staff present: Sean Brebbia, Chief Counsel, Oversight and Investigations; Jolie Brochin, Clerk, Health; Lauren Eriksen, Clerk, Oversight and Investigations; Grace Graham, Chief Counsel, Health; Nate Hodson, Staff Director; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Molly Lolli, Counsel, Health; Michael Taggart, Policy Director; Lydia Abma, Minority Policy Analyst; Hannah Anton, Minority Staff Assistant; Jacquelyn Bolen, Minority Health Counsel; Austin Flack, Minority Junior Professional Staff Member; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Stephen Holland, Minority Senior Health Counsel; Liz Johns, Minority GAO Detailee; Mackenzie Kuhl, Minority Digital Manager; Una Lee, Minority Chief Health Counsel; Will McAuliffe, Minority Chief Counsel, Oversight and Investigations; Elysa Montfort, Minority Press Secretary; Juan Negrete, Minority Professional Staff Member; Harry Samuels, Minority Oversight Counsel; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; Caroline Wood, Minority Research Analyst; and C.J. Young, Minority Deputy Communications Director.

Mr. GRIFFITH. This joint hearing of the Subcommittee on Oversight and Investigations and the Subcommittee on Health will now come to order.

I now recognize myself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. H. MORGAN GRIFFITH, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

Good morning, and welcome to this joint Oversight and Investigations and Health Subcommittee hearing examining the Federal response to COVID–19.

Before we start I would like to extend my condolences to Assistant Secretary O'Connell of the Administration for Strategic Preparedness and Response, who was planning to testify here today, but, unfortunately, her sister passed away.

To date, more than 1 million Americans have died from COVID–19. And on top of the loss of life, the pandemic brought our country to a standstill. It cost our economy around $15 trillion. That equates to more than 200,000 small businesses permanently closed due to the pandemic.

Schools were closed for far too long, setting children behind in learning and damaging their social, emotional, and, in many cases, their physical well-being. The Nation is still recovering from the pandemic's impact and the damage it caused. Given these losses, it is appalling that the last time we had the heads of the public health agencies before us was March of 2021, almost 2 years ago.

We held a hearing last week with the Governmental Accountability Office and other experts in the field of pandemic and biological outbreaks where we discussed how being able to quickly identify the root cause of a disease outbreak or biological incident is crucial for a list of reasons, ranging from countermeasure development to identifying what activities may have been responsible for the pathogen outbreak.

While the worst of the COVID–19 pandemic is likely behind us, there are a host of areas that we need to examine, including actions taken and not taken by the Federal Government, as well as how we address future pandemic preparedness. By all accounts, the risk of catastrophic biological incidents and infectious disease pandemics is increasing. So it is critical that we understand in detail the Federal response.

Since the heads of these agencies have not appeared before us in quite some time, we have a lot of questions about the Federal Government's response to COVID–19. Further, many of the questions we have are due to a lack of response to congressional inquiries regarding COVID–19.

One of the major concerns that has gone unanswered by the National Institute of Health is the lack of compliance and oversight into grant awards to EcoHealth Alliance. There are a myriad of compliance issues surrounding EcoHealth and their sub-award grants to the Wuhan Institute of Virology, specifically for coronavirus research. The NIH has been reluctant to answer our inquiries on issues such as EcoHealth withholding data, potentially double billing the Federal Government, and missing laboratory notebooks and electronic files that were supposed to be delivered to the NIH by EcoHealth.

This process does not have to be confrontational. Republican leaders have sent a similar letter to entities such as Boston Univer-

sity about an experiment involving a hybrid COVID virus that attracted press attention. Boston University fully cooperated, sending a written response letter directly addressing the questions, producing about 2,000 pages of documents, and providing a briefing to bipartisan staff. In contrast, the NIH has not provided a satisfactory or complete response. This is not acceptable.

Let me be clear: It is not acceptable to stonewall any Member of Congress with oversight authority, whether that Member be a Democrat or be a Republican, whether that Member be in the minority or in the majority. The people of America entrust us to find the answers and to provide oversight of the Federal Government.

Another one of the many issues that we hope to address today is the Centers for Disease Control and Prevention and their rationale for masking and the closure of reopening schools. We now have the findings of a comprehensive review of multiple randomized controlled trials that show "no clear reduction in respiratory viral infection with the use of medical surgical masks" or, in fact, with the use of N95 masks. The conclusion of these studies makes me wonder what evidence there was to justify forcing masking on our children.

The members of these subcommittees also have questions about pathogen research being funded and conducted by Federal agencies. In the United States we have recently seen high-risk research done to intentionally modify pathogens such as NIH experiments to enhance monkeypox virulence.

As a final note, I hope that our witnesses are more forthcoming and cooperative as we move forward. At the end of the day, we need to work together. The committee's majority is willing to work with you and our Democrat colleagues constructively to deliver solutions and pave a path forward for America. We want to work in common purpose for the national good, but we must be partners. You and your agencies must be transparent, responsive, and cooperative in order for us to be able to work together.

I thank the witnesses for being here today and for being a part of this important discussion.

[The prepared statement of Mr. Griffith follows:]

Morgan Griffith
Chair of Subcommittee on Oversight and Investigations
Joint Oversight & Investigations and Health Subcommittee Hearing
February 8, 2023
Opening Statement
As Prepared for Delivery

Good morning and welcome to this joint Oversight and Investigations and Health Subcommittee Hearing examining the federal response to COVID-19. Before we start, I want to extend my condolences to Assistant Secretary O'Connell of ASPR, who was planning to testify today, and to her family on the passing of her sister.

To date, more than 1 million Americans have died from COVID-19.[1] On top of the loss of life, the pandemic brought our country to a standstill. It cost our economy around $15 trillion dollars.[2] That equates to more than 200,000 small businesses permanently closed due to the pandemic.[3]

[1] https://covid.cdc.gov/covid-data-tracker/#datatracker-home
[2] Richard Bruns & Nikki Teran, *Weighing the Cost of the Pandemic*, Institute for Progress (Apr. 21, 2022), https://progress.institute/weighing-the-cost-of-the-pandemic/.
[3] https://www.wsj.com/articles/covid-19s-toll-on-u-s-business-200-000-extra-closures-in-pandemics-first-year-11618580619

Schools were closed for far too long, setting children behind in learning and damaging their social, emotional, and, in many cases, physical well-being.

The nation is still recovering from the pandemic's impact and the damage it caused. Given these loses, it is appalling that the last time we had the heads of the public health agencies before us was March of 2021—almost two years ago.

We held a hearing last week with the Governmental Accountability Office and other experts in the field of pandemic and biological outbreaks where we discussed how being able to quickly identify the root cause of a disease outbreak or biological incident is crucial for a list of reasons ranging from countermeasure development to identifying what activities may have been responsible for incident.

While the worst of the COVID-19 pandemic is likely behind us, there are a host of areas that we need to examine, including the past

actions taken—and not taken—by the federal government, as well as how we address future pandemic preparedness.

By all accounts, the risk of catastrophic biological incidents and infectious disease pandemics is increasing, so it is critical that we understand in detail the federal response.

Since the heads of these agencies have not appeared before us in quite some time, we have a lot of questions about the federal government's response to COVID-19.

Further, many of these questions we have are due to the lack of response to Congressional inquiries regarding COVID-19. We received responses by some federal agencies but many of our questions and letters went completely unanswered as we waited for information that would help us to better prepare our country for future pandemics.

One of the major concerns that has gone unanswered by the National Institute of Health is the lack of compliance and oversight into grant awards to EcoHealth Alliance.

There are a myriad of compliance issues surrounding EcoHealth and their subaward grants to the Wuhan Institute of Virology, specifically for coronavirus research.

The NIH has been reluctant to answer our inquiries on issues such as EcoHealth withholding data, potentially double billing the federal government, and missing laboratory notebooks and electronic files that were supposed to be delivered to NIH by EcoHealth.

It does not have to be this confrontational, Republican leaders have sent a similar letter to entities such as Boston University about an experiment involving a hybrid COVID virus that attracted press attention. Boston University fully cooperated, sending a written response letter directly addressing the questions, producing about 2,000 pages of documents, and providing a briefing to bipartisan staff.

In contrast, NIH has not provided a satisfactory or complete response. This is not acceptable. Let me make this clear, it is not

acceptable to stonewall any Member of Congress with oversight authority. Whether Democrat or Republican, whether Minority or Majority. Unless you respond with a rational, valid national security concern.

Another one of the many issues that we hope to address today is the CDC and their rationale for masking and the closure and reopening of schools.

We now have the findings of a comprehensive review of multiple randomized controlled trials that show "no clear reduction in respiratory viral infection with the use of medical/surgical masks" or with the use of N95s.

The conclusion of these studies makes me wonder what evidence there ever was justifying forced masking of children or mask mandates for interstate travel.

Looking forward, the members of my subcommittee also have questions about pathogen researched being funded and conducted by federal agencies. In the United States, we have recently seen high-risk

research done to intentionally modify pathogens, such as NIH's experiments to enhance monkeypox's virulence.

As a final note, I hope that our witnesses are more forthcoming and cooperative going forward.

At the end of day, we need to work together. The Committee's majority is willing work with you and our Democrat colleagues constructively to deliver solutions and pave a path forward for America.

We want to work in common purpose for the national good, but we must be partners, you and your agencies must be transparent, responsive, and cooperative for us to be able to work together.

I thank the witnesses for being here today and being part of this important discussion.

Mr. GRIFFITH. All right. The Chair recognizes the Oversight and Investigation Subcommittee ranking member, Ms. Castor, for 5 minutes for her opening statement.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Well, thank you, Mr. Chairman, and thank you all for being here today. Thank you to our witnesses. Thank you for all that you do to help keep Americans healthy, safe, and well.

I am sorry that Assistant Secretary for Preparedness and Response Dawn O'Connell cannot be with us today to share her expertise, and want to express my sympathies for the southern—sudden death in her family, and her loss. I appreciate, though, that she did submit testimony and has agreed to respond to written questions.

While all Americans are relieved that we are emerging from the worst pandemic in our lifetimes—over 1 million American lives lost—examining the response to COVID–19 will help us prepare for the next public health emergency.

But if we take ourselves back to those early days of the pandemic, I remember very well the public was scared. They were uncertain. But public health experts and government and across the country mobilized to better understand the virus, to develop vaccines and treatments, and try to provide us with the answers in the face of great uncertainty. They worked to follow the science and improve guidance as we learned new information about the virus and how to contain it. And they were trying their hardest to save lives in the face of a new threat.

The tone from the top, however, was very different in the earliest, most critical days of the COVID–19 pandemic. Then-President Trump downplayed the threat, saying it was one person coming in from China, and we have it under control, and it is going to go away. He improvised from the White House briefing room about potential treatments completely unsupported by science and sometimes dangerous: hydroxychloroquine, bleach, ultraviolet light. He repeatedly undercut the hard work of public health officials who were up against one of the greatest threats to our country in modern times.

Despite this, the Republican majority now somehow claims that the Biden administration is to blame for reduced confidence in public health institutions. Over the past 2 years, Republicans have repeatedly chosen to cast blame on the Biden administration and career public servants to deflect from their leader's early failures to contain the pandemic. And some have actively spread misinformation and tried to hide vital public health data.

At last week's hearing, I stated that I was hopeful that we could avoid in this committee the kind of partisan attacks on public servants that we have seen taking root in other committees across the House and, instead, focus constructively on how to strengthen our public health infrastructure for the future.

Unfortunately, just one day after last week's hearing, this committee sent a letter to NIH requesting a huge number of documents and transcribed interviews of career staffers, while implying that the agency is hiding information about the origins of COVID–19.

Democrats, however, remain focused on how to restore and maintain trust in the world's top health institutions represented here today, give them the tools and the resources they need to keep Americans safe and ensure that the public has the best information based on solid science to make decisions.

Combating the virus is an enormous challenge. It continues to mutate, and our response and strategies must evolve with it. But what will remain constant is my firm support for strong public health institutions which have saved countless lives.

I am immensely grateful for the witnesses' leadership. I look forward to hearing how you plan on incorporating the lessons learned from COVID–19 to further strengthen your agencies and these important missions for the future.

[The prepared statement of Ms. Castor follows:]

Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Oversight and Investigations Ranking Member Kathy Castor

Hearing on "The Federal Response to COVID-19"

February 8, 2023

Thank you, Mr., Chairman, and thank you all for being here today. Thank you to our witnesses, thank you for all that you do to help keep Americans healthy, safe and well. I am sorry that Assistant Secretary for Preparedness and Response, Dawn O'Connell, cannot be with us today to share her expertise. I want to express my sympathies for the sudden death in her family and her loss. I appreciate, though, that she did submit testimony and has agreed to respond to written questions.

All Americans are relieved that we are emerging from the worst pandemic in our lifetimes. Over one million American lives lost. Examining the response to Covid-19 will help us prepare for the next health emergency. If we take ourselves back to those early days in the pandemic, I remember very well the public was scared, they were uncertain. But public health experts in government across the country mobilized to better understand the virus, to develop vaccines and treatments, and try to provide us the answers in the face of great uncertainty. They worked to follow the science and improve guidance as we learned new information about the virus and how to contain it. And they were trying their hardest to save lives in the face of a new threat.

The tone from the top, however, was very different. In the earliest, most critical days of the COVID-19 pandemic, then-President Trump downplayed the threat, saying that it was "one person coming in from China, and we have it under control" and "it's going to go away." He improvised from the White House briefing room about potential treatments completely unsupported by science, and sometimes dangerous—hydroxychloroquine, bleach, and ultraviolet light. He repeatedly undercut the hard work of public health officials who were up against one of the greatest threats to our country in modern times. Despite this, the Republican Majority now somehow claims that the Biden administration is to blame for reduced confidence in public health institutions.

Over the past two years, Republicans have repeatedly chosen to cast blame on the Biden administration and career public servants to deflect from their leader's early failures to contain the pandemic, and some have actively spread misinformation, and tried to hide vital public health data.

At last week's hearing, I stated that I was hopeful we could avoid in this Committee the kind of partisan attacks on public servants that we have seen taking root in other committees across the House, and instead focus constructively on how to strengthen our public health infrastructure for the future. Unfortunately, just one day after last week's hearing, this Committee sent a letter to NIH requesting a huge number of documents and transcribed

interviews of career staff while implying that the agency is hiding information about the origins of COVID-19.

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I am immensely grateful for the witnesses' leadership. I look forward to hearing how you plan on incorporating lessons learned from COVID-19 to further strengthen your agencies for in these important missions in the future.

Ms. CASTOR. I yield back my time.

Mr. GRIFFITH. I thank the gentlelady, and I now recognize the chairman of the Health Subcommittee and the cochairman of today's joint committee, Mr. Guthrie, for 5 minutes for his opening statement.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. GUTHRIE. Thank you. I welcome all of you guys here today. Good to have you here before us. And my condolences, as well, to Assistant Secretary O'Connell and her family.

A little over a week ago, President Biden said his administration would end the COVID–19 public health emergency on May the 11th. And I am glad the President formally announced he would end the PHE and relinquish the emergency powers.

However, after over 2 years into the Biden presidency, Congress and the American people have little to no visibility into nor input on the administration's pandemic response. And we are going to change that today.

Today is the first of many opportunities for both members of this subcommittee and, by extension, our constituents to ask important questions about decisions made by our Nation's leading health—public health officials in response to the COVID–19 pandemic. My hope is that this work leads to reforms that make us better prepared for pandemics and other public health security threats in the future.

To start, public trust in our public health institutions is at a low. And this is driven by Federal Government's misguided and inconsistent preparation for and response to the COVID–19 pandemic. This is heightened by confusing, sometimes conflicting communication and guidance coming from our public health agencies.

In the earliest days of the pandemic, the CDC stumbled rolling out testing kits, the Food and Drug Administration took too long to authorize diagnostics, and the Strategic National Stockpile was ill-equipped with deficient and expired equipment. Thankfully, Operation Warp Speed was able to cut through some of this red tape in bureaucracy to facilitate the rapid development of vaccines and therapies that helped prevent serious illness and death from COVID–19 and put us on the road towards normalcy.

The pandemic has also exposed how our public health agencies failed at their core functions to be good stewards of taxpayer dollars. The National Institutes of Health flouted HHS-wide rules on conducting proper oversight of potential pandemic pathogen research. After living through COVID–19, the origins of which still largely remain unknown, it is absolutely clear that we must require strict Federal oversight of these risky research projects.

And of COVID–19 origin, NIH's refusal to acknowledge any suggestion that the COVID–19 virus may have traveled from nature to a lab to humans has—only continues to fuel the controversy and questions around it. To discover the truth and instill confidence back in our Federal research programs, why not engage in a robust, honest, and transparent dialogue and investigation?

Instead, Federal officials worked with social media companies to censure those who offered a differing viewpoint, further fueling public distrust in our public health institutions.

Unfortunately, the Biden administration's one-size-fits-all approach to the pandemic has only made our response even more challenging between inconsistent CDC COVID–19 guidance policies, testing challenges, the FDA rationing of key therapeutics, to name a few.

Among these mistakes carry significant real-world consequences. Kids and parents were left without—with limited options for in-person instruction because the Nation's largest teacher's union offered line-by-line edits on reopening guidance. This robbed our kids of the benefits of in-person instruction and has had devastating effects on kids struggling with anxiety and depression at unprecedented levels.

As members of this committee, we also cannot permit mission creep into our public health agencies. We must ensure our Federal partners are focused on their core mission of preventing, preparing for, and responding to public health emergencies.

Luckily, we have a chance to address many of these systemic issues that hindered our Federal response to the COVID–19 pandemic. I look forward to working with my colleagues on this subcommittee, and I look forward to working with our witnesses here today to consider appropriate reforms as we work to reauthorize the Pandemics and All Hazard Preparedness Act, or PAHPA, that will be led by our colleague, Mr. Hudson. Doing so could make a difference between life and death of millions of Americans.

[The prepared statement of Mr. Guthrie follows:]

Health Subcommittee Chair Guthrie Opening Statement on the Federal Government's Response to COVID-19 As Prepared for Delivery

"A little over a week ago, President Biden said his administration would end the COVID-19 Public Health Emergency on May 11.

"I'm glad the President formally announced he would end the PHE and relinquish his emergency powers.

"However, after over two years into the Biden presidency, Congress and the American people have had little-to-no visibility into, nor input on, the administration's pandemic response.

"That changes today."

IMPORTANT QUESTIONS FOR PUBLIC HEALTH OFFICIALS

"Today is the first of many opportunities for both members of these subcommittees, and by extension our constituents, to ask important questions about decisions made by our nation's leading public health officials in response to the COVID-19 pandemic.

"My hope is that this work leads to reforms that make us better prepared for pandemics and other public health security threats in the future.

"To start, public trust in our public health institutions is at an all-time low.

"This has been driven by the federal government's misguided and inconsistent preparation for and response to the COVID-19 pandemic.

"This was heightened by the confusing, sometimes conflicting, communication and guidance coming from our public health agencies.

"In the earliest days of the pandemic, the CDC stumbled rolling out testing kits, the Food and Drug Administration took too long to authorize diagnostics, and the Strategic National Stockpile was ill-equipped with deficient and expired equipment.

"Thankfully, Operation Warp Speed was able to cut through some of this red tape and bureaucracy to facilitate the rapid development of vaccines and therapies that help prevent serious illness and death from COVID-19 and put us on the road towards normalcy.

"The pandemic also exposed how our public health agencies failed at their core functions to be good stewards of taxpayer dollars.

"The National Institutes of Health (NIH) flouted HHS-wide rules on conducting proper oversight of potential pandemic pathogen research."

WE MUST HAVE STRICT FEDERAL OVERSIGHT OF RISKY RESEARCH

"After living through COVID-19 – the origins of which still largely remain unknown – it is absolutely clear that we must require strict federal oversight of these risky research projects.

"Speaking of COVID-19 origins – NIH's refusal to acknowledge any suggestion that the COVID-19 virus may have originated in a lab only continues to fuel the controversy and questions around it.

"To discover the truth and instill confidence back in our federal research programs – why not engage in a robust, honest, and transparent dialogue and investigation? Instead, federal officials worked with social media companies to censor those who offered a differing viewpoint, further fueling public distrust in our public health institutions.

"Unfortunately, the Biden administration's one-size-fits-all approach to the pandemic has only made our response even more challenging between inconsistent CDC COVID-19 guidance policies, testing challenges, and the FDA rationing of key therapeutics to name a few."

ACCOUNTABILITY FROM PUBLIC HEALTH AGENCIES

"And these mistakes carry significant real-world consequences.

"Kids and parents were left with limited options for in-person instruction because the nation's largest teachers union offered line by line edits on reopening guidance.

"This robbed our kids of the benefits of in-person instruction and has had devastating effects on kids struggling with anxiety and depression at unprecedented levels.

"As members of this Committee, we also cannot permit mission creep at our public health agencies – we must ensure our federal partners are focused on their core mission of preventing, preparing for, and responding to public health security threats.

"Luckily, we have a chance to address many of the systemic issues that hindered our federal response to the COVID-19 pandemic.

"I look forward to working with my colleagues on this Subcommittee, as well as with the witnesses before us here today, to consider appropriate reforms as we work to reauthorize the Pandemics and All-Hazards Preparedness Act, or PAHPA, that will be led by our colleague, Mr. Hudson.

"Doing so could make a difference between life and death for millions of Americans."

Mr. GUTHRIE. I thank you and I yield back.

Mr. GRIFFITH. I thank the gentleman for yielding back. I now recognize the ranking member of the Health Subcommittee, Ms. Eshoo, for her 5-minute opening statement.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. Thank you, Mr. Chairman, and good morning to the witnesses. Thank you for being here today.

On March 11th, 2020, the World Health Organization declared the coronavirus a pandemic. Now, 3 years later, we have the benefit of hindsight, and we know we were unprepared. We lost 1 million precious souls in our country: grandparents, mothers, fathers, siblings, and some of our colleagues.

Now we have to do everything possible to prepare our Nation for new and emerging threats to public health. We have to learn from the mistakes made, including the faulty coronavirus testing kits that the CDC insisted on developing on their own, which allowed infections to spread undetected; the bare cupboards of the Strategic National Stockpile, leading to our Nation's heroic healthcare workers wearing trash bags as protection; a long legacy of racial health disparities and a weak social safety net that allowed the virus to disproportionately infect and kill Black, Hispanic, and indigenous people; a chronically underfunded public health system whose poor data undercut the government's response to COVID; and confusing and opaque public health communications, which bad actors took advantage of to spread misinformation and discourage lifesaving vaccinations.

It is also clear where the Federal Government succeeded in its response. Because of the work NIH was already doing when the pandemic began, researchers were able to develop a safe, highly effective vaccine for the new virus very quickly. COVID vaccines have resulted in 120 million fewer infections, 18½ million fewer hospitalizations, and 3.2 million lives saved. Nimble decision-making by the Federal Government and Congress allowed more Americans to get health coverage, Medicare to cover telehealth and at-home care, and the FDA to use emergency authorizations and flexible clinical trial designs to provide treatments and vaccines quickly.

Three years later, our Nation is finally recovering from the pandemic. Now we have to incorporate the lessons we have learned to strengthen our public health infrastructure before a new threat is upon us. Our Nation's health and security depend on this.

I look forward to the testimony from the three heads of the agencies that are here today, and—that their testimony be highly instructive to us on how we can improve our Federal response going forward.

[The prepared statement of Ms. Eshoo follows:]

Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Health Ranking Member Anna Eshoo

Hearing on "The Federal Response to COVID-19"

February 8, 2023

Thank you, Mr. Chairman and good morning, to the witnesses, thank you for being here today.

On March 11, 2020, the World Health Organization declared the coronavirus a pandemic.

Now, three years later, we have the benefit of hindsight and we know we were unprepared. We lost one million precious souls in our country… grandparents, mothers, fathers, siblings, and even some of our colleagues. Now we have to do everything possible to prepare our nation for new and emerging threats to public health.

We have to learn from the mistakes made, including:

The faulty coronavirus testing kits that the CDC insisted on developing on their own which allowed infections to spread undetected.

The bare cupboards of the Strategic National Stockpile leading to our nation's heroic health care workers wearing trash bags as protection.

A long legacy of racial health disparities and a weak social safety net that allowed the virus to disproportionately infect and kill Black, Hispanic, and Indigenous people.

A chronically underfunded public health system whose poor data undercut the government's response to Covid; and

Confusing and opaque public health communications which bad actors took advantage of to spread misinformation and discourage life-saving vaccinations.

It's also clear where the federal government succeeded in its response:

Because of the work NIH was already doing when the pandemic began, researchers were able to develop a safe, highly effective vaccine for the new virus very quickly. Covid vaccines have resulted in 120 million fewer infections, 18.5 million fewer hospitalizations, and 3.2 million lives saved.

Nimble decision-making by the federal government and Congress allowed more Americans to get health coverage, Medicare to cover telehealth and at-home care, and the FDA to use emergency authorizations and flexible clinical trial designs to provide treatments and vaccines quickly.

Three years later, our nation is finally recovering from the pandemic. Now we have to incorporate the lessons we've learned to strengthen our public health infrastructure before a new threat is upon us. Our nation's health and security depend on this.

I look forward to the testimony from the three heads of the agencies that are here today, and that their testimony be highly instructive to us on how we can improve our federal response going forward.

And with that Mr. Chairman I yield back the balance of my time.

Ms. ESHOO. And with that, Mr. Chairman, I yield back the balance of my time.

Mr. GRIFFITH. I thank you and now recognize the chair of the full committee, Mrs. McMorris Rodgers, for her 5-minute opening statement.

OPENING STATEMENT OF HON. CATHY MCMORRIS RODGERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mrs. RODGERS. Thank you, Chair Griffith. The questions that we are asking here today are the questions that we hear from people in our communities every day. As the people's elected representatives, we have a responsibility to conduct oversight.

President Biden's public health leaders are here today because they have broken the American people's trust.

I will start with you, Dr. Tabak. I was once a huge supporter of NIH. The overall lack of responsiveness, the suppression of dissenting voices and the COVID origins investigation, the frequent mixed messaging on health precautions—the NIH is falling short of its goal of integrity and accountability. For the past 2 years we have pressed for answers about what kind of research you are funding with taxpayer dollars and what sort of oversight you are doing to ensure funds are not misspent. Your cooperation has been abysmal.

Next, Director Walensky and the Centers for Disease Control and Prevention. Your guidance was used by the Federal Government to justify mandates that have more parents questioning routine vaccination. Your guidance, influenced by teachers unions, kept schools closed. Your guidance, using unreliable studies, was used to justify mask mandates on our kids. We know these weren't decisions based upon best science and data from around the world. Now our children are paying the price. Academically, they have been set back for years. Emotionally, they are living—we are living through the most severe youth mental health crisis we have seen. And physically, cases of type 2 diabetes and obesity in children has surged.

Dr. Walensky, the CDC does not need more authority. It needs robust oversight. It has always operated without a congressional authorization, and it is going to change.

Dr. Califf, the FDA has failed to alleviate the concerns about the vaccine. I will note that, before imposing authoritarian vaccine mandates as President, candidate Biden made statements about the vaccine that did lasting damage. But top vaccine review officials Marion Gruber and Phil Krause left FDA as the Biden administration was working to authorize boosters, doses which many people have not—may not have needed.

And beyond the vaccine, FDA inspections of foreign sites are woefully lacking. Innovators can't get the guidance they need to approve standards, and patients are the ones left without the innovation or supply of products they need.

Finally, regarding Assistant Secretary Dawn O'Connell's absence. I understand why she is not here today, and I extend my deepest sympathies, condolences to her and her family. However, the Administration for Strategic Preparedness and Response is the top of-

ficial in public health emergencies. ASPR's job is to be prepared. So it is unacceptable that another leader from the administration wasn't prepared to be here today in the Assistant Secretary's place. There are no excuses, especially given the enormous amounts of resources and responsibilities we have allocated to ASPR over the years.

My message today to all the administration public health officials is that this is going to be a long road. Trust is broken a lot faster than it is built. And many will say that the American people deserve an apology, but they deserve much more. I think about every person who lost a loved one to COVID–19, the people who died alone because of COVID–19 policies, the frontline workers who sacrificed but were still forced out of their jobs because of vaccine mandates, and the children isolated and set back from school closures. Surely, we can all agree that for them we cannot repeat the mistakes of the pandemic response. They deserve full accountability and transparency, nothing less.

That is the bare minimum of what we expect today so that we can begin to heal, restore trust, and better prepare for the future.

[The prepared statement of Mrs. Rodgers follows:]

Congresswoman Cathy McMorris Rodgers

Joint Oversight & Investigations and Health Subcommittee Hearing

February 8, 2023

Opening Statement

As Prepared for Delivery

INTRO

Thank you, Chair Griffith.

The questions we're asking today are the questions we hear from people in our communities everyday... As the people's elected representatives, we have a responsibility to conduct oversight...

President Biden's public health leaders are here today because they have broken the American people's trust.

NIH

I'll start with you, Dr. Tabak.

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The overall lack of responsiveness, the suppression of dissenting voices in the Covid origins investigation, and the frequent mixed messaging on health precautions – the NIH is falling far short of its goals of integrity and accountability.

For the past 2 years, we've pressed for answers about what kind of research you're funding with taxpayer dollars and what sort of oversight you're doing to ensure funds are not being misspent.

You cooperation has been abysmal.

CDC

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Your guidance was used by the federal government to justify mandates that have more parents questioning routine vaccination.

Your guidance influenced by the teachers unions kept schools closed.

Your guidance using unreliable studies was used to justify mask mandates on kids.

We know these weren't decisions based on the best science and data from across the world.

Now, our children are paying the price.

Academically, they've been set back for years.

Emotionally, they are living through the most severe youth mental health crisis we've ever seen.

And physically, cases of type 2 diabetes and obesity in children has surged.

Director Walensky, the CDC does not need more authority... it needs robust oversight.

It has always operated without a Congressional authorization and that is going to change.

FDA

Dr. Califf, [pause]

The FDA has failed to alleviate concerns about the vaccine.

I'll note that **before** imposing authoritarian vaccine mandates as president, candidate Biden made statements about the vaccine that did lasting damage.

But, top vaccine review officials, Marion Gruber and Phil Krause, left FDA as the Biden administration was working to authorize boosters – doses which many people may not have needed.

Beyond the vaccine, FDA inspections of foreign sites are woefully lacking. Innovators can't get the guidance they need to meet approval standards, and patients are the ones left without the innovation or supply of products they need.

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Finally, regarding Assistant Secretary Dawn O'Connell's absence.

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CONCLUSION

My message today to all of the administration's public health officials..

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The people who died alone because of COVID-19 policies.

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And the children isolated and set back from school closures.

Surely, we can all agree that FOR THEM we can't repeat the mistakes of this pandemic response.

They deserve full accountability and transparency. Nothing less.

That is the bare minimum of what we expect today, so we can begin to heal, restore trust, and better prepare for the future.

Thank you.

Mrs. RODGERS. Thank you.

Mr. GRIFFITH. I thank the gentlelady and now recognize the ranking member of the full committee, Mr. Pallone, for his 5 minutes.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairman Griffith. Today we will hear from the government officials leading both the ongoing COVID–19 recovery and the efforts to bolster the Nation's public health system for the long term, which is our best defense against future pandemics. And this is no simple task.

When President Biden came into office, he inherited a year-old pandemic from the Trump administration, during which public health experts were routinely ignored and maligned, hamstringing the government's ability to respond. Deaths were soaring faster, and those involved in COVID–19 response were frequently forced to correct President Trump's misinformation about the virus, which distracted from the important goals for distributing newly authorized vaccines.

It is unfortunate that a national emergency so quickly turned into a partisan issue at a time when we most needed to come together.

Now, over the last 2 years, the Democratic Congress and the Biden administration invested in a nationwide vaccine campaign and COVID test distribution that accelerated our recovery. After facing new challenges from more aggressive COVID–19 variants, death rates and hospitalizations have once again fallen across the Nation. However, we must continue to be vigilant and monitor new variants, improve vaccination rates, and ensure that an uptick in cases does not occur.

At the same time, we know that COVID–19 is not the last pandemic we will face, and we need to be sure we are incorporating the lessons learned from the pandemic into our public health infrastructure. And today we will hear agency plans to do just that.

Now, a strong public health response includes effective communication and access to accurate, reliable information and includes consistent investment in scientific research that leads to development of safe and effective vaccines and treatments. It includes establishing partnerships between the Federal, State, and local governments and the private sector to ensure a smooth response when a public health threat arises.

We must also address the racial and ethnic disparities that affect our ability to mount an equitable response to a pandemic. These inequalities predated COVID–19 but were magnified during the pandemic. And it is unacceptable in this day and age that the burden of death and disease continues to fall disproportionately on people of color.

Unfortunately, later today we are on the floor of the House taking up yet another partisan bill that seeks to roll back COVID protections. This is the third bill from the GOP that seeks to roll back COVID protections at a time when COVID continues to spiral and variants are a real danger.

I will remind my colleagues there are 500 people still dying every day from COVID. This is still with us.

And when I was at Rules earlier this week on this third bill, there were some on the right—and that does not include members of this committee, I am not talking about our chairwoman, or Chairman Guthrie, or Dr. Burgess—but there were some extremists on the right who continue to rail against vaccines. It is very dangerous. I am not, you know, saying this is true for most Republicans, but there are certainly some on the right that give the impression that the vaccines are not safe, that they are not effective, and that somehow people shouldn't take them. And I just want to bring that up, because it disturbs me greatly. I was very disturbed when I went to Rules to hear that over and over again.

And I think that, again, I will remind my colleagues that the bill we are taking up today that says that global travelers, foreigners that come to the United States, don't need vaccines—well, that decision, the decisions about the public health emergency, about vaccine mandates, those should be made by the people in front of us at this table. Those decisions should be made by the public health experts who have the science, and not by Congress. We don't have the expertise, in my opinion, to make those decisions, which is why I continue to oppose these rollbacks of our efforts to deal with the COVID crisis.

And when Republicans put politics over science, it seriously undermines our ability to combat this pandemic and the hard work that these public agencies do every day. So I hope that we can get back to the business of regular order, of the committee taking on the Nation's challenges. None of those three bills came through this committee. None of them had regular order.

But we have a lot to do this year, and we have to reauthorize the Pandemic and the All Hazards Preparedness Act, which is set to expire in September. PAHPA has been a bipartisan effort in the past, and I hope that we can be guided by that precedent, so that we can make sure that our Nation is in the strongest position to address a future crisis.

[The prepared statement of Mr. Pallone follows:]

Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Ranking Member Frank Pallone, Jr.

Oversight and Investigations and Health Subcommittee Joint Hearing on "The Federal Response to COVID-19"

February 8, 2023

Today, we will hear from the government officials leading both the ongoing COVID-19 recovery and the efforts to bolster the nation's public health system for the long term, which is our best defense against future pandemics.

This is no simple task.

When President Biden came into office, he inherited a year-old pandemic from the Trump Administration during which public health experts were routinely ignored and maligned, hamstringing the government's ability to respond.

Deaths were soaring faster and those involved in COVID-19 response were frequently forced to correct President Trump's misinformation about the virus, which distracted from the important goals for distributing newly authorized vaccines.

It is unfortunate that a national emergency so quickly turned into a partisan issue at a time when we most needed to come together.

Over the last two years, a Democratic Congress and the Biden Administration invested in a nationwide vaccine campaign and COVID test distribution that accelerated our recovery.

After facing new challenges from more aggressive COVID-19 variants, death rates and hospitalization have once again fallen across the nation. However, we must continue to be vigilant and monitor new variants, improve vaccination rates, and ensure that an uptick in cases does not occur.

At the same time, we know that COVID-19 is not the last pandemic we will face, and we need to be sure we are incorporating the lessons learned from the pandemic into our public health infrastructure. Today, we will hear agency plans to do just that.

A strong public health response includes effective communication and access to accurate, reliable information. It includes consistent investment in scientific research that leads to development of safe and effective vaccines and treatments. It includes establishing partnerships between the federal, state, and local governments and the private sector to ensure a smooth response when a public health threat arises.

We must also address the racial and ethnic disparities that affect our ability to mount an equitable response to a pandemic. These inequalities predated COVID-19, but were magnified during the pandemic. It is unacceptable in this day and age that the burden of death and disease continues to fall disproportionately on people of color.

Unfortunately, later today we are taking up yet another partisan bill on the House floor that does nothing to strengthen our public health infrastructure or make people safer and healthier. In fact, H.R. 185 seems designed to further undermine trust in our public health officials and confidence in our lifesaving vaccines. This bill also did not go through this Committee, but rather was rushed to the floor as a political stunt.

When Republicans put politics over science it seriously undermines our ability to combat this pandemic and the hard work these public health agencies do every day.

I hope that we can get back to the business of regular order, of the Committee taking on the nation's challenges in a thoughtful, bipartisan manner. One step we must take this year is reauthorizing the Pandemic and All Hazards Preparedness Act, which is set to expire in September.

PAHPA has been a bipartisan effort in the past, and I hope that we can be guided by that precedent so that we can make sure that our nation is in the strongest position to address a future crisis.

With that, Mr. Chairman, I yield back.

Mr. PALLONE. And with that, Mr. Chairman, I yield back.

Mr. GRIFFITH. I thank the gentleman. We now conclude with Member opening statements.

The Chair would like to remind Members that, pursuant to committee rules, all Members' opening statements will be made a part of the record.

We want to thank our witnesses for being here today and taking the time to testify before the subcommittees, these subcommittees.

Each witness will have the opportunity to give an opening statement, followed by a round of questions from Members. Our witnesses today are Dr. Larry Tabak, the senior official performing the duties of the Director of the National Institutes of Health; the Honorable Robert Califf, Commissioner of Food and Drugs, U.S. Food and Drug Administration; and Dr. Rochelle Walensky, Director of Centers for the Disease Control and Prevention.

We appreciate all of you being here today, and now we will swear you in. If each of you could stand.

As you know, the testimony that you are about to give is subject to Title 18, Section 1001 of the United States Code. When holding an investigative hearing, this committee has the practice of taking testimony under oath. Do any of you have an objection to testifying under oath?

Let the record reflect no one objected.

Further, you are also advised, under the Rules of the House and the rules of this committee, that you are entitled to be advised by legal counsel. Do you desire to be advised by counsel during your testimony today?

Let the record reflect that no one requested legal counsel.

In that case, if the witnesses already—have already stood, if you will raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. GRIFFITH. Thank you very much. You all may be seated.

I now recognize Dr. Tabak for 5 minutes to give an opening statement.

Dr. TABAK. Our clock is not resetting.

Mr. GRIFFITH. The clock isn't—he is right. We need more than 23 seconds for him.

[Laughter.]

Mr. GRIFFITH. I appreciate that. And all of you know the code of green, yellow, and red. Thank you.

Go ahead.

STATEMENTS OF LAWRENCE A. TABAK, D.D.S., PH.D., SENIOR OFFICIAL PERFORMING THE DUTIES OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH; ROCHELLE P. WALENSKY, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND ROBERT CALIFF, M.D., COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION

STATEMENT OF LAWRENCE A. TABAK, D.D.S., PH.D.

Dr. TABAK. Thank you, Chairs Rodgers, Griffith, and Guthrie, and Ranking Members Pallone, Castor, and Eshoo, and distinguished committee members. I am honored to be here today to dis-

cuss NIH's role in responding to COVID–19 and other public health threats.

Biomedical research supported by NIH enabled the rapid development of lifesaving vaccines, diagnostics, and treatments for COVID–19. While we take pride in these achievements, our work must continue. We are leveraging what we have learned from this pandemic to prepare for future threats.

Many of you will recall that we had shots in arms in less than 1 year, a record time for vaccine development. But I remind you that decades of research by thousands of scientists is what enabled us to rapidly develop COVID–19 vaccines in 2020. Prior to the pandemic, NIH-supported scientists spent years studying different coronavirus proteins to define potential therapeutic targets. Researchers learned how to stabilize a key surface protein found on coronavirus, the spike protein, so that it would optimally stimulate our immune system, and this forms the basis of the COVID–19 vaccines. Structure-based vaccine design, alongside novel vaccine platforms such as mRNA, are game changers for vaccine development. In fact, these same tools have us on the cusp of safe and effective RSV vaccines for key populations.

NIH is playing an important role in the administration's national biodefense strategy. For example, we are developing next-generation COVID–19 vaccines, including a nasal spray or mucosal vaccine that could do a better job of preventing infection and transmission of SARS–CoV–2, as well as pancoronavirus vaccines designed to provide broad protective immunity against emerging SARS–CoV–2 variants, as well as other coronaviruses with pandemic potential.

We are also working to shorten the timeline between a newly emerging pathogen and development of lifesaving products by studying prototype viruses within other viral families that have the potential to cause significant disease.

NIH has also played a significant role in speeding the development, scaling up, and delivery of COVID–19 diagnostic tests. In April 2020 we launched the Rapid Acceleration of Diagnostics, or RADx, initiative as a call for scientists and engineers across the Nation to bring their most innovative ideas to the table. RADx has helped produce over 5.8 billion COVID–19 tests and test products. Thanks in part to NIH's work, the 2020 refrain of "Where can I get a test?" is no longer heard. RADx efforts continue with a new focus on developing more accessible tests—for example, for people who are blind or have low vision.

NIH's work on COVID–19 is far from over. While most people recover quickly from COVID–19, some people experience long COVID, with ongoing or new symptoms beyond the acute phase of infection.

NIH began their Researching COVID to Enhance Recovery, or RECOVER, Initiative, to better understand Long COVID, and to identify effective treatments and potential ways for preventing it. This program brings together interdisciplinary researchers and patients. Advice from patients has guided the initiative goals and protocols. RECOVER is following a large cohort of children and adults at various stages of recovery from SARS–CoV–2 infection over time to gather data that will help us fill knowledge gaps such as under-

standing what makes some people, but not others, vulnerable to long COVID.

The program will also launch clinical trials in the coming months to evaluate whether certain interventions help improve outcomes for people with various Long COVID symptoms. The information gained from this initiative will help those whose lives have been upended by the lingering effects of COVID–19.

To close, the more we know, the better positioned we will be to respond to the next infectious threat. NIH's response to the COVID–19 pandemic shows that long-term investment in basic and applied biomedical research pays off.

Thank you for your time, and I welcome your questions.

[The prepared statement of Dr. Tabak follows:]

TESTIMONY

OF

LAWRENCE A. TABAK, D.D.S., Ph.D.
PERFORMING THE DUTIES OF THE DIRECTOR
THE NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
HEALTH AND OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEES
U.S. HOUSE OF REPRESENTATIVES

AN UPDATE ON THE ONGOING FEDERAL RESPONSE TO COVID-19; CURRENT STATUS AND FUTURE PLANNING

February 8, 2023

RELEASE ONLY UPON DELIVERY

Chairs McMorris Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and distinguished members of the Committee:

Thank you for the opportunity to discuss the role of the National Institutes of Health (NIH) in the response to emerging and re-emerging infectious diseases. NIH Institutes and Centers have played a central role in addressing coronavirus disease 2019 (COVID-19), and mpox (formerly known as monkeypox) by capitalizing on decades of basic, clinical, and applied research to facilitate the rapid development of vaccines, therapeutics, and diagnostics, which continue to be important tools to reduce the threat of these diseases. As the individual performing the duties of the NIH Director, I am pleased to discuss the ongoing and future NIH research to address COVID-19 and other critical public health threats.

For decades, NIH has been poised to quickly respond and develop medical countermeasures to combat these and many other emerging and re-emerging infectious diseases, including HIV/AIDS, SARS, influenza viruses with pandemic potential, and Zika. This requires researchers to think big. One such example is the President's Emergency Plan for AIDS Relief (PEPFAR). Led by President George W. Bush and launched 20 years ago, PEPFAR demonstrates what is possible when big ideas are pursued. Over 20 year later, PEPFAR programs are in more than 50 countries and have saved over 25 million lives. The work achieved by PEPFAR was instrumental in putting many communities on track for epidemic control and served as a platform to help combat recent disease outbreaks.

Leveraging the expertise of basic and clinical researchers allowed NIH to quickly address COVID-19 and mpox in a multifaceted manner, including through the evaluation of strategies for prevention and treatment.

Developing Vaccines to Prevent COVID-19

Sustained basic research investments by NIH over decades – prior to the emergence of SARS-CoV-2 – allowed the unprecedented pace of COVID-19 vaccine development. Longstanding National Institute of Allergy and Infectious Diseases (NIAID) support enabled the development of versatile vaccine platforms and the use of tools to visualize proteins including cryo-electron microscopy, and informed the design specific proteins—called immunogens—that powerfully stimulate the immune system. Prior to the COVID-19 pandemic, scientists at the NIAID Vaccine Research Center (VRC) and their collaborators made the critical scientific discovery of how to mutationally stabilize—in a highly immunogenic form—the spike

protein that coronaviruses use to infect human cells. This strategy facilitated the design of vaccine candidates that generate robust protective immune responses. As soon as the sequence of SARS-CoV-2 was made available in early January 2020, NIAID VRC researchers rapidly generated a stabilized SARS-CoV-2 spike protein for use in COVID-19 vaccine development. This crucial breakthrough in structure-based vaccine design led to the development of COVID-19 vaccine candidates, four of which are now authorized or approved by the U.S. Food and Drug Administration (FDA) for use in the United States, built upon a range of vaccine platforms including the highly successful mRNA platform. NIAID's pivotal clinical response enabled enrollment in the dose ranging study for the Moderna mRNA vaccine candidate within 60 days of antigen design.

Through fundamental research underlying the vaccine concepts and the establishment and utilization of an extensive and diverse clinical trials network, NIH helped advance the development of six candidate COVID-19 vaccines, including fulfilling the critical need for high-throughput validated testing of Phase 3 trial samples. As part of Operation Warp Speed, NIH supported the Phase 3 clinical trials for three of the vaccines that were made available for use in the United States: the mRNA-1273 vaccine, developed through a collaboration between the NIAID VRC and Moderna, Inc., the Ad26.COV2.S vaccine candidate from Johnson & Johnson/Janssen, and the NVX-CoV2373 vaccine candidate from Novavax. NIH also supported a Phase 3 clinical trial of the AZD1222 COVID-19 vaccine candidate from AstraZeneca. An NIH-supported Phase 3 clinical trial of the investigational SARS-CoV-2 adjuvanted recombinant protein vaccine from Sanofi/GSK is ongoing.

FDA-authorized and FDA-approved COVID-19 vaccines remain the most effective tools available to prevent COVID-19. However, we have seen that, with the continued emergence of new variants, protection against mild and moderate disease decreases over time following the primary vaccine series. NIH quickly established that boosting with the same vaccine that was used for the primary vaccine series could significantly increase levels of antibodies against variants, compared to levels in individuals who received the primary regimen alone. This "homologous" boosting has translated into increased protection against COVID-19. In addition, an NIH led study showed that boosting with a COVID-19 vaccine different than the one used for the primary vaccine series ("mix-and-match" or heterologous) was safe and prompted a robust immune response. Data from this study were evaluated by FDA in their decision-making to authorize the use of a mix-and-match approach to boosters for FDA-authorized or approved COVID-19 vaccines. NIH has

expanded the mix-and-match study to include evaluation of the Novavax COVID-19 vaccine as a heterologous booster vaccine, as well as to determine if the Moderna bivalent booster vaccine can elicit (and boost) mucosal antibody responses. Bivalent vaccines target two SARS-CoV-2 variants, in this case a component of the original SARS-CoV-2 strain and a component of the omicron strain.

Responding to Emerging Variants of SARS-CoV-2

To ensure patients receive effective vaccines and therapeutics, tracking the evolution of the SARS-CoV-2 virus and its impact on treatments is a critical need. Managed by the Foundation for the NIH, NIH was joined by its sibling agencies in the Department of Health and Human Services (HHS), including Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and FDA, as well as other government agencies to establish the public-private partnership Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). At NIH, ACTIV is led by NIAID, the National Centers for Advancing Translational Sciences (NCATS), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the Office of the Director (OD). ACTIV's Tracking Resistance and Coronavirus Evolution (TRACE) Working Group is tackling the challenge of tracking emerging SARS-CoV-2 variants. TRACE is following a multi-step approach to variant monitoring and data sharing which includes monitoring global emergence and circulation of SARS-CoV-2 mutations, charaterizing prioritized mutants, and rapidly sharing data with ACTIV and the scientific community.

The emergence of SARS-CoV-2 variants—some of which demonstrate increased transmissibility and an ability to partially evade the immune response from previous infection and/or vaccination—makes the authorized COVID-19 bivalent vaccines critical to help provide better protection. Relying on collaborative research to rapidly assess the effectiveness of vaccines, monoclonal antibodies, and antiviral drugs against SARS-CoV-2 variants, NIH continues to investigate ways to enhance protection afforded by COVID-19 vaccines and to understand the impact of SARS-CoV-2 variants on infection- and vaccine-induced immunity. NIH participates in the HHS-established SARS-CoV-2 Interagency Group (SIG) along with the CDC, FDA, BARDA, Department of Defense (DOD), and U.S. Department of Agriculture. The SIG tracks variants in real time to address the potential impact of emerging variants on critical SARS-CoV-2 countermeasures. NIH formed the SARS-CoV-2 Assessment of Viral Evolution (SAVE)

consortium in January 2021 as a critical data-generating component for the SIG and to facilitate rapid data-sharing with global partners and the scientific community. The SAVE program provides a comprehensive real-time risk assessment of emerging mutations in SARS-CoV-2 strains that could impact transmissibility, virulence, and infection- or vaccine-induced immunity. NIH remains on the cutting edge of science to end the pandemic. NIAID is currently supporting the development of next-generation COVID-19 vaccines that could provide broader protection against SARS-CoV-2 infection and disease caused by emerging SARS-CoV-2 variants.

Developing Diagnostics to Detect COVID-19

At the outset of the COVID-19 pandemic, there was an immediate need for diagnostic tests for SARS-CoV-2. Confronted with this challenge, NIH decided to take a novel large-scale collaborative approach to technology development. In April 2020, NIH launched the Rapid Acceleration of Diagnostics (RADx®) initiative. This was a call for scientists and engineers across the nation to bring innovative ideas to speed the development, validation, commercialization, and implementation of COVID-19 testing. At the forefront of this effort is the RADx® Tech program, which developed and deployed innovative COVID-19 testing technologies at an unprecedented speed and scale. RADx® Tech brought together over 900 experts from government, academic, and private industry to partner and produce over five billion tests and test products. Led by the National Institute of Biomedical Imaging and Bioengineering (NIBIB), they leveraged and expanded its well-established Point-of-Care Technologies Research Network (POCTRN) to design and manage the RADx® Tech Program. In addition, RADx® established the Independent Test Assessment Program (ITAP) to accelerate regulatory review and availability of high-quality, accurate, and reliable at-home COVID-19 tests to the public. RADx® researchers have obtained 49 emergency use authorizations (EUAs) from the FDA, including seven at-home tests supported by ITAP and one point-of-care multiplex test for COVID-19 and influenza that is supported by ITAP. To date, RADx® and ITAP have produced around 5.8 billion tests and test products for COVID-19. ITAP will be utilized for other infectious diseases.

RADx® Tech is focusing on developing the next generation of COVID-19 tests with a major focus on accessibility. Recently, RADx® Tech solicitated applications for an initiative to improve accessibility of COVID-19 tests for people who are blind or have low vision, have motor skills challenges, developmental challenges, and other populations who may have difficulty using rapid tests that are currently authorized. The RADx® framework facilitated significant

productivity from the entrepreneurial-minded bioengineering community that NIBIB supports. Based on this success, NIBIB is partnering with other NIH Institutes, Centers, and offices to apply the RADx® funding model to accelerate solutions to other biomedical problems.

Identifying Therapeutics to Treat COVID-19

Safe and effective therapeutics were urgently needed at the onset of the pandemic to treat patients with COVID-19. In record time, NIH worked quickly to evaluate promising therapeutics for COVID-19 in rigorous, randomized, controlled clinical trials.

In February 2020, before many Americans had realized the magnitude of the pandemic, NIH launched a multicenter, randomized, placebo-controlled clinical trial—the Adaptive COVID-19 Treatment Trial (ACTT)—to evaluate the safety and efficacy of multiple investigational therapeutics for COVID-19. Data from ACTT were critical for FDA approval of the antiviral drug remdesivir and the anti-inflammatory drug baricitinib for treatment of COVID-19.

In April 2020, NIH established the public-private partnership ACTIV to harness the collective scientific power of both public and private sectors and develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. ACTIV is focused on late-stage clinical trials investigating candidate drugs for outpatient and inpatient settings. ACTIV rigorously assessed data on more than 800 therapeutic agents and prioritized 33 of the most promising agents to be tested in randomized, placebo-controlled clinical trials. By developing and implementing multiple master protocols, which allow coordinated, efficient, and adaptive evaluation of potential therapeutic agents across multiple study sites, ACTIV has been able to nimbly test drug and biological candidates as they became available and to swiftly weed out those that do not demonstrate effectiveness. This work was aided by leveraging the existing Clinical and Translational Science (CTSA) Program clinical trial network led by NCATS. The CTSA Program showed the power of a nationwide clinical translational research network that could quickly develop and implement large, multisite trials testing potential treatments for COVID-19.

NIH also established the COVID-19 Treatment Guidelines Panel to provide recommendations to health care providers regarding specific COVID-19 treatments based on the best available scientific evidence. Each Treatment Guidelines section consists of recommendations developed by a working group of Panel members with expertise in the area addressed in the specific section. Each working group is responsible for identifying relevant information and

published scientific literature, and for conducting a systematic review of that information and literature. The Panel meets regularly to evaluate possible treatment options for COVID-19 and update the Treatment Guidelines as new clinical evidence emerges.

COVID-19 Going Forward

NIH continues to support research on COVID-19 vaccines in important at-risk populations, such as children and individuals who are pregnant or lactating or who are immunocompromised. NIH is engaged in efforts to understand the rare, but extremely serious, multisystem inflammatory syndrome in children (MIS-C) that has been associated with SARS-CoV-2 infection in children and adolescents. NIAID is supporting multiple studies to evaluate acute and long-term clinical and immunological aspects of MIS-C and SARS-CoV-2 infection in children. In addition, there is a trans-NIH effort to coordinate MIS-C research, the Collaboration to Assess Risk and Identify loNG-term outcomes for Children with COVID (CARING for Children with COVID). This effort supports data sharing across studies funded by multiple NIH Institutes to determine the spectrum of illness and predict long-term consequences of infection in children.

While most people recover quickly and fully from infection with SARS-CoV-2, some experience ongoing or new symptoms or other health effects after the acute infection has resolved; this syndrome is referred to as post-acute sequelae of SARS-CoV-2 infection (PASC) or Long COVID. In 2021, NIH launched the Researching COVID to Enhance Recovery (RECOVER) Initiative, a trans-NIH effort, co-led by NHLBI, the National Institute of Neurological Disorders and Stroke (NINDS), and NIAID, that includes targeted funding for research in this critical area. The wide scope of RECOVER is needed due to the complexity of Long COVID, as it leaves no tissue in the body untouched. At the heart of RECOVER is a longitudinal cohort study of children and adults, including pregnant individuals, at various stages of recovery from SARS-CoV-2 infection. This initiative is focused on ensuring a diverse patient population, with a particular focus on representing the communities hardest hit by COVID-19 in the clinical trials including rural communities. RECOVER is set to be the largest, most diverse, and deeply characterized cohort of Long COVID patients in the world. Clinical trials for all the cohorts are expected to launch in 2023. RECOVER has also focused on community and patient engagement since its inception. Patients have been involved at every step of the process, including the study designs and protocols to be used. RECOVER has the potential to enhance our basic knowledge of how humans recover from viral infections in general and is likely to improve our understanding of other

chronic post-viral syndromes and autoimmune diseases. This knowledge could help inform future pandemic preparedness.

In addition to the effects of Long COVID, there has been a significant impact on mental health during the COVID-19 pandemic. Research supported by the National Institute for Mental Health (NIMH) and others has confirmed much of what we knew based on prior research on disasters and epidemics. Through the course of the pandemic, the rates at which individuals report symptoms of depression, anxiety, substance use, and suicidal thoughts have all gone up. The demand for mental health services has also increased, especially amongst children. And the effects on our youth, though still not fully quantified, are substantial. These impacts have not been felt equally across American communities, with Black, Latinx, and other underserved communities as well as care practitioners and others on the front lines bearing the brunt of both the physical and mental health impacts of COVID-19.

Pandemic Preparedness Going Forward

Strategies for next-generation COVID-19 vaccines include targeting viral antigens that are highly conserved among SARS-CoV-2 strains, vaccinating with a broad array of viral antigens, and utilizing alternative routes of inoculation. In November 2022, NIAID held a workshop to explore the state of the science of SARS-CoV-2 mucosal immunity and the potential for the development of vaccines that induce mucosal immunity against SARS-CoV-2. Importantly, mucosal vaccine approaches target the site of SARS-CoV-2 infection and could potentially do a better job of preventing transmission of SARS-CoV-2. Although significant scientific gaps and challenges exist for mucosal vaccine development, multiple intranasal approaches are being pursued. Recent studies conducted by NIH scientists on two different nasal SARS-CoV-2 vaccine candidates showed encouraging results in animal models, suggesting intranasal approaches merit further study. NIH also is conducting research on pan-coronavirus vaccines designed to provide broad protective immunity against emerging SARS-CoV-2 variants as well as other coronaviruses with pandemic potential. Since 2021, NIAID has announced awards to seven academic institutions to conduct research to develop pan-coronavirus vaccines. One NIAID-supported vaccine candidate, which uses a nanoparticle-based approach, has been shown to induce broad neutralization of earlier SARS-CoV-2 variants and to protect animal models from multiple different SARS-related viruses.

The Administration's National Biodefense Strategy and Implementation Plan on

Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security establishes a bold series of targets for developing countermeasures against pandemic threats. NIH is playing a critical role in working towards those outcomes, including the ability to surge tens of thousands of diagnostics within 7 days, develop vaccines with 100 days, repurpose therapeutics within 90 days, and develop new therapeutics within 180 days of a future pandemic threat.

To achieve these goals, it is critical that we prepare for a range of viral threats that could cause future public health emergencies. There are 26 families of viruses that infect humans, many of which exhibit pandemic potential and for which we are far less prepared than coronaviruses and influenza. To support these goals, NIH's NIAID released a pandemic preparedness plan in 2021 to focus preparedness on two fronts. These efforts are designed to shorten timelines between pathogen emergence and authorization/approval of candidate products, such as vaccines and therapeutics. The first is to focus on prototype pathogens—viruses within viral families with the potential to cause significant human disease. This will be used as a framework for rapid research and product development for other viruses within that virus family should an outbreak occur. This was demonstrated by NIAID's earlier work on SARS-CoV-1 (the virus that caused the SARS outbreak in 2002) and MERS-CoV (the virus that caused the MERS outbreak, largely in the Middle East) that informed the rapid vaccine development for SARS-CoV-2. The plan's second focus is on priority pathogens—viruses already known to be capable of causing significant human illness (e.g., Zika virus) or death (e.g., Lassa virus).

In addition, NIH has already prioritized and accelerated the development of oral antivirals against potential pandemic pathogens by collaborating with BARDA to launch the Antiviral Program for Pandemics (APP). Within NIH, this effort is led by NIAID and NCATS. APP will accelerate the development of direct-acting antivirals targeting priority families of pandemic potential from discovery to early development. APP will focus on antivirals that directly act against viral targets, specifically for RNA viruses of pandemic potential such as *Coronaviridae* (including SARS-CoV-2), *Bunyavirales*, *Filoviridae*, *Flaviviridae*, *Paramyxoviridae*, *Picornaviridae*, and *Togaviridae*. A particular focus of APP is the discovery and development of drug candidates with suitable safety profiles for broad use in the outpatient setting, such as oral or intranasal administration at home. As part of APP, NIAID established nine multidisciplinary Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern with the goal of creating platforms that will target RNA viruses with pandemic potential, helping to better prepare

the nation for future viral threats. NIAID's pathogen approach to preparedness research was key in the development of a key countermeasure used against the mpox virus JYNNEOS™ (Imvamune or Imvanex). Mpox is part of the *Orthopoxvirus* genus, which includes the variola virus that causes smallpox. In the case of the mpox outbreak, basic research and countermeasures for a prototype pathogen within a given family of viruses were used to help treat and prevent a disease caused by closely related pathogens within that family.

In 2020, NIAID announced grants to establish the Centers for Research in Emerging Infectious Diseases (CREID) Network. The global, multidisciplinary network is focusing on emerging and re-emerging infectious diseases in high-risk regions. Research projects include surveillance studies to identify the animal sources or vectors of viral pathogens, and to determine what genetic or other changes make these pathogens capable of infecting humans. The breadth of research projects being carried out in the CREID Network will allow for study of disease spillover in multiple phases of the process, where pathogens first emerge from an animal host, where and when human-to-human transmission occurs, and how transmission is facilitated in urban areas. The work of the CREID Network has already shown to be critical with another emerging pathogen in 2022, mpox virus. CREID Network investigators are helping to strengthen mpox diagnostic capacity globally. Additionally, CREID Network scientists are developing a multiplex serological assay that will facilitate future mpox seroprevalence and surveillance studies of humans and animals in endemic regions. The CREID Network will enable early warnings of emerging diseases wherever they occur.

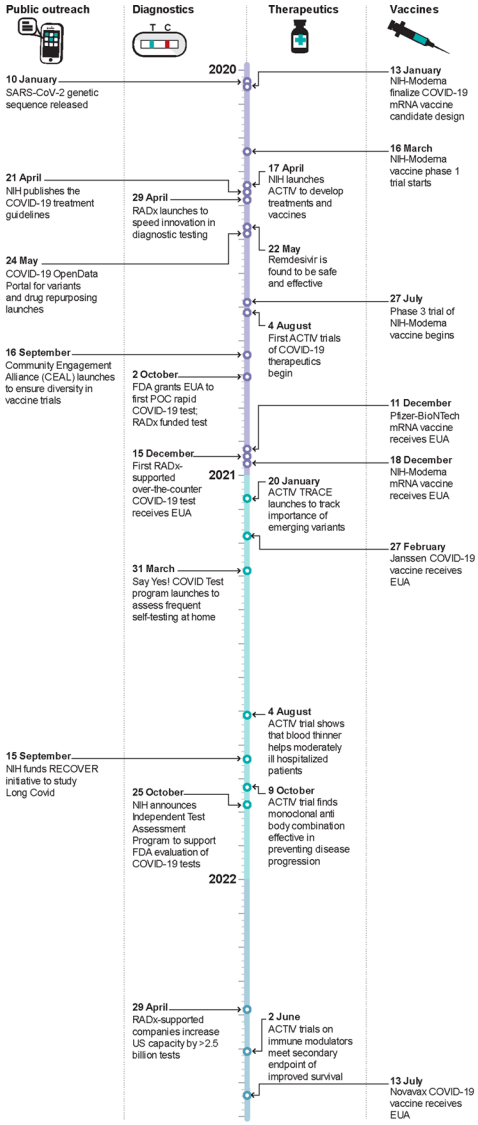
There are many lessons the global biomedical community, including NIH, have learned during past pandemics and the recent COVID-19 crisis. It is imperative that we take what has worked and apply it to other areas of research. One area that the COVID-19 response demonstrated weaknesses was that U.S. clinical trials should be better coordinated. We now have a good inventory of large-scale, well run, clinical trial networks to leverage for future health emergencies and public health needs. Through our ACTIV initiative, we found that having a consistent and connected infrastructure for clinical trials provides the foundation needed to respond quickly to any emerging disease. ACTIV benefited from the CTSA Program existing clinical trial network. In addition, NCATS developed the National COVID Cohort Collaborative (N3C), which was a secure data platform of harmonized, de-identified electronic health record data that was used to rapidly understand COVID-19. The importance of building partnerships and collaborations, using master protocols and harmonized data to ensure consistency, and a well-established clinical trial network

are strategies that NIH continues to expand to all areas of research to be better positioned to respond to the next pandemic.

We are already making significant progress on implementing this transformative agenda under the National Biodefense Strategy, which is so crucial to keep Americans safe from future biological threats from any source.

Conclusion

The more we know, the better positioned we will be to respond to the next pandemic. Sustained investment in NIH research, including basic biomedical science, has allowed the United States to respond to multiple public health emergencies. A robust understanding of the biology of infectious agents as well as a thorough understanding of immunology left the field well poised to move quickly. Additionally, the investments in enhancing infrastructure for clinical trials, developing master protocols, and establishing public-private partnerships have, and will continue to be, critical components of pandemic responsiveness. The ongoing work to begin to elucidate what the next viral threat may be will allow the biomedical community to quickly respond to the next emergent virus, in the same way that was done with COVID-19.



ACTIV, Accelerating COVID-19 Therapeutic Interventions and Vaccines; EUA, emergency use authorization; FDA, US Food and Drug Administration; NIH, National Institutes of Health; POC, point of care; RADx, Rapid Acceleration of Diagnostics; RECOVER, Researching COVID to Enhance Recovery; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; TRACE, Tracking Resistance and Coronavirus Evolution.

Mr. GRIFFITH. I thank the gentleman. I now recognize Dr. Walensky for her 5-minute opening statement.

STATEMENT OF ROCHELLE P. WALENSKY, M.D., M.P.H.

Dr. WALENSKY. Chairs Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and distinguished members of the committee, it is an honor to be with you today.

Today our Nation is in a much different position than we were at the start of the pandemic. Just 3 years ago, we were recording the first COVID–19 cases that sadly resulted in as many as 15 to 20,000 deaths per week. We were limited in treatments, and vaccines were not yet available.

Two years ago, we began the largest vaccination program in the history of this country, and along the way we have learned how to adapt to and manage an evolving virus. Thanks to 670 million vaccines administered in the United States and the work of those at CDC and thousands of Federal, State, local, and private-sector partners, and because of the more than 100 million infections Americans have endured and survived, we have built a wall of immunity and expanded the tools available to decrease the risk of severe disease and death from COVID–19.

This past week, hospital admissions and deaths are down, both nearly 9 percent, from the previous week. Though we have made remarkable progress, we also had nearly 3,500 deaths from COVID–19 in the last week. These are our family members, our neighbors, and friends, and colleagues. Their deaths are tragic and make it clear that we have more work ahead.

Entering the fourth year of our activated response to COVID–19, we are moving faster than ever to deliver information to the public. Just 3 months after the bivalent vaccine was recommended, CDC scientists published data on vaccine effectiveness against symptomatic infection, and 2 weeks later followed up with data on how well these vaccines work to prevent severe disease and hospitalization.

Only 1 month after we identified the latest subvariant, XBB 1.5, through our genomic surveillance, CDC published data to demonstrate that the bivalent vaccine was just as effective as it was against prior Omicron variants. These data continue to build on strong evidence that the best way to prevent severe disease and death from COVID–19 is to be up to date with your vaccines, including the bivalent vaccine.

Our increased speed is the result of an intentional and proactive effort to address both the challenges and opportunities at CDC. This is the work of CDC Moving Forward, an initiative I launched after an extensive agency review with internal and external input. We are focused on six key areas of improvement: sharing scientific findings and data faster; enhancing laboratory scientific—science and quality; translating science into easy-to-understand policy; prioritizing communications; developing a workforce prepared for future emergencies; and promoting results-based partnerships.

Two weeks ago, I announced a reorganization to reduce bureaucracy, break down silos, promote public health capabilities, and increase accountability. This strengthens the foundation of the agency to tackle our focus areas. But we know that moving boxes

around alone will not modernize CDC. We are equally focused on how we do our work, on our systems and processes internally.

For example, we reduced internal scientific review times by 50 percent and are publishing our science and data faster. We were the first in the world to produce and share data showing real-world performance of the JYNNEOS vaccine against mpox. We are investing in accessibility and communications, fostering clearer public health communications by rebooting the front door to CDC, streamlining content to make it easier for American people to find what they need. And we have established a CDC Ready Responder Program to better prepare CDC's workforce to engage at a moment's notice to future health threats, no matter where they work at CDC, and to sustain that engagement throughout a response.

We are committed to this work and more. But to maximize our potential and to fully protect the Nation's health, we also need critically important help from you in Congress.

Workforce authorities, such as strengthening student loan reimbursement authority, expanding danger pay to appropriately compensate our staff when put in harm's way, and providing flexibility to quickly move staff to respond to a threat would provide the opportunity to fully turn CDC into a response agency.

We need data authorities so that we can access better quality, standardized, and timely data so individuals and families can make informed decisions about their health and policymakers can better target resources and respond to threats.

CDC must be the most advanced and capable agency in the world when it comes to disease detection, tracking, and forecasting. Data authority coupled with investments in our data modernization initiative will make that possible.

I am committed to working with you to find common ground to support public health and to make strides toward achieving health security for all Americans. Thank you, and I look forward to your questions.

[The prepared statement of Dr. Walensky follows:]

TESTIMONY

OF

ROCHELLE P. WALENSKY, M.D., M.P.H.
DIRECTOR
CENTERS FOR DISEASE CONTROL AND PREVENTION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
HEALTH AND OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEES
U.S. HOUSE OF REPRESENTATIVES

AN UPDATE ON THE ONGOING FEDERAL RESPONSE TO COVID-19; CURRENT STATUS AND FUTURE PLANNING

February 8, 2023

RELEASE ONLY UPON DELIVERY

Chairs McMorris Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and distinguished members of the Committee, it is an honor to appear before you today to discuss the Centers for Disease Control and Prevention's (CDC) response to the COVID-19 pandemic, the lessons we have learned, and the steps we are taking now to strengthen our broader response capabilities.

COVID-19 Update

As I come before you today, I am pleased to report that we've made significant progress in our response to COVID-19. Today, the nation is in a different position than when we began our response to this pandemic. The rapid development and deployment of safe, effective, and life-saving COVID-19 vaccines has prevented millions of severe illnesses, hospitalizations, and deaths. Nearly 70 percent of the U.S. population have completed their primary series and more than 51 million updated bivalent booster doses have been administered.

As of the week of February 6, hospital admissions have decreased nearly 9 percent from the previous week, total weekly deaths are also down about 9 percent from the previous period, and our COVID-19 Community Levels show that 96 percent of counties have a low or medium level. While these are encouraging trends, with nearly 4,000 deaths from COVID-19 in the last week, we know there is more work to be done ahead.

CDC continues to track COVID-19 variants including the Omicron subvariant XBB.1.5 which has grown to be the dominant subvariant across the country. All other virus lineages are predicted to have very slow or no growth in proportion. CDC Nowcast projections for the week ending February 4 estimates that XBB.1.5 comprises about 66.4 percent (95 percent PI 59.8-72.5 percent) of cases nationally.

Tragically, more than one million Americans, including over 2,000 children (under the age of 18), have died from COVID-19 since the detection of the first case of the SARS-CoV-2 virus over three years ago. Nearly six million people have been hospitalized, and many more continue to suffer from post-COVID conditions ("long COVID"). Vaccinations and treatments continue to be the best protection against serious illness and death from COVID-19. Unfortunately, uptake of the new bivalent booster has been low. More than 50 million people have gotten an updated booster, but that is only 15 percent of the eligible U.S. population. Staying up to date on COVID-19 vaccines is critical because our data show that immunity decreases over time. This is particularly important for those over age 65, as they bear a disproportionate burden of the deaths from COVID-19 compared to other age groups. In December 2022, CDC published two different studies showing the effectiveness of the bivalent booster at preventing severe illness and hospitalization among both adults with competent immune systems aged ≥18 years and older adults aged ≥65 years. Additionally, these studies demonstrated the increased protection the bivalent booster provides for those with past monovalent vaccination only. CDC recently released a vaccine effectiveness study showing that bivalent COVID-19 vaccines add protection against symptomatic illness with Omicron XBB/XBB.1.5-related variants among people who previously received doses of the original COVID-19 vaccines. Vaccine effectiveness against symptomatic XBB/XBB.1.5-related infection was 49 percent among persons aged 18–49, 40 percent among persons aged 50–64 years, and 43 percent among those aged ≥65 years.

RSV/Influenza Update

In addition to sustaining the ongoing COVID-19 response, CDC identified and responded to early and elevated co-circulation of respiratory syncytial virus (RSV), influenza, and COVID-

19 in the fall of 2022 that placed significant stress on our health care systems. National trends in RSV activity currently indicate that the peak of seasonal activity has passed, and seasonal influenza activity continues to decline across the country. However, CDC remains vigilant and recommends that everyone six months and older get vaccinated against flu as circulation continues.

In the face of these ongoing outbreaks, we must remain committed to prevention. During the COVID-19 pandemic, we saw a concerning drop in routine immunizations for adults and children. For example, among kindergarteners, overall vaccination coverage dropped from 95% reported in the 2019-20 school year to 93% in the 2021-22 school year which means that there are nearly 250,000 kindergartners who may not be completely protected against measles alone. Routine vaccination is rebounding, but unevenly, and has not yet recovered among all groups, leading to localized outbreaks of measles and polio. While we continue to investigate the impact of the pandemic on routine immunizations, it is crucial that we take steps to help get everyone back on schedule.

Other Outbreaks Update

CDC confronted significant public health challenges in 2022 beyond COVID-19, influenza, and RSV. In May, CDC confirmed the first domestic case of mpox as part of a global outbreak and acted immediately to detect additional cases; educate clinicians and the public about a pathogen unknown to many that was transmitting in a novel way; and support state and local public health responses. CDC engaged our Laboratory Response Network and commercial partners from the beginning to establish robust, accessible diagnostic testing capacity and is working hand-in-hand with our HHS and state and local partners to distribute the JYNNEOS

vaccine from the Strategic National Stockpile to protect persons at increased risk. While we have been pleased to see a dramatic reduction in mpox cases from the outbreak's peak last summer, disparities in cases and vaccination rates persist. CDC's public health efforts have led to a significant reduction in cases, from early August 2022, when cases peaked with a 7-day average of 457 cases, to the end of January 2023, when the 7-day average was 3 daily cases – a decline in mpox cases of over 99%. CDC's public health work continues to promote equitable access to vaccine for those eligible and to guard against a resurgence in mpox cases in the future.

On September 20, 2022, the Ugandan Ministry of Health confirmed an outbreak of Ebola (Sudan virus) in central Uganda. CDC deployed multiple staff skilled in epidemiology, surveillance, laboratory, and ecology to Uganda, and worked in close collaboration with the Ugandan government, World Health Organization (WHO), and other partners to immediately respond to the threat. With our partners, we trained doctors, nurses, and community health workers, disease detectives and laboratorians. Together, we equipped laboratories and treatment centers. CDC's efforts with our partners ultimately helped extinguish the Ebola outbreak in under four months – an enormous accomplishment and relief, as there are currently no FDA-approved countermeasures for the Ebola Sudan virus. To prepare domestically, CDC engaged on a near-daily basis with state, local, tribal and territorial health partners, providers, the Ugandan diaspora, the Department of Homeland Security (DHS), and the agencies represented here today, throughout the outbreak to conduct entry screening and public health monitoring of travelers from the affected area, issue clinical guidance, and implement tabletop exercises to prepare states and other jurisdictional partners in the event of a domestic Ebola case. CDC's decades-long investments in developing strong public health collaborations and relationships with the Ugandan Ministry of Health were critical in facilitating the successful containment of

this outbreak, which was officially announced last month on January 11, 2023. CDC continues to be a recognized global leader on the forefront of advancing and strengthening global preparedness to prevent, detect, and respond to future outbreaks – and ultimately safeguard the health of the American people.

Moving Forward

Americans and people around the world rely on CDC to detect and respond to public health threats both foreign and domestic. For decades, CDC has been on the front lines of the public health response, providing assistance to states, tribes, territories, and local communities on the most pressing public health outbreaks and emerging issues within the United States and across the globe; threats such as H1N1, Ebola, Zika, opioid overdose, e-cigarette or vaping product use associated lung injury (EVALI), seasonal influenza, COVID-19, polio, mpox and others. This tireless dedication and commitment to response has saved countless lives by mitigating the spread of disease and preventing outbreaks before they start.

In addition to balancing the priorities of sustaining active ongoing responses to multiple outbreaks, concerted actions were initiated beginning in spring 2022 to address long-standing challenges highlighted during the COVID-19. I launched an extensive review of the agency's organizational structures, systems, and processes to strengthen its ability to deliver on its core mission to equitably protect the health, safety, and security of Americans. In August 2022, based on this review and other substantial internal and external input, I launched the CDC Moving Forward initiative which focuses on the following top improvement areas:

- Share scientific findings and data faster
- Enhance laboratory science and quality

- Translate science into practical, easy to understand policy
- Prioritize public health communications
- Develop a workforce prepared for future emergencies – CDC and nationwide
- Promote results-based partnerships

On January 24, 2023, I announced a CDC reorganization, one of several foundational steps to achieve progress in the improvement areas outlined above. This reorganization aims to eliminate bureaucratic reporting layers, break down silos in the agency, promote foundational public health capabilities, and improve accountability at CDC. For example:

- We are consolidating the work of two centers, the Center for Surveillance, Epidemiology, and Laboratory Services and the Center for State, Tribal, Local, and Territorial Support, into one new Center that will better support communication and engagement with jurisdictions and public health partners, and align investments to build a public health infrastructure and workforce for the future.
- We are elevating the Center for Preparedness and Response to the Office of the Director, creating a centralized office to promote greater accountability and operational excellence. The office will include data, modeling, and analytics capabilities and support for a response ready workforce across the agency.
- We are creating an Office of Public Health Data, Surveillance, and Technology, which is in the Office of the Director, to support data infrastructure improvements and connect all levels of public health to critical data needed for action.
- Reorganized the Director's Office of Communications to prioritize communication with the American public and improve the integration across CDC.

Parallel to the reorganization, my leadership team has engaged staff from across the agency on priority actions that will improve how we do our work. This work is ongoing, but I'm proud to say that CDC has already implemented numerous actions, including:

- Reduced scientific review clearance time for CDC publications by 50 percent;
- Initiated the CDC Infectious Disease Test Review Board, an internal group to promote quality assurance prior to national deployment of laboratory tests;
- Established process for institutions to submit applications for access to investigational drugs; reducing time required for institutions to apply from 14 days to 6 hours – utilized with tecovirimat for mpox; and
- Implemented executive leader performance plan changes that outline expectations for CDC leaders in response participation, data modernization, and scientific quality and timeliness.

New Authorities

As the CDC community tackles challenges internal to the agency, we also need support from our partners, particularly Congress, to support revised and new authorities so that CDC can be better prepared and respond to the next emerging disease.

Historically and today, CDC is often forced to rely on "work-arounds" within our existing authorities and policies to effectively meet operational and programmatic needs, especially when dealing with administrative challenges and unnecessarily burdensome processes in the lead up to or during public health emergencies, when time is of the utmost essence. The COVID-19 pandemic and other outbreaks have only underscored how much these challenges have hampered the agency and continue to do so. If CDC is to play a key role in rapidly detecting pathogens to

ensure all levels of government are ready to respond to biological threats as envisioned in the new National Biodefense Strategy and Implementation Plan, these gaps must be addressed.

We have identified flexibilities and authorities that are critical to the agency's ability to be more effective and responsive during fast moving, large-scale public health outbreaks, and we can only achieve these in partnership with Congress. These proposals fall under two broad categories: 1) operational readiness and 2) strengthening workforce capacity. On their own, these proposals are not likely to be sufficient to change how CDC responds to the next emerging threat. However, taken together, they offer a roadmap to provide the tools and resources CDC needs to better prepare for, and respond to, the next emerging public health threat, whether from a local outbreak or a global pandemic. I have highlighted examples of a few authorities below and welcome continued discussion on ways to strengthen CDC to protect our national security through public health.

Data

Data must serve as the foundation for everything we do, particularly in the context of a public health emergency response where critical decisions on where and how to target interventions must be made quickly. Having timely, high-quality data on where disease is spreading, the severity of illness, and the populations most impacted is a critical element of operational readiness. It allows state and local public health and other health care professionals, and policy makers to target resources to mitigate an outbreak and predict future spread. We are grateful that Congress has authorized and funded CDC's newest center, the Center for Forecasting and Outbreak Analytics, to improve the nation's ability to prepare for and respond to public health threats using data, modeling, and analytics. But if CDC must continue to rely on a decentralized framework for data reporting, subject to a patchwork of individually negotiated

Data Use Agreements, we will not be able to provide the best forecasts and modeling in the world.

Where we can, we are making improvements on sharing data. CDC's Center for Forecasting and Outbreak Analytics delivered four technical reports on the mpox outbreak. These reports are publicly available, have been shared widely, and provided timely updates on CDC's response to the outbreak, including our estimates of the trajectory of the outbreak. These reports were developed at the speed of the outbreak, to get the best information we had out to decision makers quickly. We included qualitative risk assessment information in these reports to deliver the bottom line up front while also making it clear the level of confidence we have in our analyses.

The way in which public health data are collected and shared has resulted in fragmented and inconsistent reporting to CDC, and to state and local public health partners. To address this issue and support more comprehensive data sharing, CDC will need updated legislation providing public health data authority for CDC to support decisions at the federal, state, and local levels, while reducing burden on providers. For example, authority included in the Coronavirus Aid, Relief, and Economic Security (CARES) Act to require COVID-19 laboratory test reporting during the Public Health Emergency (PHE) has greatly improved the availability of laboratory data. However, this authority included in the CARES act was limited to COVID-19 laboratory testing and only lasts until the end of the current PHE. It does not help CDC gather data on other infectious diseases and conditions or during future emergencies.

Vaccines For Adults (VFA)

Unlike the public health infrastructure that exists for children to receive recommended vaccines from their pediatricians, no such infrastructure exists for adults. In response to the COVID-19 pandemic, CDC built infrastructure to rapidly deploy safe and effective vaccines to the entire US population. A Vaccines for Adults (VFA) program would provide uninsured individuals access to Advisory Committee on Immunization Practices (ACIP)-recommended routine and outbreak vaccines at no cost. Establishing a robust infrastructure for adult vaccination will support response readiness by reducing vaccination coverage disparities, improving outbreak control of vaccine-preventable diseases, and enhancing and maintaining the infrastructure needed for responding to future pandemics.

Strengthening Workforce Capacity

In addition to operational improvements, CDC needs a workforce that is nimble and response ready. CDC is enhancing its work to better prepare and coordinate staff across the agency ahead of emergency events to ensure they are ready for response roles when and where needed. However, CDC needs additional operational authority to implement policies to address issues such as overtime pay caps, danger pay, loan repayments, and other flexibilities that enable CDC to rapidly respond to urgent public health needs. These authorities would greatly improve CDC's workforce capacity.

Conclusion

In conclusion, CDC is taking the necessary steps through our Moving Forward initiative to drive needed changes in the operations, incentives, and structure of the organization to address longstanding challenges and fully meet the public health needs of the American public today and in the future. Yet, to fully enable CDC to better prepare for, and equitably respond to, the next emerging public health threat, the agency needs the same or similar support, flexibilities, and

authorities as other federal response agencies. We must look for opportunities to apply lessons learned and advance bipartisan solutions to be better prepared for future public health challenges. Congressional action to support these proposals will improve how CDC responds to future emerging threats and will support the agency's modern-day mission. I look forward to working together to implement the solutions that will make this agency - the work of which is so critical to America's health - and our partners at the state, local, tribal, and territorial level, better prepared for what comes next.

Thank you, and I look forward to your questions.

Mr. GRIFFITH. I thank you and now recognize Dr. Califf for 5 minutes for his opening statement.

STATEMENT OF ROBERT CALIFF, M.D.

Dr. CALIFF. Good morning, Chairs Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and members of the subcommittees. Thank you for the opportunity to be here today to update the American people on our COVID–19 response. FDA appreciates your partnership in ensuring our country overcomes this pandemic and in preparing for future threats.

This pandemic underscores the importance of a swift and agile response coordinated across all levels of government and in collaboration with the private sector. While the pandemic has caused great loss across our Nation, through extensive communication, dexterity, and innovation, we have been able to mitigate the impact of the pandemic and prevent innumerable illnesses and deaths.

Most unfortunately, the proven effectiveness of authorized and approved vaccines and therapies have been undercut by a constant flow of misinformation, causing many Americans to forgo lifesaving treatments, leading them to many unnecessary deaths and hospitalizations. Nevertheless, FDA employees have poured their efforts into COVID–19 response to protect the American people. I am grateful for their tremendous work, and to Congress for your support of these efforts.

I want to provide a brief update on FDA's efforts related to COVID–19 medical products.

First, vaccines. Currently, there are three authorized monovalent vaccines, two approved vaccines, and two bivalent vaccines that meet FDA's expectations for safety and effectiveness. The current vaccines reduce the risk of contracting symptomatic infection and remain highly effective at preventing serious clinical outcomes associated with SARS–CoV–2 infection, including hospitalization and death. Staying up to date on COVID–19 vaccination is the best thing Americans can do right now to protect themselves and their families from the risk of becoming seriously ill or dying from COVID–19.

Second, diagnostic tests. FDA remains focused on speeding the process to get appropriately accurate and reliable tests in the hands of all Americans who want one. The agency prioritized at-home tests since the beginning of the pandemic, authorizing 30 over-the-counter at-home tests, resulting in hundreds of millions of additional tests available monthly to American consumers. Importantly, the agency has also detected numerous and accurate tests that would have done substantial harm if allowed to have unfettered access to the market.

FDA also continues to issue EUAs as appropriate for other types of devices and facilitates the availability of critical devices and supplies. Today we have issued EUAs or provided traditional marketing authorizations to over 2,800 medical devices for COVID–19, which is 15 times more EUAs than all other previous emergencies combined.

Third, we continue to expand the country's arsenal of COVID–19 therapies and have facilitated the development and availability of

three approved drugs to treat COVID–19, and EUAs for 14 therapies.

It is also important to note our critical supply chain work, which has protected consumers by preventing medical products that do not meet import requirements from entering the country. This includes continuously surveilling the medical product and food supply chains for potential shortages, disruptions, and contaminated or fraudulent products, with focused examinations on COVID–19 relief supplies.

The agency remains committed to continuing the use of every tool available to us to continue to mitigate the threat of this virus and others that we have simultaneously worked to counteract, such as mpox, RSV, and pandemic influenza. Many of these tools are thanks to the work of Congress and your understanding of the importance of preparation and addressing the needs of our supply chain before an emergency strikes.

FDA employees are anything but complacent, and they will continue to work to make sure that we are even more equipped to address any future threats. Preparing for future emergencies depends on using the many strategies that led to a successful response, as well as the establishment and refinement of authorities and flexibilities that allow the agency to identify and mitigate risks while promoting innovation outside the public health emergency.

It is essential that we improve our system for evidence generation. That is, doing the right clinical trials and having access to the data that Dr. Walensky has brought up. For example, the COVID–19 pandemic also underscored the importance of both diagnostic test access and test accuracy, and the critical need for a modernized regulatory framework that applies to all in vitro diagnostics. After years of collaborative work, including with leaders of this committee, we believe the VALID Act would achieve this goal, and is appropriately balanced. Modernized authorities would enable us to act faster, prevent problems, and allow for greater insight into FDA's regulated products for greater safety.

We look forward to continuing working with you to ensure a continuation of our COVID–19 response success and future readiness. Thank you, and I look forward to your questions.

[The prepared statement of Dr. Califf follows:]

TESTIMONY

OF

ROBERT M. CALIFF, MD
COMMISSIONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON HEALTH
AND
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

THE FEDERAL RESPONSE TO COVID-19
FEBRUARY 08, 2023

RELEASE ONLY UPON DELIVERY

Introduction

Chairs McMorris Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and distinguished members of the Committee, thank you for the opportunity to testify before you to discuss the Food and Drug Administration's (FDA's or the Agency's) coronavirus disease 2019 (COVID-19) response and our preparedness efforts moving forward. Our efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the federal government, to help facilitate the development, authorization, licensure, approval, and availability of critical, safe, and effective medical products to address current and future threats.

The COVID-19 pandemic underscores the need to continue to optimize our preparedness and response capabilities. The Agency's continued preparedness for, and capabilities to respond to, public health emergencies and disease threats such as COVID-19, mpox, respiratory syncytial virus and pandemic influenza have been strengthened by Congress' support of our work. We look forward to continuing work with you this Congress to ensure future readiness.

COVID-19 response efforts

This testimony is just a snapshot of the Agency's extensive work to address this pandemic. From the beginning of this public health emergency (PHE), FDA has taken a leadership role in the all-of-government response and continues to focus on facilitating the development and availability of medical countermeasures to diagnose, treat, and prevent COVID-19; surveilling the medical product and food supply chains for potential shortages, disruptions, and contaminated or fraudulent products; and helping to mitigate or prevent such impacts. FDA is committed to continuing to use every tool in our toolbox to fight this pandemic, including pivoting as the virus adapts, to arm ourselves with the best available medical countermeasures to fight this virus.

Data show the current vaccines remain highly effective at preventing serious clinical outcomes associated with SARS-CoV-2 infection, including hospitalization and death. Staying up to date on COVID-19 vaccinations is the best thing Americans can do right now, in addition to other precautions, to help protect themselves and their families.

Biologics, Including Vaccines: FDA's Center for Biologics Evaluation and Research (CBER) continues to facilitate the development and availability of vaccines and other biological products to combat the COVID-19 pandemic expeditiously and safely. Through our transparent scientific evaluation, FDA has issued Emergency Use Authorizations (EUAs) for four monovalent COVID-19 vaccines: the Pfizer-BioNTech COVID-19 Vaccine for use in individuals six months of age and older; the Moderna COVID-19 Vaccine for use in individuals six months of age and older; the Janssen COVID-19 Vaccine for use in certain individuals 18 years of age and older; and the Novavax COVID-19 Vaccine, Adjuvanted for use in individuals 12 years of age and older. FDA has also approved Comirnaty (known as Pfizer-BioNTech COVID-19 Vaccine under the EUA) for use in individuals 12 years of age and older and Spikevax (known as the Moderna COVID-19 Vaccine under the EUA) for use in individuals 18 years of age and older. Additionally, FDA has authorized two COVID-19 vaccines that have a bivalent composition (original and Omicron BA.4/BA.5) as a booster dose: Pfizer-BioNTech COVID-19 Vaccine, Bivalent; and Moderna COVID-19 Vaccine, Bivalent. Pfizer-BioNTech COVID-19 Vaccine, Bivalent was also authorized as a third dose in the 3-dose primary series in individuals six months through four years of age. On January 26, 2023, FDA held a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to consider whether and how the composition for primary doses of the currently available COVID-19 vaccines should be modified and how and whether the composition and schedule for booster doses should be adjusted moving forward. By a unanimous vote, the committee recommended harmonizing the vaccine strain composition of primary series and booster doses used in the United States to a single composition, e.g., the composition for all vaccines administered currently would be a bivalent vaccine (Original plus Omicron BA.4/BA.5.).

We have relied on the Agency's rigorous standards for safety, effectiveness, and manufacturing quality. These COVID-19 vaccines were developed without cutting corners or compromising our regulatory and scientific standards. As part of each EUA, manufacturers and vaccination providers are required to report certain information, including serious adverse events, even if it is unclear whether the vaccine was the cause, including those that result in hospitalization or death to the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program jointly run by FDA and the Centers for Disease Control and Prevention (CDC). Vaccine safety is a top priority for the federal government, and we take reports of health

problems following COVID-19 vaccination very seriously. FDA and CDC have implemented a coordinated and overlapping approach for continuous safety monitoring of all COVID-19 vaccines using state-of-the-art technologies.

Drug Products: FDA's Center for Drug Evaluation and Research (CDER) continues its successful work to facilitate the development and availability of diverse therapeutics for use by patients, physicians, and health systems. FDA accelerated the development and publication of guidance and other information for industry and researchers on developing COVID-19-related treatments. Further, FDA created an emergency review and development program for possible therapies for COVID-19, the Coronavirus Treatment Acceleration Program, or "CTAP." Under CTAP, FDA is using every available authority to facilitate the development of safe and effective products to treat patients with COVID-19. As of January 22, 2023, there are more than 720 drug development programs in the planning stages and the Agency has reviewed more than 440 trials of potential therapies for COVID-19.[1] These therapies include antivirals, immunomodulators, neutralizing antibodies, and combinations of these products, as well as cell and gene therapies regulated by CBER. The diversity of therapeutic approaches being investigated rapidly expands our understanding of the effect of different categories of potential treatments. As of January 22, 2023, FDA has approved three drugs to treat COVID-19 and there are currently fourteen EUAs for COVID-19 therapies.

Medical Devices: FDA's Center for Devices and Radiological Health (CDRH) has also worked to meet the unprecedented demand for medical devices including tests, personal protective equipment (PPE), and ventilators, while continuing to fulfill the Center's mission to protect public health and facilitate medical device innovation.

CDRH staff also utilized vital EUA authorities and interacts frequently with test developers and other device manufacturers through the pre-EUA process, including through rolling reviews to further expedite emergency use authorization of critical medical devices. This interaction included working closely with these developers and adapting CDRH's policies to addressing public health needs, as those needs changed. These efforts resulted in increased testing capacity and broadened public access to rapid tests, including those purchased over-the-counter (OTC), as well as assuring access to other critical devices. CDRH prioritized at-home tests since the

[1] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

beginning of the pandemic, authorizing 30 OTC at-home tests, resulting in hundreds of millions of additional OTC tests available monthly to American consumers. Since January 2020, FDA has engaged with over 1,000 developers and authorized over 443 tests.

CDRH continues to issue EUAs as appropriate for other types of devices and has taken various actions to help facilitate the availability of critical devices and supplies for health care providers and patients. To date, we have issued EUAs or provided traditional marketing authorizations to over 2,800 medical devices for COVID-19, which is 15 times more EUAs than all other previous emergencies combined. In total, CDRH has reviewed 510(k)s for and cleared over 1,900 devices that can be used for COVID-19 and certain similar diseases, including future pandemics. CDRH also issued 28 guidance documents (as well as 21 revisions) outlining policies to help expand the availability of medical devices needed in response to COVID-19.

As we look to transition from the COVID-19 PHE to normal operations, FDA has worked on guidances[2] for transitioning devices that fall within enforcement policies issued during the COVID-19 PHE or that received EUAs to help facilitate a clear and predictable path to market for interested developers. FDA intends to facilitate continued access to devices for patients and health care providers during the transition and while marketing submissions are under review.

Human and Animal Food: As a key part of FDA's mission, a safe and accessible food supply is critical to the health and well-being of families across the United States. As such, FDA has worked with federal, state, local, and industry partners to help ensure a safe and adequate food supply for humans and animals. We have seen that the broad supply chain imbalances impacting so many products are also impacting food, including infant formula, for which COVID-19 had caused supply chain tensions well in advance of the February 2022 recall of certain Abbott infant formulas. To help mitigate the shortage, FDA worked to facilitate the importation of millions of cans of infant formula. Overall, food production and manufacturing in the United States has been remarkably resilient, but we continue to monitor the food supply and apply mitigation strategies for products impacted in part by pandemic-related issues.

In response to the pandemic, FDA's Foods Program developed *21 Forward*, a food supply chain data management tool, to help identify where risks for interruptions in the continuity of the food

[2] https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023

supply may be greatest. As part of this tool, FDA conducted targeted outreach to the food industry to offer additional resources and technical assistance in addressing challenges, including monitoring and supporting the infant formula supply chain.

Imports, Inspections, Compliance and Protecting the Medical Supply Chain: Throughout the pandemic, import investigators have been on site protecting the medical supply chain at our ports of entry, courier facilities, and the international mail facilities (IMFs), with uninterrupted support from the Office of Regulatory Affairs (ORA) laboratories. Through continued vigilance, FDA has helped prevent pharmaceuticals and other medical products that do not meet import requirements from entering the country. Since March 2020, with the cooperation of and in coordination with U.S. Customs and Border Protection, FDA has refused and destroyed more than 148,904 drug products, totaling over 28,521,139 capsules, tablets, and other dosage forms of violative drugs shipped via international mail. FDA has maintained pre-pandemic levels of screening for products offered for import and refused approximately 202,746 medical product lines offered for import. FDA has focused examinations on COVID-19 relief supplies to ensure that reviews of compliant products are expedited while maintaining our commitment to refusing medical products that appear to be misbranded, unapproved, counterfeit, or otherwise violative.

Throughout the pandemic ORA continued to conduct mission critical foreign and domestic inspection and investigations including those in support of EUAs for critical medical countermeasures (MCMs) as well as to ensure the quality and availability of medical products. Since October 1, 2021, FDA has been performing domestic inspections at normal operational levels and in April 2022 began to conduct foreign facility inspections, including surveillance and other inspectional work. As FDA works through the inventory of postponed surveillance inspections, the Agency is prioritizing higher-risk establishments. The ORA inspectorate also continues to partner with foreign regulators to conduct inspections and share information to increase global access to medical products.

FDA's Public Health Emergency Preparedness and Response Mission

The Administration's National Biodefense Strategy and Implementation Plan on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security describes in detail a set of transformative capabilities the U.S. government aims to build to defend against future pandemics and biological threats. These include the capability to develop

and safely deploy medical countermeasures against novel pathogens much more rapidly than is possible today. These capabilities will require additional resources and scientific breakthroughs. FDA is playing a key role in this effort, to ensure that medical countermeasures can be rapidly and rigorously validated to ensure their safety and efficacy for pandemic response.

The COVID-19 pandemic underscores the importance of a swift and agile response coordinated across all levels of government and in collaboration with the private sector. Through effective communication, dexterity, and innovation, we were able to mitigate the impact of the pandemic and prevent innumerable illnesses and deaths. Preparation for future PHEs depends on utilizing the many strategies that led to a successful response as well as the establishment and refinement of authorities and flexibilities that allow the Agency to identify and mitigate risks while promoting innovation. This includes continuing to proactively leverage existing relationships with entities outside of FDA in emergency response situations. For example, FDA leveraged an ongoing partnership with U.S. veterinary diagnostic laboratories to strengthen COVID-19 testing at the height of the COVID-19 pandemic. In ordinary times, this partnership, the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), helps the U.S. animal health infrastructure rapidly respond to animal health incidents, but during the critical need for COVID-19 testing, it successfully increased capacity to accurately test both human and animal samples for COVID-19. FDA's capacity to drive future PHE responses depends on maintaining and further building collaborations with regulatory, academic, and industry partners even in the absence of a crisis.

Facilitating Access to Safe and Effective Medical Products

As FDA prepares to combat future pandemics, assuring access to safe and effective medical products continues to be of utmost importance. Several areas can provide support in this mission.

Drug Product Supply Chain

The COVID-19 pandemic served as a reminder that the drug supply chain is extremely vulnerable to supply disruptions and surges in demand. Prior to this pandemic, most shortages were due to manufacturing issues that disrupted supply, for which manufacturers of drugs and active pharmaceutical ingredients (API) are required to notify FDA. This notification requirement provides FDA more time to mitigate or prevent a shortage, and the Agency used this

authority often during the pandemic to prevent supply disruptions. However, during the pandemic we also saw unprecedented *demand* for drugs for which the Agency cannot require notifications.

Looking to future preparedness, and in accordance with the National Strategy for a Resilient Public Health Supply Chain, it is critical for the U.S. government to have visibility into the end-to-end supply chain data access. We believe there are several areas where Congress could build on our current authorities to improve our visibility into the supply chain, strengthen our ability to oversee the drug supply chain, and ensure continued access to critical drug products. As noted, the ability to require drug manufacturers and distributors to report surges in demand to FDA could help the Agency prevent or mitigate shortages, including their severity and impact on patients. Additional improvements in the drug supply chain include:

- Requiring labeling of bulk drug substances to include the original manufacturer and labeling of finished drug products to include additional supply chain information to help identify sources of APIs, thereby providing greater insight into the supply chain; and
- Enhancing information that manufacturers must report, including the suppliers they relied on to manufacture the listed drug and the extent of such reliance, to provide more complete supply chain insight. Having this information would allow the Agency to work more proactively to diversify the supply chain and reduce the risk of shortages.

Finally, as more manufacturers enter the vaccine and biotherapeutics industries and as we face future pandemics, a robust response by ORA's inspectorate will depend on operational readiness and surge capacity. For example, FDA could achieve more effective and efficient oversight through enhanced authorities for conducting remote regulatory assessments. This could include explicitly extending the ability to request records or other information, in advance of or in lieu of inspections, to all FDA-regulated products, as well as authorizing mandatory remote interactive evaluations. Congress recognized these authorities were key to future preparedness in the fiscal year (FY) 2023 Omnibus by expanding FDA's authority to request records and other information, in advance of or in lieu of an inspection, to devices and to sites or facilities subject to bioresearch monitoring inspections. However, the Agency could achieve even greater regulatory compliance if this records request authority were expressly extended to all FDA-regulated products. Critical investments in this space also include increasing the inspectorate's

workforce capacity for oversight of medical products and funding training and continuing education of the inspectorate's workforce.

Medical Device Supply Chain and Safety

Shortages: In the COVID-19 pandemic, CDRH has worked with manufacturers, health care providers, suppliers and our U.S. government partners to mitigate over 350 reported medical device shortages, which equates to thousands of medical devices. Using the new device shortages authority we received through the CARES Act, we were able to facilitate device availability for patients across the United States. This is a vital authority, as our most vulnerable populations are those most often impacted the greatest by critical device shortages.

Based on our experience with this pandemic, as well as with shortages and supply chain disruptions that occur outside a PHE, we believe the public health would benefit from removing the temporal limitation in statute that only requires manufacturers to notify FDA about interruptions or discontinuances in the manufacture of certain devices *during or in advance of a PHE*. The FY2023 Consolidated Appropriations Act (FY23 Omnibus) added voluntary notifications from manufacturers about certain device discontinuances or disruptions, but an effective device supply chain program requires a more comprehensive and consistent flow of information between manufacturers and FDA, similar to what is required for drug products. Without this, the Agency remains limited in its ability to collect information that can mitigate or prevent medical device shortages, protecting U.S. patients and health care providers.
Critical shortages occur in many situations that are outside of or unrelated to PHEs, including natural or human-made disasters, recalls, geopolitical conflict and production shutdowns, and cybersecurity incidents, among other triggering events for which device shortages can still significantly impact patient care. Furthermore, by the time there is an emergency, it is often too late to mitigate or prevent shortages. For example, supply chain disruptions began even before COVID-19 cases were identified in the United States, as other nations had outbreaks and needed PPE, testing supplies, and other equipment in excess of supply.

Another important aspect of supply chain preparedness are risk management plans. The ability to require a risk management plan for critical devices would help ensure manufacturers have plans in place to ensure resiliency and mitigate future supply chain disruptions. COVID-19 showed us that manufacturers are not always prepared for situations where their ability to manufacture

product may be disrupted or may be insufficient to meet increases in demand, especially where they are dependent on one source for a critical raw material or component that was in shortage. Risk management planning that occurs even outside of an emergency will result in greater resiliency in the critical device supply chain.

In Vitro Diagnostics: The past few years have also highlighted the critical need for a modernized regulatory framework that applies to all in vitro diagnostics. The COVID-19 pandemic underscored the importance of both test access and test accuracy. Beyond COVID-19, tests are used for many different purposes and are based on many different types of technologies, and they are becoming increasingly important to our entire health care system. According to CDC, 70 percent of health care decisions are based on clinical lab test results.[3] Some of those tests are the sole determinant of a patient's treatment. A modern oversight framework that is specifically tailored to assuring tests work is critical to position ourselves for the future – whether it is to prepare for the next pandemic or to realize the full potential of diagnostic innovation.

Such a system can balance innovation with assurance of accuracy and reliability for tests. For example, a technology certification approach could provide assurances for most tests without individual FDA review of the tests. These assurances are critical. We have seen many examples of tests that do not work – from COVID-19 tests submitted during the pandemic, to tests that are the sole determinant of which treatment a cancer patient receives. In particular, we are concerned that there may be inaccurate laboratory developed tests, or LDTs, in use today.[4] This puts patient health at risk, undermines our health care system, and hinders the country's ability to effectively address PHEs.

We look forward to continuing our work with Congress and stakeholders to create a modern framework for all tests and to strengthen supply chain authorities. In the meantime, we intend to move forward using our current regulatory authorities to offer providers and patients confidence in the diagnostic tests that they use.

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[3] https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html#print

[4] For example, see: Case studies of 20 LDTs that may have caused patient harm (http://wayback.archive-it.org/7993/20171114205911/https:/www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm472773.htm) and FDA's analysis of 125 EUA requests for COVID-19 tests from labs that found 66 percent were not designed or validated appropriately (https://www.nejm.org/doi/full/10.1056/NEJMp2023830).

Overseeing Products Critical to Public Health and Fostering Medical Countermeasure Development

We have also seen that during a PHE or a supply disruption that other critical products can have immense impact on families, as we saw in the infant formula shortage. Preventing food shortages is critical to public health and we are grateful that Congress included a provision in the FY23 Omnibus to require manufacturers of infant formulas and certain medical foods to notify FDA of potential shortages. Looking forward, parallel authority to require notifications of anticipated interruptions in the supply chain of additional categories of foods designated by FDA during a declared PHE could help prevent future shortages in the food supply.

Further, enhancing FDA's regulatory capabilities and readiness to respond to emerging pathogens, ensure blood safety and availability, and expeditiously review new vaccines, existing vaccines and other medical products, is vital to the Agency's continued success in PHE preparation and response. Our staff have had to be pulled off other work and have been working relentlessly on pandemic issues for the past three years, leading to a significant backlog and fatigue. During COVID-19 we have seen that FDA staff need to be prepared to continue to address the current pandemic needs while also preparing for potential future pandemics and staying on top of our daily work to ensure blood safety and availability and regulate vaccines and other medical products. Through the creation of a specialized program within CBER to defend against emerging pathogens, the Agency would be well positioned to respond to identified threats of concern and focus experienced resources to work quickly on MCM development to address these concerns. In consultation with HHS partners, the program could: provide recommendations and guidance to developers of vaccines and other medical products and relevant federal partners; use real-world data or real-world evidence to study the safety and effectiveness of products for addressing biological incidents and identify which products may be best suited for specific pathogens or for use in different populations; and facilitate product development including advances in manufacturing. It could also support scientific research within CBER that contributes to development and review of biological products to counter biological incidents and emerging pathogens.

FDA's ability to monitor the safety of vaccines would also benefit greatly by a coordinated federal public health data reporting authority. Through the Biologics Effectiveness and Safety (BEST) Initiative, part of the FDA Sentinel Initiative, FDA can analyze information occurring in

millions of health insurance claim submissions or electronic health records (EHR) recorded in large data systems. FDA's contractors assist with this program and analyze the data itself behind their firewall as part of data privacy protections. While the BEST Initiative has been essential for our work and provided us with a robust picture of safety data, our ability to analyze claims information is limited by the fact that some vaccinations are not recorded in health insurance claims data. Further, when insurance claims databases or EHRs detect an adverse event, FDA often needs to quickly verify information or access additional information to evaluate the adverse events of interest. When we request records to verify adverse events detected by the BEST Initiative databases it has taken FDA around 8-12 weeks in some cases to receive voluntary access to these records. Additionally, coordinated federal public health data reporting authority would help the Agency to more swiftly identify adverse event patterns and trends associated with the use of vaccines or other MCMs, and swiftly be able to communicate with health care providers and patients about safety signals.

Finally, across all these areas, FDA's partnerships with state, local, and U.S. territorial governments continue to play an important role in the protection of public health, particularly as FDA partners with them in the regulation of products, helping to ensure the safety and integrity of supply chains, and assisting in enforcement against products that are being unlawfully sold. Allowing for disclosure of non-public information to these agencies with complementary functions related to FDA-regulated products could achieve faster and more effective action to protect the public health during national public health emergencies, other state/local disaster declarations, outbreaks or other public health events, and for routine regulatory oversight.

Conclusion

FDA continues to advance its mission to protect and promote public health by helping to ensure the safety of human and animal food, and the safety and effectiveness of medical products in the COVID-19 pandemic. The Agency is continuing to monitor its policies, the marketplace, and national needs, and will continue to adapt as the circumstances of the pandemic evolve. We take our public health mandate very seriously and will continue to work each day to help end this pandemic and prepare for the next one. We look forward to continuing to work with the Committee on the Agency's public health emergency preparedness and response mission and strengthening FDA's authorities to continue building a resilient supply chain for critical medical products, foods, and medical countermeasures. Thank you again for the opportunity to testify.

Mr. GRIFFITH. I thank the gentleman. We now have concluded our testimony. I appreciate all the witnesses giving their testimony. We will move into questions and answers, and I will recognize myself for the first 5 minutes of questions.

Dr. Tabak, I, along with now-Chairs Rodgers and Guthrie, have sent the NIH 14 letters requesting information. Those letters ranged in date from March 18, 2021, to November 30th, 2022, and most have gone completely unanswered. We received responses from other agencies, such as the CDC, to our letters.

It appears there was a standing policy at the NIH to disregard letters from the minority members of this committee. Is that true, yes or no?

Dr. TABAK. No.

Mr. GRIFFITH. So it is just incompetence that caused 14 letters to go basically unanswered. I will take that as a given.

We sent you a letter on February 2nd last week requesting documents and information from the NIH related to the COVID origins and the EcoHealth Alliance grant to support our legislative efforts on pandemic preparedness and NIH grant management. NIH sent us over 580 pages of documents last night after the close of business and shortly before the President's State of the Union address that consisted mostly of repeat documents already given out or made public. That is not true cooperation.

So I ask you, is the NIH going to fully cooperate with our requests?

Dr. TABAK. We will continue to cooperate fully.

Mr. GRIFFITH. You will cooperate on this request. Thank you.

We sent the NIH a letter on November 30th, 2022, asking you not to destroy evidence related to COVID. Last week we sent another letter asking that you "take all reasonable steps to prevent the destruction or alteration, whether intentionally or negligently, of all documents, communications, and other information, including electronic information and metadata that are or may be responsive to this congressional inquiry."

Will you vow to follow this request and not destroy these vital records? Yes or no.

Dr. TABAK. Yes.

Mr. GRIFFITH. Thank you. Even though the NIH suspended EcoHealth's grants in July of 2020, before our COVID–19 inquiries began over grant noncompliance concerns, and later that it was found that EcoHealth did not follow important grant terms, the NIH subsequently gave a new grant to EcoHealth in September of 2022.

Why would you allow a company who breached their contract with the NIH and failed to comply with some important reporting requirements to get more of the American taxpayer dollars?

Dr. TABAK. We follow process. They were put under advisement of these deficiencies. They have been working with us to correct them, and that is why we proceeded.

Mr. GRIFFITH. But they can't correct the information that they didn't require their partners at the Wuhan lab to give them to give you 3 years later. So we don't have the information that we learned last week was important in determining both the origins and how

to treat those origins at an early date. They failed in a major respect. How can that possibly now comply with your processes?

Dr. TABAK. And we have corrected with them their administrative shortfalls, and continue to work with them.

We are unable to disbar an organization that——

Mr. GRIFFITH. So do you want authority from Congress to be able to disbar an organization that breaches their contract and fails to get us information from a subcontractor that may have had vital information in helping us to respond to the COVID–19 outbreak?

Dr. TABAK. The shortcomings of the Wuhan Institute of Virology have been noted in the GAO report, as you know.

Mr. GRIFFITH. I know.

Dr. TABAK. And they recommend that disbarment be considered. And this is something that, you know, we will, of course——

Mr. GRIFFITH. Do you need new authority from us to disbar?

Dr. TABAK. We do not disbar. That—the disbarment official sits in HHS.

Mr. GRIFFITH. All right. Should we add financial penalties to NIH contractors to ensure stricter compliance if they fail to meet their contractual obligations into—and to fail to give you vital records? Do they need a financial incentive that is a negative incentive?

Dr. TABAK. We can put such incentives, if you will, or disincentives in our terms of condition.

Mr. GRIFFITH. You can or cannot?

Dr. TABAK. We can.

Mr. GRIFFITH. You can? I suggest you do so.

Should we add financial penalties to the NIH if they fail to do oversight on important research being done with the American taxpayer dollars?

Dr. TABAK. I can't speak to that.

Mr. GRIFFITH. All right. Dr. Tabak, from 2015 to 2019 EcoHealth Alliance gave multiple—NIH grantee for coronavirus research—gave multiple subaward transactions to the Wuhan Institute of Virology. EcoHealth has serious deficiencies, as we have discussed. The Office of the Inspector General even confirmed this in a recent report.

How do you allow that to happen without consequences?

Dr. TABAK. The consequences were the initial suspension, reinstatement, suspension of the grant. And we have worked with the primary grantee, EcoHealth Alliance, to get them back into proper order.

Mr. GRIFFITH. It does not seem sufficient to this Member.

I yield back to myself and now recognize the gentlelady, Ms. Castor, ranking member of this subcommittee, for her 5 minutes.

Ms. CASTOR. Thank you, Mr. Chairman.

The witnesses here today represent the most important scientific institutions in our fight against the COVID–19 pandemic and other diseases, and I greatly appreciate your work and the work of countless health professionals, everything that you have done in facing down this virus and your work to save lives.

Unfortunately, President Trump's early minimization of COVID–19, followed by numerous instances of pushing misinformation,

eroded public confidence in these vital public health and health institutions at a time that we relied on them the most.

This wasn't limited to the White House, however. In Florida, Governor DeSantis and his surgeon general have peddled conspiracy-driven propaganda that runs counter to the consensus of every major scientific and health organization. The Governor has actively discouraged public health protocols and vaccines. He has hidden data. He has withheld aid. He has put dangerous policies in place that have cost lives and have put Florida children and families at risk.

So you have an enormous job to combat this misinformation and rebuild the public trust. So I would like to hear what you all are doing to ensure that we are operating on proper science, and that the public has trust in your institutions.

Dr. Tabak, I will start with you.

Dr. TABAK. One of the programs that we have established is known as CEAL. It is a community engagement alliance where we do localized approach, partnering with faith and community leaders, particularly in underserved communities, to address all questions about COVID vaccines, therapeutics, et cetera.

In the RECOVER trial, we are engaging patients and communities broadly, again, trying to build—work with them through trusted community voices.

Ms. CASTOR. Dr. Walensky, I will ask you the same question, but I know you have undergone a very extensive review. It has been called "unflinching" in your examination of past mistakes by the CDC and how you improve going forward. You have done some reorganization. So how are you working on building public trust in the agency's mission?

Dr. WALENSKY. Thank you. Yes. Obviously, much of—some of the challenges, or challenges this administration inherited, they have been longstanding challenges at the CDC, and we have taken this opportunity to learn from what we—the challenges of the COVID–19 pandemic. That includes sharing our scientific data faster, enhancing our laboratory quality, translating that science into clear, concise communications.

I do want to highlight the real importance of mis- and disinformation and how it has undermined our vaccine efforts. It is the case that we anticipate vaccine rates have gone—well, we have seen vaccine rates of incoming children into kindergarten have gone down from 94 percent to 93 percent just in this last year. That is a quarter of a million children not coming to kindergarten with being up-to-date in their vaccines. We are doing a lot of work at CDC, but this is not something that CDC can do alone. It is going to take all of our agencies. It is going to take all of the government, and every single one of us has a role in mis- and disinformation.

Ms. CASTOR. I have seen it in Florida. The vaccination rates for children are down, and I know it is a direct result of a lot of this, the scare tactics and misinformation.

Dr. Califf, I am going to ask you to respond for the record, because I would like to ask Dr. Walensky about the CDC's data modernization initiative.

So we are—it is so important that we aim to get—to empower the agency to get better, faster, more actionable insights on public health data. But I heard from folks back in Florida and all across the country it was so outdated. We have given the CDC funds to modernize it. I know that is just a drop in the bucket. So how—what are you doing to ensure that the public has the most accurate data that is up to date?

Dr. WALENSKY. So just to give you a scope of the problem, it took us 6 months to get data use agreements for—to receive data during COVID–19, and it was over 100 data use agreements. So we are working through our data modernization efforts to have a singular highway through which data passes so that data from your districts can come to CDC, and then we can give it back to your districts——

Ms. CASTOR. And not by fax machine.

Dr. WALENSKY. No, not by fax machine. And, in fact, in those districts where we have seen—where we have stopped using the fax machines, there are data to suggest we saved 140 million person hours, so that we know that these highways will work.

And then we can receive those data from your districts, and we can give those data back to you so you can see what is happening in your districts and the districts around you, what threats might be at your front door.

Ms. CASTOR. So we save lives and save money at the same time. It sounds good. Thank you so much.

I yield back.

Dr. WALENSKY. Thank you.

Mr. GRIFFITH. The gentlelady yields back. I now recognize the chairman of the Health Subcommittee, Mr. Guthrie.

Mr. GUTHRIE. Thank you very much. I appreciate it.

And responding to what our ranking member said, we obviously have to listen to experts, because we are not experts. But we don't have to give away our right to oversight. We are responsible for oversight of what is going on at the agencies. That is in our purview. I know we didn't have hearings when they were in the majority, but we are now.

And quite honestly, Dr. Walensky and Dr. Califf, you all have reached out to me, so I think you all appreciate our role in oversight, and that is noted and appreciated.

And so—and the reason is this, and as an example we are going to talk about school closure. I think we talked of that before.

In summer of 2020, the Kentucky schools were getting ready to start back again. This is before you guys were in office, I understand that. And then the Governor delayed, said—told schools they couldn't open. Then he went to a point and said, "OK, I am going to suggest you don't open, or ask you not to open, but not force it."

We had school systems say, "We have been spending the summer getting ready. We are going to get open, we are going to stay ready." So they met in the fall of 2020, a handful of school systems in my district. One superintendent didn't want to meet, but the nonexperts who are elected school board members voted down, and they met. And the kids were better off for what—the decisions that the nonexperts made.

And the Governor even pointed out our school system, some of my superintendents by name, for—"You all are going to cause problems, you are opening your school system." Well, it didn't take too long to understand—not that there weren't any cases in our school system, but none traced to the school system. And we learned pretty quick the kids weren't super-spreaders like they are with the flu. And not a single person from Frankfort went to one of our schools that were open every day and said, "Is there some—what are you guys doing to make it work?"

And so then you fast forward to, you know, 2021, and then the guidance, Dr. Walensky, coming out from CDC. That was highly reported, heavily reported that teachers union were involved in a line-by-line edit of the guidance. And it would have been helpful if one of my superintendents would have had the opportunity to apply.

So it gets not just to that situation, but also you're the experts. But how do we—how is it transparent? How do we know? How can we have confidence in guidance, when we have school systems meeting, and meeting effectively, but then guidance came out that a lot of people used to keep the—I know you didn't order the school systems to close, but they used your guidance to do so.

Dr. WALENSKY. Yes, I appreciate the opportunity to speak to this.

So I came in on January 20th, and it was my—among my highest priorities to get our schools open. And it demonstrated—the work that we did was demonstrated to be successful. So when I came in, 46 percent of schools were open. By the end of May we had 63 percent of schools fully open. And by September we had 94 percent of schools fully open.

Among the first guidances that I released, I think within 3 weeks of my arrival, was how to get our schools open. That is the guidance to which you are referring. And I would just like to speak to how we put that guidance together. We take subject matter experts, we have our scientists review the data, review the science——

Mr. GUTHRIE. Did the teachers union have specific—I have just got so much time, I am sorry—but did the teachers union have specific access to it——

Dr. WALENSKY. So——

Mr. GUTHRIE [continuing]. That others didn't?

Dr. WALENSKY. In a penultimate version, what we do is we look at our key stakeholders. We reached out to over 50 key stakeholder groups. That included parents, that included superintendents, that included teachers, because we really need to make sure that those stakeholders can actually implement on the guidance that we put forward.

There was a key piece missing in that penultimate version, and that is what do you do for teachers who are immunosuppressed, those teachers who are getting breast cancer treatment, teachers who have had a heart transplant. That piece had been missing. It was the reason that we requested that feedback, is so that we can say, "What is missing to implement?" And it was that piece that was changed after those discussions.

Mr. GUTHRIE. So are you going to do things differently, or do you feel like——

Dr. WALENSKY. So we are strengthening our processes as to how we standardize and do that outreach, but I think that outreach is—continues to be critically important. We need to know how the end users will receive our guidance to understand what is implementable for the——

Mr. GUTHRIE. We want to make sure that everybody has access from all parties——

Dr. WALENSKY. And we did speak to superintendents and parents. We spoke to over 50 groups.

Mr. GUTHRIE. Thank you.

And Dr. Califf, I understand that FDA has—that people have said it has really good guidance practices. Can you speak to that, to your guidance practice, when you get input from folks moving forward?

Dr. CALIFF. As I think you know, there is a draft guidance that is put out, and then comments are achieved from the public, really, at that point. But during the course of drafting guidances we may have discussions with interested parties. Many of our guidance, as you know, deal with the medical products industry, for example. And we do talk with people, because we can't—you know, can't do these things in a vacuum.

Mr. GUTHRIE. OK, thank you.

And Dr. Walensky, I only have about a half a minute, so I am going to try to get my question quick. But we talked a little bit about mission creep.

When CDC is the pandemic preparedness and response, and—CDC, over 100 years since we have had our big—last big nationalwide pandemic, and just the response to—is CDC prepared for a—it wasn't prepared, it did appear, at the very beginning. Is it prepared now for another——

Dr. WALENSKY. A lot of what we are doing in CDC moving forward is strengthening our piece or component that is a response-based agency. We have a new CDC responder—Ready Responder Program.

What we could really use from Congress is the workforce authorities to be able to do that, workforce authorities that are similar to other response agencies like FEMA, work for—danger pay, overtime pay, loan repayment, tax-free loan repayment. So those workforce authorities would be really helpful for us to be even more ready to respond.

Mr. GUTHRIE. I am sorry, 5 minutes goes fast. I yield back.

Mr. GRIFFITH. I thank the gentleman for yielding back and now recognize Ms. Eshoo, the head of the—or the ranking member of the Health Subcommittee.

Ms. Eshoo, you are recognized for 5 minutes.

Ms. ESHOO. Thank you, Mr. Chairman. Just to comment about the last exchange, in my view something was left out of it: the American Rescue Plan.

In March of 2021, the Congress passed, the President signed into law billions and billions of dollars for vaccines for all of the things that would protect the American people, and that cannot be overlooked. It is an important discussion about schools, and understanding how guidances work, and who the agencies meet and talk to to come up with the best policies going forward. It is all impor-

tant in a hearing. But I—this cannot be overlooked. I don't know what would have happened to the people of our country without that rescue plan. And it wasn't unanimous. But it got done.

Dr. Tabak, I would like to ask you about—speaking of money—the Congress appropriated $1 billion to NIH to study long COVID. Patients have been waiting—and they have been more than patient—since December of 2019. And I think the effort is called RECOVER, and it is to research, you know, potential treatments. Where is that? How close are you to coming out with what is needed for those that have been waiting a long time?

Dr. TABAK. We have put together a national cohort of patients at different stages of infection with COVID–19, and those who have already reported that they suffer from long COVID.

Ms. ESHOO. I am familiar with that.

Dr. TABAK. And——

Ms. ESHOO. I want to know how close you are to——

Dr. TABAK. Well, we are within the next——

Ms. ESHOO [continuing]. The mission——

Dr. TABAK [continuing]. Few months to launch the first interventional trials.

The reason it has taken the time it has is because we wanted to build a large enough cohort of patients so that we would actually get actionable answers.

Ms. ESHOO. So it took from 2019 to now to get the cohort?

Dr. TABAK. Indeed, it has, because——

Ms. ESHOO. And how many are in it?

Dr. TABAK. I am sorry?

Ms. ESHOO. How many are participating in it?

Dr. TABAK. I would have to get back to you the specific numbers, but please appreciate that, as the virus evolved, so too has long COVID. The——

Ms. ESHOO. Well, exactly. That is why I am asking.

Dr. TABAK. And that is why we need to continue to build a cohort that is representative of the disease, so that the answers that we get with our interventional trials will have some actionable——

Ms. ESHOO. OK. Well, if you have anything else that you can add to that, I would appreciate learning it, getting it from you.

To both the CDC and the FDA, I think the public and certainly Members of Congress became all too familiar with advisory committees during—and that impacts your work. But I think that it also added to the confusion of the American people.

Advisory is exactly that, it is advisory. And I have to say that I found it troubling. It seemed to me that there was a lack of balance between the ultimate decision maker and an advisory committee, an advisory committee.

So can you—well, first of all, do you think that there should be some streamlining of these advisory committees, and really make them more practical?

Dr. Califf.

Dr. CALIFF. Thank you for that question. I actually chaired an FDA advisory committee for——

Ms. ESHOO. There you go.

Dr. CALIFF [continuing]. Some period of time back in the good old days.

I think advisory—it is like democracy. It is messy. And I think advisory committees are critical. The FDA full-time staff need to interact with outside experts in a structured manner.

But you're right, they are advisory, They are not decision-making. Our regulatory decisions are made by full-time civil servants who don't have a conflict of interest financially and whose mission is preserving and protecting public health.

We are looking across the FDA right now at what we can do. Streamline is one word, I would say, to optimize the use of advisory committees. They're so important, whether it is food, tobacco, or rare diseases, for example. We need to have that kind of input. So it is critical. We need to make it better.

Ms. ESHOO. Dr. Walensky?

Dr. WALENSKY. Yes, I don't have much to add to that, except to say that there is incredible value in the independent expert opinion of nongovernmental officials who are very well-recognized across the country in their field of vaccine that we have on our Advisory Committee on Immunization Practices.

I agree they are messy. They have been challenging during——

Ms. ESHOO. So are you looking to change anything?

Dr. WALENSKY. We are reviewing the advisory committee processes, yes. However, you know, I do think that there is an important component of our Advisory Committee on Immunization Practices that has been steadfast through all the vaccines. Certainly, it has been in the spotlight during COVID–19 vaccines, but there are many pediatric vaccines that have been reviewed carefully through this committee.

Mr. GRIFFITH. The gentlelady yields back. I now recognize the chairman of the full committee, Cathy McMorris Rodgers, for her 5 minutes of questions. Thank you.

Mrs. RODGERS. Thank you, Mr. Chairman. I want to start with Dr. Walensky.

Dr. Walensky, there is serious distress today with our public health agencies. I recently saw one poll that nearly 40 percent of the public does not trust our public health agencies to handle the next public health emergency. And I don't blame them. While I appreciate that we were dealing with an evolving virus, there were also a lot of mistakes, too many mistakes with communication and decision making from the CDC.

And one relates to mask mandates. You know, there has been several studies that have looked at the effectiveness of masks to prevent the COVID spread. And there was one just recently that came to several important conclusions. First, there is—there was a notable lack of reliable studies on the efficacy of face masks. And second, there remains much uncertainty about the impact and the effect of face masks.

While acknowledging the limited data pool, it found no clear sign of a reduction in transmission when using either medical or surgical mask. Yet today CDC still recommends masks in schools for all ages, even though the emotional, mental, physical, and educational toll masking has had on our kids is widely recognized. In fact, the CDC is currently the only national or international public health agency that recommends masking 2-year-old children.

I would like you to explain in detail the process and the timeline by which evidence such as this is used by the CDC to update, modify, or necessarily withdraw current guidance.

Dr. WALENSKY. Great. Thank you for the opportunity to clarify on those points.

So I believe you're referring to the Cochrane Review study. This is an important study.

Mrs. RODGERS. Yes.

Dr. WALENSKY. But the Cochrane Review only includes randomized clinical trials. And as you can imagine, many of the randomized clinical trials that were included in that were for other respiratory viruses, not COVID–19. Some of them were for COVID–19, just to be clear. But it is very different for COVID–19, because you have a pre—a virus that—different from flu, potentially different from SARS or MERS, transmits before you actually have symptoms.

Mrs. RODGERS. So——

Dr. WALENSKY. It is also the case that the—one of the limitations in that study was clearly stated that people were not actually engaged in the intervention. So you actually have to wear the mask for it to work.

Mrs. RODGERS. OK, OK.

Dr. WALENSKY. So there are lots of studies now——

Mrs. RODGERS. Dr. Walensky?

Dr. WALENSKY [continuing]. In Georgia——

Mrs. RODGERS. Dr. Walensky, why are we masking our kids today?

Dr. WALENSKY. You know, thank you. Also, so our guidance for school-based masking is related to our COVID–19 community levels. And fortunately, we are in a place now in this country where most of our country is in green or yellow, has low or moderate transmission COVID–19 community levels. And in those situations we actually don't recommend masking. We recommend it for high COVID–19 community levels.

Mrs. RODGERS. So what is your timeline for updating, reevaluating these guidance?

Dr. WALENSKY. You know, our masking guidance doesn't really change with time. What it changes with is disease. So when there is a lot of disease in a community, we recommend that those communities and those schools mask. When there is less disease in the community, we recommend that those masks come off.

Mrs. RODGERS. So—OK. So it is just going to continue. That is——

Dr. WALENSKY. We will continue to recommend that, when there is high amounts of hospitalization, severe disease, and disease in the community——

Mrs. RODGERS. Despite the emotional, mental, physical, educational toll that we know masks are having on our kids.

Dr. WALENSKY. As you and I have spoken about——

Mrs. RODGERS. Yes.

Dr. WALENSKY [continuing]. Yes, indeed, it is important that we recognize that our kids need to be in school.

Mrs. RODGERS. OK, yes.

Dr. WALENSKY. We know that when masks don't—when masking doesn't happen in high COVID–19 community levels, those do——

Mrs. RODGERS. OK, thank you. We will continue this conversation.

Dr. Tabak, just this last weekend New York Times published an article about the astonishing, horrible learning loss resulting from government recommendations that led to lockdowns and virtual schooling. NIH has a budget over $40 billion. Has NIH initiated any studies looking at learning loss or the impact of shutdowns on childhood development?

Dr. TABAK. Yes, we have, both through the National Institute of Mental Health and the National Child Health and Development.

Mrs. RODGERS. I would—I am anxious to see those studies, the reports. So I just would ask you to give me that list, and where the funding was provided, and a summary of the studies. That would be great.

And in my final minute here, Dr. Califf, you know, I continue to hear concerns about the FDA having virtual meetings, and especially for innovators and others that have some amazing breakthroughs being told by the FDA that you can only meet through Zoom, or not even through Zoom. I had one—yes, can't even meet through Zoom, you have to be—have written correspondence. You know, it slows down approvals for everything from flu tests to novel vaccines.

So I would just like to ask, when is everybody going to be back to work? Or what percentage of employees are back to work 5 days a week? What percentage of meetings are via Zoom?

Dr. CALIFF. One hundred percent of our employees have been at work every day since the beginning of the pandemic, and will continue to do so. In fact, working——

Mrs. RODGERS. In the office?

Dr. CALIFF [continuing]. Nights and weekends.

Mrs. RODGERS. In the office?

Dr. CALIFF. Many of our employees aren't in the office to begin with. We have inspectors, we have people reviewing data. We have 200 locations around the country.

I would also add we have now added back in-person meetings. They are being scheduled. Interestingly, when I have said, "Would you like all in-person meetings," the industry, by and large, has said, "We would sort of like both," because the ability to have a meeting on the spot via Zoom, it is a period of trying to get a bunch of people to Silver Spring and stay in a hotel——

Mrs. RODGERS. Well, my time has expired.

And I suspect sometimes it makes sense to do it via Zoom. It was most concerning to me when it was—the response was it requires written communication as the only way. We all know that that is going to cause all kinds of delays.

So bottom line, bottom line, we need all of you to be responsive. We need you to be accessible. And we do look forward to greater communication between all of your agencies and Congress. We are the elected representatives of the people.

Thank you for being here today.

Mr. GRIFFITH. The gentlelady yields back. I now recognize the gentleman, the ranking member of the committee, Mr. Pallone, for his 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

As we know, the President has announced that he plans on unwinding the current COVID–19 public health emergency by May 11th. And this is possible because of the work that this administration was able to do to control this disease. This administration orchestrated the largest free vaccination campaign in U.S. history, delivered hundreds of millions of dollars—well, hundreds of millions of tests to the public, and provided guidance to schools and offices to open safely.

And in no small part because of these successes, my Republican colleagues have declared that the pandemic is fully over, and that the administration should suspend the public health emergency immediately. This, of course, was the first of the three bills that I mentioned in my opening statement that seek to roll back, in my opinion, COVID protections. And I have been very critical that such an abrupt end to the emergency would seriously undermine the progress that we have made. It would also ignore the sad fact that an average of nearly 500 people are still dying every day from COVID–19.

The decision to base—to end the emergency should be based on science. It should be with the agencies that have the expertise. And again, the President has said he plans to do this, which means that that could change if the COVID situation got worse with more variants, whatever.

So the Republicans have also claimed that the administration does not have a plan for winding down the public health emergency. And I would like to give our witnesses an opportunity to respond to that. I am interested in hearing how we can continue to protect the health and well-being of Americans and minimize disruption. So let me ask each of you quickly, because I have two sets of questions: How are you planning for the next phase of the Federal response to this pandemic, and what should Congress do to help facilitate a smooth transition?

Dr. Tabak, I guess 30 seconds or so.

Dr. TABAK. Specific effects on us are modest. We will have to work with our grant community for the slight changes that they will have to address when the PHE is over.

Mr. PALLONE. And Dr. Califf?

Dr. CALIFF. Our effects are also a little modest, because our EUAs are independent of the public health emergency. So we can keep them going as long as we need to.

We have been preparing the industry since day one to be ready for the transition. We will put a Federal Register notice out about exactly how to make the transition as these products go to routine use and are no longer used on an emergency basis.

Mr. PALLONE. And Dr. Walensky?

Dr. WALENSKY. I would like to be clear that we plan to address this emergency and work towards the safety and security of all Americans 24/7, regardless of whether there is a public health emergency in place.

It is the case that when the public health emergency comes down, we lose some of our ability to see the data. We will lose testing data that we have as part of the public health emergency. We will lose other data, as well. And we are actively working right now to set up data use agreements so that we will have the data that we need in the absence of those authorities so that we can see the data and be able to present them back to the American people.

Finally, we do not in this country have a vaccines-for-adults program. We don't have a vaccine program for the uninsured adult, as we do for children. And so it would be really helpful. And we are working now to see how we can ensure that uninsured adults will get vaccinated.

Mr. PALLONE. And as I said, winding down the public health emergency has to be grounded in science. And I think that public experts like yourselves are in the best position to make that decision.

But as we look towards the future, can you just briefly discuss how important it is that these decisions are made based on data trends and up-to-date information, and not ideology or politics?

Thirty seconds each, Dr. Tabak.

Dr. TABAK. We believe in data. The data is very important to review, and the public health experts need to weigh in once they are able to review those data.

Mr. PALLONE. Dr. Califf?

Dr. CALIFF. We have a saying at FDA: "In God we trust, all others must bring data." And I have lived my whole life as a cardiologist, basing my practice on evidence. We need to have the evidence to make good decisions.

I think, Dr. Walensky's statements about the need for the CDC to get accurate, up-to-date data quickly is absolutely critical to the future.

Mr. PALLONE. And Dr. Walensky?

Dr. WALENSKY. My job is to provide the best public health science for decision making. I do that by being informed, and I can only be informed if I can see the data.

And so I would like to be informed, so that we can make those decisions and then give them back to you so that you can make the decisions at the local level.

Mr. PALLONE. Thank you. And you know, I stress I know that—I am not arguing that there doesn't need to be oversight of what you do, which is, of course, the purpose of this hearing today. That is a very important function that we serve as elected officials and Members of Congress. But I do think that, ultimately, these decisions about when to start or end the public health emergency have to be made by the agencies and the experts. That is what the statute says. And I don't want to substitute your expertise for ours, because I don't think we have the same level of information that you have, or expertise.

So thank you, Mr. Chairman.

Mr. GRIFFITH. I thank the gentleman, who yields back. And we like information, too.

I will say at this point we have—the chairs of—sub chairs and chairs have gone over a little bit, but we have a 2:00 drop dead.

So I am going to try to be aggressive with the gavel. It is nothing personal, I am just going to try to move this along.

I recognize Dr. Burgess for his 5 minutes of questions.

Mr. BURGESS. Thank you, Mr. Chairman. I appreciate your aggression.

Dr. Walensky, just a quick followup from something Chairwoman McRogers—McMorris Rodgers said. You maintained that mask—your guidance is your guidance. But I presume, if there is new data that comes forward, you will reevaluate your guidance. Is that not correct?

Dr. WALENSKY. Of course.

Mr. BURGESS. OK.

Dr. WALENSKY. We are already reevaluating in real time.

Mr. BURGESS. And just a general statement. Look, the country has been through hell with this. Our doctors and nurses on the front lines have been through hell. You all in public health have been through hell, and policymakers have been through hell.

There is a piece making the rounds currently, a Newsweek oped piece written by a doctor—or medical student, more correctly, Kevin Bass. And he observes, "It's clear to me that for public trust to be restored in science, scientists should publicly discuss what went right and what went wrong during the pandemic, and where we could have done better. It's OK to be wrong and admit where one was wrong and what one learned. That's a central part of the way science works."

So it is with that backdrop—and I appreciate so much doctor-to-be Kevin Bass making that observation and sharing it with us. Look, no one—you and your predecessors, when this was visited upon us, you didn't know what was to come, and it made things very, very difficult. And sometimes I think it is OK just to have the humility that we didn't anticipate that there would be that 2-week lag. And when Dr. Fauci came and talked to us in this room about how—what a good job they had done with SARS–1, nobody knew at that point about that 2-week lag that might occur from exposure, now you are infective, and now you are symptomatic and should be isolated.

Dr. Tabak, I do have a couple of questions. You know, we got the big OIG report the other day, and it generated a lot of interest. Some questions have come up from that.

Let me just ask you, roughly, how many awards does the National Institutes of Health issue every year?

Dr. TABAK. About 55,000.

Mr. BURGESS. So that is a lot. In the report, in the OIG report, you know, they, obviously, discuss—there were some potential risks associated with research being performed under EcoHealth awards, NIH did not effectively monitor or take timely action to address EcoHealth's compliance with some requirements. These costs included salaries exceeding the NIH salary cap, employee bonuses, travel costs, tuition costs, indirect costs. This audit covered all three NIH awards to EcoHealth between 2014 and 2021 and found $89,171 in inallowable costs.

That is in one grant. And you just said how many grants do you administer?

Dr. TABAK. We—about 55,000 a year.

Mr. BURGESS. So 89,000 multiplied by 55,000 is a lot. Are you taking steps to tighten this process up, so we don't have 55,000 OIG reports down the road?

Dr. TABAK. So certainly, this is an outlier, and the——

Mr. BURGESS. Well, Mr.—Dr. Tabak, with all due respect, we are not sure, because we didn't know about the outlier status of the current OIG report.

Dr. TABAK. I take your point. We accepted all of the OIG's recommendations, and we are working to address each of them. We now have modified our systems to prevent some of these missteps from occurring in the future.

Mr. BURGESS. So you will get back to us with your plan.

Dr. TABAK. I am happy to do that, yes.

Mr. BURGESS. Let me just ask you, too, because you made the offhand comment that disbarment resides with an official at HHS.

Dr. TABAK. That is correct.

Mr. BURGESS. Who is that official?

Dr. TABAK. I don't know the name of the person——

Mr. BURGESS. Will you——

Dr. TABAK [continuing]. But there is an——

Mr. BURGESS. Will you get it for us?

Dr. TABAK. [continuing]. A disbarment office.

Mr. BURGESS. Will you get that? Because I am——

Dr. TABAK. Of course.

Mr. BURGESS [continuing]. Interested in speaking with that individual.

So let me ask you a question. This committee back in 2006—I know it was a long time ago—the NIH Reform Act established the Scientific Management Review Board, an oversight board meant to make NIH more efficient. The—this board has not convened since 2015, according to recently published information in a healthcare publication, and the members of the board don't know why they haven't met. Can you enlighten us as to why that board is no longer meeting?

Dr. TABAK. The board no longer meets because we found that board to be completely redundant to the advisory committee to the Director in every aspect.

Mr. BURGESS. So that is good, and I will stipulate that. However, the annual cost of the board, $488,000 a year, 2 full-time employees at a cost of over $320,000. Without convening the board, I am concerned that the NIH may have diverted these funds to other activities.

Dr. TABAK. The—well——

Mr. BURGESS. It still appears on your books.

Dr. TABAK. OK, I will check into that and get back to you, sir.

Mr. BURGESS. Thank you.

Mr. Chairman, I have got a lot of questions that I am going to submit for the record. Clearly, there is a lot of pent-up demand because of the 3 years of the pandemic and this really being the first oversight hearing we have had in person in a long time. So thank you, Mr. Chairman, and I will yield back.

Mr. GRIFFITH. I thank the gentleman. I will now recognize the gentlelady from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you so much, Mr. Chairman, and welcome to all of our witnesses.

I have been on this committee long enough to remember all of our previous efforts in addressing what we saw as looming pandemics. And each time we thought that we had put things together within your various agencies to make that happen.

I remember back when I was the chair of Oversight, we had a hearing in December right before the pandemic hit, the December before it hit, and Dr. Fauci was here and some of his colleagues, and I said, "What is the one thing that keeps you up at night?" And they said the fear of a—some kind of a virus pandemic. And lo, it came to be.

So, you know, we—it is easy to sit here and blame the three of you. But in truth, our agencies are in need of continual updating and expansion and resiliency to deal with both evolving types of viruses but also to deal with ways we can receive and disseminate information and ways we can structure our agencies. So I want to thank you all for what you are doing in—with your rearview mirror to try to improve the way we do this in the future.

And I want to once again tell my colleagues on the other side of the aisle that this is really what we should be doing in a bipartisan way. It is all well and good to blame this administration for what started under a Republican administration. It would be easy for me to blame President Trump, but I don't think that that blame game is what is going to help us when the next virus emerges.

Having said that, and in this effort, I led a delegation last summer to the CDC in Atlanta, where I was joined by Ranking Member Castor, Dr. Ruiz, Mr. Peters, and Dr. Bucshon. Dr. Walensky, we met with you and your staff, and we learned about your attempts to modernize through institutional reforms.

Now, since then, I have been really pleased to see that the CDC has issued plans to improve accountability, collaboration, communication, and timeliness both within the organization and to the American public. Part of those efforts—and you have talked about it—are creating a new governance model through an executive board that relates directly to the CDC Director, and you have talked also this morning about making sure that you could get access to timely, high-quality data and strengthening workforce capacity to respond to these needs.

I am wondering if you could just talk very briefly about what congressional authority you might need to do that as we start thinking about developing legislation.

Dr. WALENSKY. Thank you, Congressman. It was a pleasure to host you, and would welcome anyone else who wants to pay us a visit down to Atlanta.

It is the case that workforce has been one of the challenges. It is one of the things—one of the lessons that we learned. A study from the de Beaumont Foundation demonstrated that our public health workforce across this country is 60,000 in deficit. That means we have a lot of work to do, not only at the CDC but across the country, to develop a public health workforce that is as diverse as the communities we serve and that is upskilled in our resources and data.

So among the things——

Ms. DEGETTE. So—I don't mean to interrupt you, but I have a question for Dr. Califf, too.

Dr. WALENSKY. OK.

Ms. DEGETTE. What congressional authorities do you need to achieve that?

And also the information——

Dr. WALENSKY. Workforce authorities would be incredibly helpful: overtime, danger pay, overtime pay. So pay so when we send somebody to Mubende, Uganda, in an Ebola outbreak, that we are able to pay them danger pay. Those things would help, workforce authorities.

Data authorities would be incredibly helpful, so that we don't have to sign 100 data use agreements with individual jurisdictions before we receive the data. That takes months in happening.

And then finally, a vaccines-for-adults program, which would be able to provide vaccines for uninsured adults.

Ms. DEGETTE. Right.

Dr. WALENSKY. We have one for children.

Ms. DEGETTE. We look forward to working with you.

Dr. WALENSKY. Thank you.

Ms. DEGETTE. Dr. Califf, I was—Dr. Bucshon and I were very happy to hear you talk about our VALID Act, which ensures the reliability of testing and diagnostic tools for diseases and infections, including COVID–19. I am wondering if you can talk why you think it is important to authorize FDA to regulate laboratory-developed tests, why it is so urgent, and what we can do.

Dr. CALIFF. Well, there is a lot of what we do that I think of as the Goldilocks problem. We want to spur innovation. We need our academic medical centers, for example, to develop new tests as new viruses come along. You can't figure out what is going on with a pandemic if you can't make the diagnosis with a test.

On the other hand, the quality that is needed in these tests is very important, because if you get the wrong answer and you get the wrong treatment, that is a tragedy.

And so we need a framework for regulating laboratory tests that enables and spurs innovation, but also protects the public from tests that are bad. And as I have already mentioned, in areas like molecular testing, over half the tests that we saw, once the gates were open to allow them out, turned out to have major problems.

Ms. DEGETTE. And there is no regulation right now, right?

Dr. CALIFF. Well, we have the authority to regulate, but for decades now there has been enforcement discretion to basically allow people to pretty much act freely. So we want to really fix that so that, again, people can innovate but there is a framework to do it. But then, when there is a problem, we have the authority to bring it under control.

Ms. DEGETTE. Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. GRIFFITH. The gentlelady yields back. Now I recognize the gentleman from Ohio, Mr. Latta, for his 5 minutes of questioning.

Mr. LATTA. Well, I want to first thank the chairs of the Oversight and the Health subcommittees and the rankers for both of these subcommittees for holding today's hearing. This is very, very important, the answers that the American people want to have an-

swered today. So I thank you for it. I also thank our witnesses for being with us today.

Dr. Walensky, Dr. Fauci said that natural immunity was one of the best forms of protection against viruses. Knowing this, and that the vaccines do not stop the spread of COVID–19, do you plan to continue to provide CMS input on the vaccine mandate, especially given that this isn't connected to the public health emergency expiring on May the 11th?

Dr. WALENSKY. CDC provides public health data, scientific data to the best of our ability. We have put out a scientific review on the importance and value of infection-induced immunity. But we continue to see in all of our data that, if you have—that vaccines are the best and safest way to protect yourself against severe disease and death.

Certainly, if you have previously had an infection that adds and bolsters your immunity. But we continue to see data that demonstrates that vaccines are the safest way to protect yourself against severe disease and death, and we will offer that information to the administration as those decisions are made.

Mr. LATTA. Let me follow up. How does the administration intend to fix our depleted healthcare workforce?

And, you know, I am sure that you are out all the time in the communities. And across the 5th Congressional District in Ohio, I visit our hospitals and all of our areas that we have so many people out there that really strained during COVID, and saw, you know, from doctors, nurses, respiratory therapists, and you go down the entire line. And, you know, in one of my recent visits to one of our hospitals, they need about 5 to 600 people back into that hospital because, again, they can't service and serve these patients across the region unless they are there.

So how are we going to get our depleted healthcare workforce back because of everything that has happened with COVID?

Dr. WALENSKY. Yes, I appreciate the opportunity, because one of the big challenges, especially in our public health workforce, is our inability to have longstanding funding to support that workforce. And because of the lack of that longstanding funding, those are not jobs that people are generally applying for when there is not long-term funding, sustainable funding for them.

Through the American Rescue Plan, we did put out $3.2 billion to over 100 districts, jurisdictions, States, locals, cities so that they could work on and develop their workforce—again, having the workforce as diverse as the communities that they serve, but also upskilling the current workforce.

We also have a new public health AmeriCorps plan, where we are training up to 3,000 public health providers through the Public Health America Corps plan over a 5-year plan.

Mr. LATTA. You know, let me follow up on that real quick, because, again, you know, a lot of people say they don't want to be in a certain area. Maybe they don't like rural areas, they want to be in a more urban area. But how are you going to get the people back?

Because again, when I look at my area—because I go from urban to suburban to very rural, but we have to get people back in our rural areas for—to be able to be out there. Because I know, again,

the folks that are in these more rural communities are really putting in the hours, and they are burning out.

Dr. WALENSKY. That is exactly right. And in fact, that is the import of the sustainable funding in those areas. People often want to go back to the communities in which they were raised, but there aren't necessarily sustainable funding in those communities for those efforts. And that is a lot of the work that we are doing right now. Thank you.

Mr. LATTA. Let me follow up. You suggested several times in the past that fully vaccinated people don't carry or transmit COVID–19. Unvaccinated Americans were demonized, shadow-banned, and fired from their professions due to this poor guidance.

How does the CDC intend to build America's trust back now?

Dr. WALENSKY. Oh, thank you for this question. So it is true that, over time, we have seen the evolution of our vaccine recommendations, and that is because we have learned a lot about this vaccine. We have also seen an evolution of the virus itself.

So when we first had the vaccine that was first launched in December of 2021—December 2020, sorry—we had the wild-type strain. The vaccine worked very well at preventing severe disease, death, and also transmission for both the wild type and with Alpha. What happened with Delta is that the vaccines still continued to work against severe disease and death, but less so—still some, but less so—against transmission. That has also been the case with Omicron and its subvariants: very effective against severe disease and death, less effective, though, still somewhat effective, against transmission.

Among our efforts in our CDC Moving Forward initiative is to improve and strengthen our communications to the American people. It is the case that, prior to this pandemic, most people who came to the CDC website were public health officials, academics. It is now the case that Americans are coming to our CDC website. I inherited over 200,000 webpages on our CDC website. We are doing a lot of work now to—in a project called Clean Slate to update our website to make it accessible for everyday Americans to come to our website. Thank you.

Mr. LATTA. Well, and again, I just want to thank the chairs for today's subcommittee hearing. But I think we just said, you know, it is—communicating back to the American people is absolutely essential, because this trust has got to get gained back.

And Mr. Chairman, with that I yield back——

Mr. GRIFFITH. I appreciate the gentleman yielding back. I now recognize the gentlelady of Illinois, Ms. Schakowsky, for her 5 minutes.

Ms. SCHAKOWSKY. I just really want to thank our witnesses, not only just for being here today, for the—to answer all of these questions, but for 3 years of an unprecedented challenge, working every day to try and protect the American people. So thank you for that.

I wanted to talk a little bit more about just information and the effect that it really had. Over a million Americans died from COVID. I am just wondering if there is even any estimate of what—if there had been the acceptance of the—and the opportunity to be able to use the vaccines, if there is any estimate of how

many lives we might have saved. Dr. Walensky, is there anything like that?

Dr. WALENSKY. You know, I am not familiar. I wouldn't be surprised if folks who—at Yale, who have done some of these estimates that you previously heard about in terms of the lives saved, the millions of lives that have been saved, would be embarking on that. But I am not familiar with that. I would have to get back to you.

Ms. SCHAKOWSKY. Well, let's just—can you talk a little bit more about what the consequences—did anybody else want to answer that?

Dr. CALIFF. Yes.

Ms. SCHAKOWSKY. Oh, go ahead.

Dr. CALIFF. I mean, if I may. It is pretty unusual for a person who is up to date on vaccination and had access to the powerful antiviral drugs that we have to die from COVID. It is a rare exception when that happens.

So, in fact, there is a great study that just came out last week about doctors. We were losing hundreds of doctors until the vaccine came out. It has a beautiful graph in it that shows that, once the vaccination—because doctors almost all got vaccinated right away and have stayed up to date—we now have a lower-than-expected mortality rate in doctors because of this intervention. So you can pretty much extrapolate that—remember, the number to be relatively precise—it is hard to be completely precise—80 percent lower chance of being dead.

Now, I am a cardiologist, so I am used to thinking about life and death. And most people can pretty simply think about this. Something that reduces your risk of being dead by 80 percent, that is important. And you can then back extrapolate. We can't put exact numbers on it, but it is rare for someone to die from COVID if they are up to date on vaccination and have had access to the antivirals.

Ms. SCHAKOWSKY. Well, thank you so much.

You know, 209,000 nursing home residents have died because of COVID. And I just wanted to talk to you about what we can do to address this particular population to make sure that we can keep them safer.

I don't know, any—Dr. Walensky or whoever.

Dr. WALENSKY. Yes, I very much appreciate your work and advocacy for this population, because it is, in fact, this population that, in this moment, is most vulnerable. We are seeing deaths more in elderly population right now, those who are not vaccinated.

Right now we have about 51 percent of our residents living in nursing homes who have received the bivalent vaccine. But in my mind, that is not enough. And our team is working really hard. We have engaged with our long-term care facility pharmacies to see—make sure that we get vaccine into those pharmacies.

One of the challenges also was the multidose. So we are working with those pharmacies to get single-dose vials so that they can actually use those single-dose vials.

We are also working within the States to have home health aides and EMTs go to those long-term care facilities, where they may not have medical care on site, so that those people can actually visit them and provide vaccine.

And then we have actually waived the data needing to come in to facilitate it even further.

So we have had an—enormous amounts of efforts for exactly the reasons that you note. Thank you for that.

Ms. SCHAKOWSKY. So I want—not just about COVID, but what has CDC learned about best practices to address infections, et cetera, that are in nursing homes? This is a real problem.

Dr. WALENSKY. Right. Well, in fact, we have a whole unit that works on infection control prevention and that has been specific to nursing homes. We have data that come in weekly from our 15,000 nursing homes through our National Health Survey network. So a lot of work happening within the nursing homes because of this particularly vulnerable community, not just that we see in COVID–19 but as we saw with influenza, as we see with RSV, again, prone and vulnerable to numerous infections and other threats.

Ms. SCHAKOWSKY. Thank you. And I see my time is almost up. I will yield back, thank you.

Mr. GRIFFITH. I thank the gentlelady, and now I recognize the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you. I appreciate it. Thanks very much.

OK, Dr. Walensky, I have a question for you regarding the cruise industry. Throughout the pandemic I expressed significant concerns, and actually led multiple letters, about the COVID–19 restrictions for cruise ships and the Level 4 travel advisory that unfairly targeted the industry. These restrictions were not backed by facts or science, but rather an executive branch overreach, and they did nothing to actually mitigate public health concerns. They unfairly punished Floridians and others throughout the country, businesses who rely on the cruise industry for their livelihood, by creating a baseless no-sail order that cost local economies billions of dollars.

Dr. Walensky, do you know how long the cruise industry was prohibited from operating as a result of the CDC orders?

Dr. WALENSKY. I know we worked closely and hard to try and open the cruise industry as soon as possible, for all of the reasons that you note.

We also know that, during the COVID–19—initially came to our shores, literally, through cruises. And so we worked closely to make sure that those cruises would be safe, that we could implement mitigation strategies with the cruise liners so that they could be both safe and operational as soon as possible.

But I would have to go back. I don't know off the top of my head, but I would be happy to get you the information as to how long they were closed, and the timeline there.

Mr. BILIRAKIS. Does 16 months sound about right?

Dr. WALENSKY. It may be. I would have to go back.

Mr. BILIRAKIS. OK. The no-sail order remained in effect, in my opinion, far too long. What do you say to the people of my State who lost their livelihoods due to your agency's inability to make nimble and timely fact- and science-based decisions?

And how will you commit to changing your agency's approach to the way it handles the travel and tourism sector? Because it is so vital to my particular State and, of course, other Members. We

have hidden treasures throughout the world, but the cruise industry is very important to our economy.

Dr. WALENSKY. The cruise industry and many other industries have suffered gravely from the last 3 years. And so, you know, what I can tell you is that we at CDC are working to put the science of public health forward so that we can work with—across the agencies to create policies that—where health is one piece of the puzzle.

And so, you know, that is our job at CDC.

Mr. BILIRAKIS. Thank you.

Dr. Califf, according to recent GAO reports, they reiterated longstanding concerns about the FDA's ability to oversee the global pharmaceutical supply chain, an issue that has been on their high-risk list since 2009. GAO found that the FDA needs to increase monitoring of medical products manufactured overseas and improve planning for drug shortages.

GAO reported that the FDA had vacancies among each of the groups of investigators who conduct foreign inspections. For example, within its foreign offices in China and India, about one-third of its drug investigator positions were vacant. Inexcusable, as far as I am concerned. This is a serious issue.

Dr. Califf, how much progress have you made in filling these vitally important vacancies?

Dr. CALIFF. I appreciate your bringing this up. I couldn't agree with you more that there is a lot of work to do on the supply chains.

I would also point out it is not just an FDA issue. It is really an interaction of FDA and industry and other parts of government, in addition.

We are, thanks to the omnibus bill now, we have additional hiring authority in these areas to bring on more people. And we are hard at work in doing it. Our numbers of inspections are growing daily now, and we are catching up to what was lost during the pandemic.

And particularly in China, as you know, this has been a big issue because of lack of access to entry into China until very recently. So we are glad to provide you with the numbers, and also we will have a lot to discuss about how to make this better.

It is a global supply chain. It is fragile. The only industry where we are not seeing supply chain problems is tobacco, as far as I know, which is not exactly the way I would like to see it.

Mr. BILIRAKIS. Yes. I would like to see also if you can provide me this information, or even give me a rough estimate now as to how many jobs have been filled since the legislation was passed and how many remain—I mean, particularly, you know, with the—with—overseas, China and India.

Dr. CALIFF. Well, we will get back to you with the details.

Mr. BILIRAKIS. Please.

Dr. CALIFF. I am happy to follow along with you.

I have done a lot of work in China and India myself in my previous life in academia and industry, and we have got to be there, because that is where a lot of our supplies are coming from now, whether we like it or not. And I hope we can also fix that, and bring more of it back to the U.S.

Mr. BILIRAKIS. Thank you very much. I yield back, Mr.——

Mr. GRIFFITH. The gentleman yields back. I now recognize the gentleman from California, Mr. Cárdenas.

Mr. CÁRDENAS. Thank you, Mr. Chairman. And also thank you to the ranking member for having this important hearing.

The COVID–19 pandemic has taken a devastating toll and highlighted the ugly reality of health disparities in our country. It is our responsibility to learn from these lessons that COVID–19 forced us to confront. Otherwise, people are going to suffer systemic disparities over and over again. And this lens extends to our research infrastructure, as well.

Dr. Tabak, you note in your testimony that the impacts of the pandemic have not been felt equally across American communities, with Black and Latino and other underserved communities, as well as care practitioners and others on the front lines bearing the brunt of both the physical and mental health impacts of COVID–19.

How have these lessons about health inequity informed the approach to our research infrastructure, and how are you ensuring our clinical trials include people from traditionally underrepresented communities and those with traditionally under-represented lived experiences, as we look at the long-term physical and mental health impacts of COVID–19?

Dr. TABAK. What we have learned is we have to proceed at the speed of trust in order to engage people from what are very often marginalized communities. We have to reach out, often through trusted advisors, community leaders, to build the basis of why the research that we are proposing to conduct is important.

We are also working very hard to recruit a much more diverse workforce. When somebody looks like you, it is easier to engage in what are very important and serious discussions.

We—during the COVID response we have had specific programs. For example, the RADx underserved populations program, where we reached out to communities to understand why there wasn't an uptake in some of the over-the-counter testing procedures.

And so we are using a broad range of approaches. Within NIH, of course, all of our research is being informed by these lessons, certainly, not just that restricted to COVID.

Mr. CÁRDENAS. Thank you, thank you. I also want to pivot to discuss future management and communications during a public health emergency.

So, Dr. Walensky, it is great to see you again, and thank you so much for all the wonderful work that you do, and also being one of the facing-forward individuals that Americans hear from. So thank you for all the wonderful work you have been doing.

You talk a bit in your testimony about the importance of translating science into practical, easy-to-understand policy. You came to my office, and I actually understood what you were explaining to me. So thank you. I am not a doctor, like some of my colleagues are.

In districts like mine, where the majority of households report speaking Spanish at home as their primary shared language, it is absolutely critical to make sure we have health resources in Spanish and other languages in our great country. How are you looking

to improve health messaging across many languages, and what challenges have you seen in your attempts to combat COVID and misinformation in non-English languages?

We have a big problem in the Spanish-speaking community when it comes to what people see on the internet and the misinformation and disinformation.

Dr. WALENSKY. Yes, thank you for that question. It has been critically important for us to bridge the equity divide that we have seen in this country through COVID–19.

So much of what we have done are—many of our guidances are not just available in Spanish but in dozens of languages, actually. And it is critically important. But yet we still have people who may not be able to access those guidances, either a digital divide, a literacy divide, many other reasons. And even in—yes, many other reasons.

So, you know, much of our work has been in how we reach people. Is it through community health workers? Is it through community-based organizations? Much of our divide we have seen has been in the rural/urban divide. So what we really—46 million rural Americans who were—you know, have half the vaccination rates in their pediatric populations. So we really need to reach people where they are.

The mis- and disinformation often reaches them faster. And that is really critically important to emphasize. We all have a role, because we at CDC will do a lot of work to try and tackle that. But it may not be the government official that they want to hear from. It may be an academic society, it may be an academic official, it may be, you know, somebody in their local pharmacy, it may be their local pediatrician.

So we have much work to do in the mis- and disinformation. And I would urge, again, all of us have a role in addressing mis- and disinformation. Thank you.

Mr. CÁRDENAS. Thank you, Mr. Chairman. My time having expired, I yield back.

Thank you, Doctor.

Mr. GRIFFITH. The gentleman yields back. I now recognize the gentleman from Ohio, Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman, and thanks to our panelists for being with us today.

Dr. Walensky, thank you especially for being here. You got a tough job. CDC has got a tough job. And public trust and confidence in what the organization does is so vitally important. And I know you know that.

In the American Rescue Plan, passed almost unilaterally by our Democrat colleagues, it included a staggering $47.8 billion of new spending for "activities to detect, diagnose, trace, and monitor SARS–CoV–2 and COVID–19 infections and related strategies to mitigate the spread of COVID–19."

In addition, that law provided CDC 1 billion for "vaccine confidence" activities. Would you say the 1 billion for vaccine confidence activities was successful in building confidence in the vaccines?

Dr. WALENSKY. Thank you for that question. I think that what we don't know is what would have happened in the absence of those resources.

Mr. JOHNSON. No, but do you think it helped in instilling confidence?

Dr. WALENSKY. I absolutely know that we have been using those resources——

Mr. JOHNSON. No, but did you——

Dr. WALENSKY [continuing]. To reach——

Mr. JOHNSON. Did it improve the confidence level of the public? That is what I am asking you, yes or no.

Dr. WALENSKY. Compared to where it otherwise would have been in the absence of it, yes.

Mr. JOHNSON. OK, all right.

Dr. WALENSKY. But we also have a——

Mr. JOHNSON. Well, I am not sure that we got our money's worth, because in my district people tell me not only are they losing confidence in the COVID vaccines, but now other more proven vaccines, as well. We are going backwards.

A recent study showed that, from 2019 to 2022, the percentage of American parents who opposed requiring the measles/mumps/rubella vaccines for school jumped from 23 percent to 35 percent. This is dangerous, and it is because people do not know who to trust. There is a crisis of confidence in our public health authorities, including the CDC after a series of major missteps in the last couple of years. This is exactly why we need to have this hearing today.

So, Dr. Walensky, continuing on, do you know how much funding the American Rescue Plan gave CDC to conduct or to support contact tracing activities?

Dr. WALENSKY. I would have to get back with you to have that specific number.

Mr. JOHNSON. Please. Do you know how much money from the recent omnibus does the CDC plan to spend on contact-tracing activities?

Dr. WALENSKY. I would have to get back with you on that specific number. We are no longer endorsing contact tracing——

Mr. JOHNSON. Do you know——

Dr. WALENSKY [continuing]. Specifically for COVID–19.

Mr. JOHNSON. OK. Do you know how much was provided for staffing?

Dr. WALENSKY. Again, I won't be able to give you specific numbers on any of these, but I would be happy to work with your staff to do so.

Mr. JOHNSON. OK, I would appreciate it if you would get back to me on that.

Then is it fair to say that the CDC has, through grants, technical assistance, and research, spent billions of dollars over the course of the COVID–19 pandemic on supporting contact-tracing activities?

Dr. WALENSKY. Again, I don't know the specific number off the top of my head, but I would—what I would say is it is contact tracing, mitigation, testing, outreach——

Mr. JOHNSON. It has been allocated, though, right? Contact tracing. Billions has been allocated and approved to the CDC for that purpose.

Dr. WALENSKY. I would need to get back to you specifically on the——

Mr. JOHNSON. What is your——

Dr. WALENSKY [continuing]. Line items——

Mr. JOHNSON. What is your contact tracing staff doing now?

Dr. WALENSKY. Well, I am not sure that we have contact tracing-specific staff at the CDC.

Mr. JOHNSON. That answers my next question.

Dr. WALENSKY. Well, I do want to say, though, that we had 25 people—2,500 people deployed who had—into our response who had full-time previous jobs.

Mr. JOHNSON. OK. Well, you kind of answered my next question.

I ask this because I was surprised to find out that, as of last Friday, the CDC's contact tracing website hasn't been updated since February of 2022 during the Omicron surge. The CDC has not changed or updated its guidance in a year. Adding insult to injury, there is a notice on the contact tracing webpage stating that "CDC is reviewing this page to align with updated guidance." This notice has been on the website since August 11th, 2022. This means the CDC's contact tracing guidance has been undergoing alignment for 181 days.

And Mr. Chairman, I would ask unanimous consent to put these website documents into the record.

So when we talk about CDC losing its credibility, it is things like this. CDC and its supporters argued as recently as December 2022 that it needed billions of dollars for, among other activities, contact tracing. But the CDC can't even be bothered to update its public-facing guidance in a timely fashion. Public confidence and public trust is important, Dr. Walensky.

Thank you, and I yield back, Mr. Chairman.

Mr. GRIFFITH. Thank you. The gentleman yields back. The Chair now recognizes Dr. Ruiz for 5 minutes for questions.

Mr. RUIZ. Thank you. Thank you all to the witnesses who are here and for your heroic work and for your service to our country during this public health emergency. I appreciate that you are taking the lessons learned through this unprecedented experience and are applying them to future pandemic responses.

Lessons learned means things that—we must take a look at the things that we did well, and then the things that need improvement. And we need to be honest in the scope and the proportionality of those good works and the things that need improvement, as well. For example, let me remind everybody that we have lost 1 million people and 1 million of our citizens, residents, mostly our most vulnerable individuals. But at the same time, we saved 3.2-plus million lives with the efforts that were done.

We must look at why our Nation had the highest death rates than any other nation and tackle those difficult questions in order to prevent that from happening.

One thing for sure is that this pandemic shined a spotlight on what we already know, which is that there are glaring disparities

in access to healthcare based on where a person lives, the color of their skin, ZIP Code, or how much money they make.

And so, for those who live perhaps in safer areas with the resources to stay safer, you know, the issue of the pandemic may not have been a high risk for them, and they are mostly concerned of the enormous, enormous inconvenience that this pandemic, unfortunately, gave to everybody. But if you are living in a very concentrated household with people who are sick and don't have access to healthcare, that—and you know that the risk is much higher in your community, then the precautions that the CDC and other experts are saying is lifesaving.

And so that is why this is so important, because we must understand in the public health world, as a physician, you must ask the question: Who are the most vulnerable, the most likely to die, and how are you going to prevent them from dying?

But it seems like our approach here is very malaligned, and we need to really understand this issue.

In my district, for example, the Coachella Valley Volunteers in Medicine and the Desert Health Care District in Southern California worked to address these issues, to run testing sites and vaccine clinics in the least-served areas of the community, the hardest hit, hardest to reach, for the homeless under the bridges, for the farm workers in the workplaces, for the most vulnerable uninsured at their churches. We took care to the people, and it helped.

Together with my office, and even myself rolling up my sleeve, inoculating, conducting the testing in Spanish and English, we met people where they were, reducing barriers that people often face in getting the care that they need, like a lack of transportation, the ability to take time off of work.

And I applaud the Biden administration for implementing programs to help level the playing field through the HRSA and the CDC programs that distributed vaccines directly to our community health centers and the retail pharmacies who serve as the very communities that traditionally have lower access to care. And this was a response because of Governors who did not follow the equity rule, did not believe in this approach, and did not allow the monies to go to the hardest-to-reach areas.

As a member of this committee, and as the ranking member of the Select Committee on the Coronavirus Pandemic, I truly want to understand what we have learned about best practices in addressing inequities, and how the agencies here today are applying those lessons to close the gap in our pandemic response and ensure equal access to care for all.

Dr. Walensky, what did the CDC learn about the tools needed to address health disparities in the COVID–19 response?

And how is CDC incorporating these lessons into its strategic reorganization to make equity a strategic part of our effort in future healthcare pandemics?

Dr. WALENSKY. Thank you, Dr. Ruiz. You note what we learned in COVID–19, but what we have known in infectious diseases all along, which is infectious diseases go to the most vulnerable. That is how they work, and that is how they—that is—it happens in HIV, it happens in hepatitis C, it happened in COVID–19, it happens in influenza.

We knew that that was going to be the case, and we immediately put out resources, once we had them, in order to address exactly, as you did—go to the community-based organizations, go to those trusted messengers, make sure you have crossed the divides where people might not be reached, because we know that it is going to be the elderly, the vulnerable, those in multigenerational households, those who, when you say you should isolate, actually don't have any place to isolate to, right?

And so that was the work of CDC. We have developed—8 weeks after I came into office I declared racism a serious public health threat. We developed an Office of Equity. That equity office now in our reorganization announced 2 weeks ago will be reporting immediately into the immediate office of the Director. And we are looking forward to continuing those efforts to address equity issues. Thank you.

Mr. GRIFFITH. The gentleman yields back. I now recognize gentleman from Indiana, Mr. Bucshon—Dr. Bucshon.

Mr. BUCSHON. Thank you, Mr. Chairman. I want to start by saying to all of our witnesses that I appreciate you being here, and I know your jobs are very difficult.

The last 3 years have proven a rough time to work on public health issues. And while I believe most public health officials work in good faith, including you all, I also believe that you and your predecessors have at various times been pressured by your respective White Houses to take certain actions or make certain statements in order to achieve political objectives. Again, previous, current. And I just want to say that I cannot understate my disapproval for such behavior.

It is so important that our public health agencies be places of science and transparency. And if they are not, the American people find out, trust is destroyed. And when that—and then what reason do citizens have to listen to further advice? So we all need to work together to reestablish the trust in our public health agencies.

Dr. Walensky, I would like to discuss one aspect as it relates to vaccine mandates. I want to make it clear I support vaccination. I am personally vaccinated, as is my family. That said, I strongly believe that any medical decision, medical therapy is the decision of an individual and not of the Federal Government.

Beginning in 2021, vaccine mandates were imposed across the country. And as a result of these mandates, unvaccinated people were fired from jobs, excluded from higher education, even denied organ transplants and punished by judges in probate hearings and child custody cases. And finally, many were kicked out of our military.

The prevailing argument for the mandate was this: The more people that got vaccinated, the less the virus would spread. It is my understanding that, from the start, the vaccine manufacturers provided evidence that vaccines were safe and effective at reducing the severity of infections. But from the start they did not provide evidence that COVID–19 vaccines provide sterilizing immunity, preventing transmission of the virus. Is that correct, Dr. Walensky?

Dr. WALENSKY. Yes, let's just—so the clinical trials actually were not—did not have an endpoint on transmission. But ultimately, through both the wild type and the Alpha variant, there were data

that were released in the New England Journal that demonstrated that they did prevent for transmission for the wild type and the Alpha variant.

Mr. BUCSHON. Yes, and you said that earlier in the hearing. The question is what—when did that happen? What was the date that that happened, do you know?

Dr. WALENSKY. I couldn't give you the date of the New England Journal piece, but I could tell you that, by the time we saw Delta at the end of July of 2022, we knew that transmission——

Mr. BUCSHON. OK, because in 2021, March of 2021, you said vaccinated people do not carry the virus and don't get sick. That was based on previous information. That is what you are saying.

Dr. WALENSKY. That was based——

Mr. BUCSHON. It was an evolving situation.

Dr. WALENSKY. That was based on the wild type and the Alpha, yes.

Mr. BUCSHON. OK, so that clarifies why the CDC said what they said at that time, I guess.

And so I would like to really know specifically when the CDC knew that vaccines did not prevent transmission, how early in the process. And the reason this is important—and I know you said that you don't know the exact dates of the article and all that. But, you know, the CDC continued to support vaccine mandates throughout all this, and still do, even though we have knowledge now that, although they are very effective—again, I have been vaccinated, I wish everyone would get vaccinated—that they don't prevent transmission, at least the current variants. So why mandates?

And, Doctor, you know—and the FDA can answer that question, too.

Dr. WALENSKY. Yes, so maybe—I do want to correct. It was July of 2021, not July of 2022. But it was after the New England Journal piece that you are speaking about.

Mr. BUCSHON. OK.

Dr. WALENSKY. I do appreciate your actually emphasizing the importance of vaccines, and how they prevent severe disease and death.

Mr. BUCSHON. Understood. So I have a limited amount of time. So on the last question, you know, with that information, why does currently we still recommend mandates?

Dr. WALENSKY. You know, my job at the CDC is to provide the scientific data that demonstrates the safety, efficacy of these vaccines in preventing severe disease——

Mr. BUCSHON. OK, fair enough. And I saw—it is basically——

Dr. WALENSKY [continuing]. Larger policy puzzle.

Mr. BUCSHON. It is basically policy driven, probably, from the White House.

And, you know, the White House says their executive order requiring COVID–19 vaccination for travelers to the U.S. is based on CDC's advice. But what—you are telling me that you have given them advice, and they are quoting you and saying that they are maintaining this vaccine for people to come in, even though we have just now discussed the fact that we know that it doesn't prevent transmission. It will prevent the individual from getting really

sick, but there is no—there is—it doesn't prevent the risk of someone coming into the country and spreading it to other people.

Dr. WALENSKY. As well. So it does prevent severe disease and death. It doesn't prevent transmission as well as it did for prior variants, but it does still prevent some.

I would like to offer——

Mr. BUCSHON. So I just—I am out of time. But we need to lift this mandate on travelers that has a big impact on our tourism industry, and most other countries are doing it.

I will yield back.

Mr. GRIFFITH. The gentleman yields back. Now I recognize the gentlelady from Michigan, Mrs. Dingell.

Mrs. DINGELL. Thank you, Mr. Chairman, and I want to thank all of our panelists for all of the work that you have been doing under not the easiest of circumstances, and I have a lot of questions, so I need to get to them, but I need to say that we are going backwards on vaccines, and we are building—we are—I hope our hearings do not contribute to the lack of public trust.

I look at measles, which has been in my community because people are afraid to get it. And I say this as someone who got Guillain-Barré from the swine flu shot and was more afraid of anybody in the Congress of the COVID flu shot. But I did my research, I got it, I didn't die, and I got every other one. So we need to make sure that we understand vaccinations save lives and all kinds of things as we are doing these hearings. We can ask questions, but let's not contribute to the lack of trust in the community.

But since the outbreak of the pandemic, we have encountered new challenges with emerging variants and other diseases. Just this past fall we saw triple—with an increase in COVID–19 cases, an earlier-than-unusual flu season, and RSV, which hit children and seniors especially hard.

In the midst of this latest challenge, we heard from parents across the country struggling to find common, over-the-counter pain relievers such as Tylenol and Advil for their kids, as well as the antibiotic amoxicillin that is used to treat all kinds of infections. You know, when you are sick and you need it, you get scared when you can't find it.

So, Dr. Califf, we know FDA can't wave a magic wand and immediately start producing more drugs when there are supply chain issues. But what can the agency do in a situation like this? What has the agency done to address these shortages?

And because we are going to be short on time, what authorities or resources would it be helpful for the FDA to have to better anticipate and deal with these increases in demand and shortages?

Dr. CALIFF. Well, as you know, the industry is increasingly developing digitized supply chains. Each company has great detail about its own supply chain, but there is no central hub. And right now our authorities across drugs, devices, biologics are somewhat different. None of them are as complete as they need to be.

Particularly, we need to—for the companies to notify us when they see a shortage coming, whether it is because of a manufacturing problem, which currently exists for the most part, or because there is a great increase in demand that they are forecasting that will outstrip their ability to manufacture the product.

Ultimately, I would like us to envision 10 years from now a digitized supply chain that could undergo stress testing like we do for banks and the financial sector now.

Mrs. DINGELL. So for the record, could you tell us later for—in writing—if there is something Congress needs to be doing to give you more support, so we don't have——

Dr. CALIFF. Yes, we will give you a list.

Mrs. DINGELL. Thank you.

Dr. CALIFF. There is a—it gets into details, because——

Mrs. DINGELL. I want details.

Dr. CALIFF [continuing]. It is like a puzzle.

Mrs. DINGELL. But we will do it—I think all of us would like to see that.

I would like to now turn to another over-the-counter drug issue. When the pandemic was declared, we saw an increase in demand for another commonly used drug: hand sanitizers. Individuals and hospitals alike were having trouble finding it, and through an enforcement discretion policy the FDA leaned on the ingenuity of small business owners like local distilleries to start producing product. Other producers, both in and outside of the country, also increased their supply.

However, we saw some producers were importing hand sanitizers that had been contaminated with benzene and methanol, known carcinogens, and microbiologics that can infect and cause illness. FDA put out statements alerting consumers and asking manufacturers to recall their products, but FDA could not order any manufacturers to take their products off the shelves.

Although it may be shocking to many Americans—as it was to me because, unfortunately, I bought one of those hand sanitizers—FDA does not have the authority to recall most drugs, even when they are contaminated with these harmful chemicals.

Dr. Califf, can you explain how having the authority to actually order a recall would be helpful in times when a product is putting consumers at risk?

Dr. CALIFF. Of course, most companies want their products to be good, so they will recall them on their own. But we run into companies that don't do it and put people at risk. If we can't order it to happen—all we are trying to do is then inform the public about something that can be lethal or cause serious illness.

So we really need to have the authority to do it. We wouldn't use it unless we couldn't work it out with the company.

Mrs. DINGELL. Some in the past have suggested that, instead of ordering a recall when a sponsor fails to comply with a voluntary recall, FDA can simply revoke a product's approval or declare the products misbranded. Are these options acceptable substitutes for recall authority? Why or why not?

Dr. CALIFF. Absolutely not. Remember that, in a recall, you have got to go to the shelf and take what has already been there and notify people in their homes. It is not enough to say, "Don't sell any more." A lot of it is going to be out there in commerce.

We have a situation going on outside the U.S. right now in diethylene glycol in Tylenol and ibuprofen, which is one reason we can't just import it. We have got to have control of the situation.

Mrs. DINGELL. Thank you.

I yield back, Mr. Chairman, but we have got some good areas to work on together.

Mr. GRIFFITH. Thank you very much. The gentlelady yields back. I now recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman, and thank you for this hearing, Mr. Chairman. We have—we are committed to a government that is accountable, and we need to be accountable, and so do the agencies, especially the agencies, and especially when we are talking about the government's response to COVID–19 pandemic. The American people deserve—they deserve this information. They deserve answers and accountability, because there have been clear failures by this administration over the past 2 years.

We still got existing vaccine and mask mandates that are—and we have experienced diverting funds away from frontline healthcare workers to COVID campaigns. It is no wonder why the American people have lost their trust in our public health institutions.

I am no different from any other Member of Congress up here. I have a lot of pride in my State. I am very proud that the CDC is in my State. But I am very concerned about the public perception right now of the CDC, especially after what we have been through. That is of concern to me as a native Georgian, and as a representative from the State of Georgia.

So, Dr. Walensky, I hope that you will help me with this, but I want to start with Dr. Tabak, because there is something that is very important to me, as a healthcare professional, and that is gain-of-function research.

I want to ask you. In the fiscal year 2023 omnibus, section 2315, there was a provision included that would ban the funding of HHS dollars towards certain types of research involving pathogens of pandemic potential or biological agents or toxins that are at risk to be a severe threat to public health and safety, effective immediately. This ban is in effect until the agency conducts certain review and oversight of protocol, and it can't be lifted. It cannot be lifted without the appropriate notice to Congress.

My interpretation of this provision is that it is a ban of gain-of-function research. And we may have a different definition of gain-of-function research, but I want to ask you: Can you please speak to how NIH is implementing this provision?

Dr. TABAK. So we do need to have a short conversation about gain-of-function research. That is a generic term, and it gets us in all sorts of trouble.

The type of research that you and everybody is concerned about is a very narrow portion of that, where you take, for example, a virus and attempt to make it more transmissible. You attempt to make it more pathogenic.

Mr. CARTER. OK, I will accept that, and I appreciate that answer. That is what this was intended for——

Dr. TABAK. And we——

Mr. CARTER [continuing]. In the omnibus.

Dr. TABAK. And——

Mr. CARTER. And that—and my question is, are you implementing this?

Dr. TABAK. And we currently are not funding that type of research. We have nothing in that category. The NSABB, which is an advisory committee to the USG, just provided a set of draft recommendations which will presumably tighten our approach to this type of research. Once the report is finalized, which we expect will occur very shortly, I will send a memorandum to the Secretary of HHS, and he, in turn, I presume, will reach out to the NSC and to the OSTP——

Mr. CARTER. So what——

Dr. TABAK [continuing]. To convene a governmentwide effort to update the framework with which we work in these——

Mr. CARTER. I want more. I want to hear more than just the effort. This has to be done.

So what you are telling me is that it has been done, and has been done immediately.

Dr. TABAK. The——

Mr. CARTER. And I will accept your limited definition of gain-of-function research.

Dr. TABAK. That is the definition.

Mr. CARTER. OK. Then it goes on to say that—in the 2023 omnibus—that we banned the funding of pandemic potential research in foreign countries of concern, and we defined "foreign countries of concern" as China, North Korea, Russia, and Iran. Can you tell me, has that been done?

Dr. TABAK. There is no funding of EPP research in any foreign country today that is sponsored by NIH.

Mr. CARTER. Has there been in the past?

Dr. TABAK. No.

Mr. CARTER. There has not been in the past?

Dr. TABAK. There has not been in the past, funded by NIH, related to the SARS–CoV–2 virus. Many years ago there was EPP research conducted in the Netherlands, and that was an influenza.

Mr. CARTER. OK, let me ask you one other thing. This legislation also mandates that all funding for the research be stopped no later than 60 days after the bill is enacted, and that is the end of the month. Can you commit that your agency will fully comply with the law, fully comply with the law and completely defund any relevant grants at this time?

Dr. TABAK. We have no current grants funded, so there is nothing to defund.

Mr. CARTER. OK. So I just want to make sure I am clear. You are not funding anything with your limited definition of gain-of-function research, nor have you in the past. Yes or no?

Dr. TABAK. In the past there was funding, an influenza research. But currently there is no such research funded.

Mr. CARTER. And there will not be in the future.

Dr. TABAK. We are—we have no plans that I am aware of.

Mr. CARTER. Thank you, and I yield back.

Mr. GRIFFITH. The gentleman yields back. I now recognize the gentlelady of New Hampshire, Ms. Kuster.

Ms. KUSTER. Thank you so much, Mr. Chairman, and thank you to our witnesses. This is a challenging time over the last 3 years, and I admire your patience.

I can't help but think honestly, if the former President had just taken the vaccine on television in January when he apparently took it in private, a million—you know, thousands of lives could have been saved. So I am grateful for all that you do.

It has been 3 years since COVID–19 flipped our lives upside down and changed our world. And I want to acknowledge what the Federal Government has accomplished to save lives and keep our economies safe, as well as identify areas for improvement.

And I thank Mr. Bucshon for his comments that, under several administrations, you have been challenged. And I think we can work together, going forward.

So I want to focus on two specific issues: first, the need to improve collection of real-time data to help us assess pandemic threats; and second, the need to facilitate data sharing to enhance our responsiveness to pandemics and other public health challenges.

At the start of the pandemic, the U.S. did not have an efficient system for collecting real-time data. This made it difficult for public health officials to understand how to respond to the pandemic. Recognizing this challenge, this Congress invested billions of dollars to build, update, and modernize data systems that served as the backbone of our pandemic response efforts.

The American Rescue Plan provided billions of dollars in funding to support a whole range of COVID–19 vaccine activities that we have discussed today, including improvements to information technology to enhance the quality and availability of real-time data at the Federal, State, and local level.

This funding was vital, but we need a common framework that guides us through these investments. Last Congress I worked on bipartisan legislation to provide such a framework through immunization infrastructure modernization. Dr. Walensky, why is safe and secure collecting and reporting of public health data so important, even beyond COVID?

And what has hindered State and local health departments from bringing their systems into the 21st century?

Dr. WALENSKY. Yes, I appreciate all of your efforts here, especially in immunization.

What I can tell you is, through our data modernization efforts, we are standardizing how data are collected, and we are creating similar highways so that data from jurisdictions from your districts can come in to CDC, and then we can deliver them back to you in real time. You can see what is happening around you.

Some of the limitations that we have—maybe I will just say those efforts have been successful. And prior to the pandemic we had 187 healthcare facilities that could give us real-time data. We now have 22,000. We are not where we need to be. But because of those efforts at the beginning of the mpox outbreak, we had 22—28 States that could actually give us data electronically, and we were getting them in real time. Oregon Health Community Center has saved 140,000 person hours because they are no longer submitting test data by fax. So those data modernization efforts are paying off.

We need congressional help in our data authorities. It took us 6 months to get data use agreements in the beginning of COVID–19.

It took us 3 months to get data use agreements in the beginning of the mpox outbreak so we could see how immunizations were rolling out in communities.

Those immunization efforts specifically help us see where we need to do further outreach, are vaccines reaching where the disease is, where do we need to do further outreach. And important, those immunization data provide us opportunities to provide you back the information that you want, which is do these vaccines work?

It is because of those immunization data that we were able to be the first in the world to provide vaccine performance on the JYNNEOS vaccine. Thank you.

Ms. KUSTER. Great. So the second problem, once you have the data, is data sharing. We need a clear need for efficient data sharing between all sectors—the public, public health leaders, government—to ensure that healthcare resources are directed to those communities most in need.

Recognizing there are barriers to complete integration, what can Congress do to help facilitate better data exchange needed to respond appropriately to a—the next pandemic?

Dr. WALENSKY. So that would specifically be the data authorities. So data authorities and immunizations data authorities—to this day I can't tell you who is immunized in the hospital. And we are going to lose our capacity to look at laboratory testing and COVID–19 at the end of the public health emergency.

So it is those data authorities, the sharing of data from local districts to the States to CDC so that we can fluently share it back to you so you know what pathogens may be knocking on your front door.

Ms. KUSTER. Terrific, thank you. I look forward to working with—on a bipartisan basis to get that passed. Thank you.

Dr. WALENSKY. Thank you so much.

Ms. KUSTER. I yield back.

Mr. GRIFFITH. I thank the gentlelady and now recognize Mr. Duncan of South Carolina for his 5 minutes of questioning.

Mr. DUNCAN. Thank you, Mr. Chairman. This has been an interesting hearing.

I, first off, want to thank you all for all the efforts that you put forth during the global pandemic crisis.

Dr. Tabak, you may want to talk to staff and amend your definitive answer on gain-of-function grants or subgrants that flowed through NIH. I think that would be important.

Dr. Walensky, you are a medical doctor. So, outside of residency, did you ever serve in a hospital as a hospitalist, a clinical practitioner, or anything like that?

Dr. WALENSKY. I was the chief of infectious diseases at Massachusetts General Hospital for the 4 years prior to the—3 years prior to the pandemic, and clinically practiced for 25.

Mr. DUNCAN. Thank you. Oftimes doctors prescribe off-label pharmaceuticals and treatments. Is that correct?

Dr. WALENSKY. Yes.

Mr. DUNCAN. Did you ever have an instance where the CDC directed you, as a doctor, getting between you and the patient, what you could prescribe off label?

Dr. WALENSKY. Certainly, as you make clinical decisions, you look at guidance. But at an individual level, those guidances are intended at——

Mr. DUNCAN. Guidance, but not directives, right?

Dr. WALENSKY. I am sorry?

Mr. DUNCAN. Guidance, but not directives.

Dr. WALENSKY. No. Guidance, but not directives.

Mr. DUNCAN. Right. So I am concerned that, during the COVID pandemic, that the CDC, through various sources—and it could have been HHS funding through CMS—got between the doctor and the patient by telling doctors that you could not prescribe off-level—off-label treatments for their patients.

The doctor is educated. He has clinical experience and should be able to treat that patient however they see fit, if they think that is the best. I don't care if it is a knee replacement or if it is COVID–19 treatments. That is the doctor's decision. Would you not agree with that?

Dr. WALENSKY. I would challenge a premise that we at CDC have guidance on how—and definitive guidance on how—prescribe drugs or—drugs are prescribed.

Mr. DUNCAN. Well, let——

Dr. WALENSKY. What I would say is that, in CDC, we have clinical recommendations for——

Mr. DUNCAN. In the essence of time, let me just say that we witnessed—I talked to a lot of doctors—that they were told by the administrators of the hospital—because it was pushed down from Washington, DC—that you couldn't prescribe certain off-label therapeutics if—even if the doctor felt like that was how they wanted to treat that patient.

Dr. WALENSKY. We could have a further discussion about that, but I don't believe that was related to CDC guidance.

Mr. DUNCAN. Then why were the doctors being told that by their administrators?

Dr. WALENSKY. Well, so we are the public health agency, not the prescribing agency.

Mr. DUNCAN. Is that an HHS issue? Was it a CMS issue?

Dr. WALENSKY. I would have to defer. I don't know. I don't know who would—but it is not CDC guidance.

Mr. DUNCAN. There were treatments, therapeutics, that were working around the globe that doctors wanted to prescribe to patients in the United States.

Dr. WALENSKY. There are——

Mr. DUNCAN. Would you also agree that people following the guidelines of CDC that treated patients with Remdesivir or whatever that died, would you agree that patients died based on those treatments?

Dr. WALENSKY. There are COVID–19 treatment guidelines. Those are—guidelines come out of the NIH, and I would like to pass it to Dr. Tabak, if that is OK.

Dr. TABAK. So the treatment guidelines that Dr. Walensky refers to are a compilation from NIH as well as outside experts across the country.

Mr. DUNCAN. I get guidance, sir, and I appreciate guidance. What I have been told is doctors were told they could not use cer-

tain therapeutics that they thought might be in the best interest of treating that patient and saving a life. Patients died based on the treatments that were pushed down from Washington, like Remdesivir. Patients died in this world, and doctors make better decisions than when government gets in between that doctor-and-patient relationship.

I would love to have a further followup, but I agreed to yield some time to Dr. Burgess, and I yield as much time as I have left.

Mr. GRIFFITH. The gentleman yields. Dr. Burgess?

Mr. BURGESS. I thank the gentleman for yielding.

Dr. Walensky, I just had a followup question. Thank you for hosting me last October when I came down to CDC. And as you remember, one of the things that I had been terribly concerned about is the excess mortality, the fact that life expectancy—according to your website, life expectancy in the United States has declined to its lowest level since 1996.

Granted, the COVID deaths, granted the fentanyl deaths, methamphetamine, diseases of despair. But I am not sure that we are not missing something, and I want us to be very thorough in looking at the data. And that is where I ask your help, because CDC is the data repository in the country.

Is there something 5 years from now we are going to look back and say, "I can't believe we missed that"? So that is my concern, that there is something hidden within all of this in the excess mortality that we should be—where our focus should be now.

Dr. WALENSKY. Yes, thank you for that question.

So we have different ways of looking at deaths. We have aggregate data that come from the Department of Health. We have line-level data also that lag a little bit, and then we have the death certificate data, where we have the most definitive information that we are going to get based on how that death certificate is filled out.

Those death certificates are filled out with an underlying cause and contributing causes. And we look at that for COVID–19 and other related deaths. It is the case that there is—COVID is an underlying cause, but then many other causes, as you know, opioid-related causes and then lack of access to medical care. At emergency departments, ICUs, people had surgeries deferred.

Mr. BURGESS. Yes.

Dr. WALENSKY. So that is a lot of what we are looking at right now.

Mr. BURGESS. I am going to need to yield back, but I am going to submit a question that I would like a response in writing.

Thank you, Mr. Chairman.

Thank you, Jeff.

Mr. GRIFFITH. The gentleman yields back to the gentleman. The gentleman yields back to the chair. The Chair recognizes the gentlelady from Delaware, Ms. Blunt Rochester, for her 5 minutes.

Ms. BLUNT ROCHESTER. Thank you, Mr. Chairman, for the recognition, and I want to thank the witnesses.

I want to thank you not only for your work, but your work during one of the most challenging times in the history of our planet. As I sit here, I was thinking about the physical, the mental, the economic toll that it has taken on all of us, and the fact that there was so much that we did not know. And so I just want to commend

you, because I know you are sitting here and, you know, getting some very tough questions, but it was also something that we collectively went through and are still going through.

I have a family member who died 2 months ago from COVID, so I want us to remember this was unusual and that, even as we ask our questions, that we remember we are still in this together.

I am glad that you brought up workforce needs, data authority, supply chains. These are all things that have impacted every single piece of this, including research and development and innovation.

I know in its 76 years the CDC has never faced a public health emergency of this magnitude. So it is not surprising that there were a lot of lessons learned for all of us. And one of the things that we learned is that the CDC lacked critical data when COVID–19 emerged, resulting in an incomplete national picture of this global threat.

I am glad there were a lot of questions already asked on data authority, but, Dr. Walensky, what kinds of questions would data authority allow the CDC to answer?

Dr. WALENSKY. I——

Ms. BLUNT ROCHESTER. Can you give us a few examples also of how data authority could have helped in Federal decision making?

Dr. WALENSKY. Sure. What fraction of people in the hospital are vaccinated? What is—now, with—we have these authorities through the public health emergency. But what is going to be our percent positivity for testing? In impacts before we had all of our data use agreements signed is who is getting vaccinated. So those are key things as we have—we are in the position to make important decisions. We are making those decisions without the benefit of data that exist, and it makes it harder to make them. Thank you.

Ms. BLUNT ROCHESTER. I know, for me, one of the biggest things that I learned was that there were just basic things like collecting data on race and ethnicity that were not clear, and it ended up being one of the strongest indicators for death and contraction.

Can you tell us how—what steps were taken to bridge the gaps in data like race and ethnicity, or what more should be done?

Dr. WALENSKY. Right. So we are working through our data use agreements with each of our individual jurisdictions to be able to receive those data.

Oftentimes, those data are not fully completed. And so that gives us a limited view, as well. But if, through our data monetization efforts, we can then standardize the data that are collected and link them, then we—they would immediately populate.

Ms. BLUNT ROCHESTER. Yes, thank you.

One of the issues that I hope is not lost or forgotten is the issue of long COVID. And I am glad that that has also been one of the topics of discussion here. I know individuals that are still concerned, struggling. We have healthcare providers that don't really know what to do.

And Dr. Tabak, what guidance do you have for healthcare providers trying to understand and treat patients with long COVID now?

Dr. TABAK. At the moment there are no treatments that we know are effective against all forms of long COVID. What clinicians are

doing is they are treating symptoms based upon their similarity in other diseases and conditions.

We hope to launch the first interventional trials using our recovered cohort within the next few months and hopefully get more definitive answers than that one.

Ms. BLUNT ROCHESTER. I can say I am pleased that I have been working with stakeholders in this space, because I, again, don't want us to forget it. This also, in addition to our health impacts, it has impacts on our economy and jobs and people being able to go to work.

I ask unanimous consent to enter into the record a collection of published medical research and scientific literature from the COVID Patient Recovery Alliance. I have been—I ask for permission to enter into the record.

Mr. GRIFFITH. Without objection.

[The information appears at the conclusion of the hearing.]

Ms. BLUNT ROCHESTER. Thank you. Thank you, Mr. Chairman.

I have been working with these stakeholders, and again, as I said, I want to make sure that we don't forget those individuals and that we continue to have a focus there.

We will have a lot more questions to enter into the record. But again, thank you so, so much for your efforts. Again, we are still all in this together.

I yield back.

Mr. GRIFFITH. The gentlelady yields back. I now recognize the gentleman from Florida, Dr. Dunn.

Mr. DUNN. Thank you very much, Mr. Chairman.

So 3 years have now passed since this onset of this pandemic, and I think there's a lot of lessons that we can learn. Some things our government did very well, and I think we made some bad calls too. Operation Warp Speed was a resounding success at developing vaccines and a great example of what happens when we cut red tape.

I am concerned, however, that some policies were not grounded very well. Specifically, I am concerned about the mandates and the lockdowns. You know, when I was in med school, we were taught that mandates caused the public to distrust public health authorities. They undermined the public's confidence in our advice. And that was reconfirmed in a very large study out of Oxford International, a study of 29 countries in 2021. So mandates, I think, were counterproductive.

The lockdowns. Lockdowns of economy are a new and strange concept. We never had that. That was never in the playbook for epidemiology in med school. I am reading now economists who estimate $100 trillion damage to the free world's economy from these lockdowns. Our great grandchildren will be paying for this.

Dr. Walensky, whatever comes in the future, whatever the next pathogen is, we can never do this again. Do you agree with me?

Dr. WALENSKY. I agree that we should do everything in our power not to have it happen. But I will tell you that I was a practicing clinician in March of 2020, and we had a morgue sitting outside the hospital. And so, when you can't take care of a motor vehicle accident and you can't take care of a brain tumor, extraordinary measures are necessary.

I would very much like to never be back——

Mr. DUNN. Yes, but the lockdowns didn't help. So, I mean, what happened——

Dr. WALENSKY. Well——

Mr. DUNN. It was an if/then, but that is not like you got any gain out of it.

Dr. WALENSKY. I do think when there are lockdowns, there was further need—there is decreased need for things like motor vehicle accident care. So I do——

Mr. DUNN. You locked down our whole economy.

Let me move on with the time here. So another concern I have is our failure in diagnostics. We have known for over 10 years that the principal source of immunity—the principal mediator of immunity to coronaviruses are in T cells, not B cells. However, to this day we lack coverage for any cellular immunity testing in this country. That is the T cell testing that you see.

NIH and CDC have ignored this kind of testing, despite the fact that we know this. This is the way the coronaviruses are principally—to the degree that we have long-lasting immunity from any coronavirus, it is mediated in the T cells. Still no coverage.

You know, it is—the other thing you get with T cell testing is you can—it is a test for natural immunity. So we test whether or not somebody has been infected. Imagine how helpful it would be to know who has some level of immunity, to know how many people were infected with this virus. We could still do population studies with this testing.

You know, Dr. Tabak, would you commit to the NIH studying some T cell immunity?

Dr. TABAK. So, in fact, we are having conversations now through our active consortium, which is a public-private partnership, Federal agencies, and industry to do just that, to look at T cell readout. And so——

Mr. DUNN. Please do, please do.

Dr. TABAK [continuing]. We are working towards that goal.

Mr. DUNN. You know, Singapore studied SARS–CoV–1 and T cell immunity, literally, 6, 7 years ago. I mean, that is a long time ago. We have known about this for quite a while.

I am also concerned, actually, about the shortage of studies on therapeutics for early outpatient treatment. I mean, we had a guidance nationally that basically said, "If you test positive, go home, quarantine, wait until your lips turn blue, and then go to the hospital, and maybe we can save you." That was it.

I mean, there were a lot of broad spectrum antivirals out there of potential use. Specifically, I am thinking about in Japan. This is not approved in America, but it has been approved in Japan. In fact, it is a generic drug in Japan, and it is Favipiravir. And we did—we just ignored it, we sailed right past Favipiravir, never mentioned it, and we instead approved, Dr. Califf, we approved Molnupiravir. Molnupiravir is a another RNA polymerase inhibitor, but it inhibits human RNA polymerase as well as viral. Favipiravir is specific for viral.

Can you tell me something about why we didn't take a look at Favipiravir?

Dr. CALIFF. Of course, the FDA will look at anyone who brings this data and seeks approval. So I will have to go back on the specifics of this.

But Molnupiravir, as I know you know, had randomized clinical trials that it brought——

Mr. DUNN. So did Favipiravir. It had—Favipiravir, when I looked in 2021, had 96 trials.

Dr. CALIFF. Well, we also have to look at the quality of the trial. So I will have to get back with you.

Mr. DUNN. Japanese trials are pretty high-quality medicine.

You know, I think—my time is expired, so I will have to—I have to yield here. But I think there is some real disappointments in targeting and choice of therapeutics and diagnostics.

With that, Mr. Chair, I yield back.

Mr. GRIFFITH. The gentleman yields back. I now recognize the gentlelady from Illinois, Ms. Kelly.

Ms. KELLY. Thank you, Mr. Chair, and I want to thank the chairs and ranking members for your insights on the challenges and successes we have had—faced in strengthening our response to the COVID–19 pandemic.

And excuse my voice.

And I want to thank the witnesses for all the work that you do.

Vaccinations have proven to be a powerful tool. The Biden administration's decision to make vaccinations free was a pivotal step in our continuing journey toward health equity and response to reluctance in communities of color to get vaccination.

The evolution of COVID–19 messaging created opportunities to address challenges and create strategy around increasing confidence in public health messaging for Black and Brown communities, including continued efforts to increase vaccination rates and booster compliance. Still, bivalent booster rates continue to lag, with 19.4 percent of Black communities, 12.7 percent of Latino communities receiving updated boosters, as compared with almost 30 percent of White communities.

Dr. Walensky, considering the pending PAHPA reauthorization, are there key learnings from COVID–19 that will help to increase Black and Brown awareness and uptake of public health strategies during the ongoing pandemic and other future public health emergencies? Because there will be others.

Dr. WALENSKY. Yes, there will be others. Thank you for that question.

Among the key points of our CDC Moving Forward is creating partnerships, results-based partnerships. And part of those partnerships is working with community-based organizations, recognizing that people know how their communities will react, and people know their questions that they would like answered.

We do have programs like Vaccinate with Confidence, race and ethnicity, access to community health, Let's Rise, promoting vaccine confidence. So all of these things are working within communities, from people—from—with people from those communities to understand what it is—what are their questions, the local questions that they have related to vaccine confidence.

It is a concern not only for COVID–19, but also for other routine pediatric vaccinations as well.

Ms. KELLY. So I know COVID is not over, but it is waning. So do you see that continuing, or we just did that during COVID?

Dr. WALENSKY. Those efforts are continuing, not only for—through the bivalent boosting, but we always have a vaccine campaign for flu vaccines every year.

And then we really do have work to do in our pediatric vaccines, as has been noted. We lost pediatric vaccination rates this year, down from 95 percent 2 years ago, 94 percent in the last year, 93 percent this year. A quarter of a million less children entering kindergarten with their routine vaccinations being up to date.

Ms. KELLY. Thank you.

How do you say your name?

Dr. TABAK. "Tayback."

Ms. KELLY. "Tayback." I want to be correct.

Dr. Tabak, can you elaborate on how initiatives such as NIH's CEAL, Community Engagement Alliance, against COVID–19 disparities increased clinical trial diversity for COVID–19 vaccines and treatments?

Dr. TABAK. Yes, I am pleased to do that. What we did was we partnered with local organizations within the community, faith-based organizations and other community leaders, people who are trusted, and met with them to explain things, basic questions about COVID, about therapeutics, about vaccines, and, importantly, why it is important to participate in clinical trials.

We wanted our trials to represent the Nation. And that, of course, gives better comfort to people that a particular intervention may work, if they know that somebody who looks like them was part of the trial.

We are building this into everything that we are doing now at NIH. We are not stopping just with the COVID response, because, obviously, the same tenet holds true for all clinical research. And so we are working hard to extend that.

Ms. KELLY. I am glad to hear that, because I was going to ask how can the successes of these efforts be replicated to ensure racial and ethnic diversity in clinical trials more broadly. So I am glad you are continuing.

Dr. TABAK. Thank you.

Ms. KELLY. I just want to say thank you again. This is very important to me, and I look forward to partnering in a bipartisan way with my colleagues to ensure clinical trial diversity.

Thank you. I yield back.

Mr. GRIFFITH. The gentlelady yields back. I now recognize the gentlelady from Arizona, Mrs. Lesko, for her 5 minutes of questioning.

Mrs. LESKO. Thank you, Mr. Chair. My first question is for Mr. Tabak.

You told Congressman Carter that NIH did not fund ePPP research in foreign countries, except for an influenza experiment in the Netherlands. Was that experiment funded by a direct grant or a subgrant?

Dr. TABAK. The experiment in the Netherlands, I believe, was a subaward, but I would have to check to confirm that. And that was done in the—I think it was in the early 2000s. It has been a while.

Mrs. LESKO. OK. And how, then, did the NIH know about the experiment, if it was a subgrant?

Dr. TABAK. It was approved under the then-DIRK/P3CO framework, and we use the normal monitoring procedures for that, yes.

Mrs. LESKO. In the case of EcoHealth and the Wuhan lab, the NIH was unable to get the records of a humanized mice experiment because the Wuhan lab, the subgrantee, refused to provide this to EcoHealth.

Given the failure of an NIH grantee to get lab records, there could be other cases where NIH can't get the lab records. Isn't that right?

Dr. TABAK. It is possible. As you know, that subaward has now been terminated. They are no longer funded by NIH to do anything.

Mrs. LESKO. So how can you state—how can the NIH know for sure that it hasn't funded ePPP, when NIH can't be sure it can get the lab records of experiments funded by NIH?

Dr. TABAK. As a result of them failing to provide us with the adequate documentation, they no longer have any funding from NIH.

The NIH funding, we approve what they are to do from their progress reports and from their publications they have done what they said they would do. The work was commensurate with the modest sums of money that we provided to them. I don't know what other work they are conducting.

Mrs. LESKO. Yes, I guess what I am saying is that, if you—if we couldn't get the reports accurately, how can you definitively say that there was no funding of this?

And so, anyway, I have another question for you. As the vice chair of the Oversight and Investigation Subcommittee and a member of the Select Committee on the Coronavirus Pandemic, I can't stress how inexplicable the failure I believe any of NIH oversight on the EcoHealth Alliance grant is to me.

In 2019, EcoHealth Alliance failed to submit a required annual report on the research it was conducting related to the emergency of the bat coronavirus. The 2019 progress report was due by September 2019. The COVID–19 pandemic began late 2019. Despite a bat coronavirus pandemic emerging in the city where NIH-funded bat coronavirus research was taking place, NIH failed to even ask for the missing progress report until 2021, and it was still not actually submitted until months later, more than 2 years after the due date.

Given these circumstances, how did the agency fail to notice that the annual report on research done by EcoHealth and the WIV was overdue for 2 years?

Dr. TABAK. The most important point to appreciate here is that the viruses that were under study in that subproject bear no relationship to SARS–CoV–2. They are genetically distinct. They are absolutely unrelated to SARS–CoV–2. That is the most important thing to understand.

As far as the administrative oversight——

Mrs. LESKO. And how do you know that for sure, sir?

Dr. TABAK. By looking at the phylogeny of—by looking at the genetic sequence. It would be equivalent to saying that a human is equivalent to a cow. That is how distant the sequences of the vi-

ruses that they were using in this work were to the actual SARS–CoV–2.

Now, the administrative overlap, the administrative issues, we concur with that. We concurred with the oversight report. We have taken steps to redress those administrative issues.

Mrs. LESKO. Thank you.

I have only 13 seconds left, so I will yield back.

Mr. GRIFFITH. I thank the gentlelady and now recognize the gentlelady from Washington, Dr. Schrier.

Ms. SCHRIER. Thank you. Thank you, Chairman Griffith. And thank you to the witnesses for being here today. I appreciate all the work you have done over the past few years, with a rapidly changing pandemic and tricky messaging.

We have learned a lot in these past few years, and I just want to make sure that we remember these lessons when the next public health challenge comes along. Today there is a lot to talk about, but I would like to focus on testing and on therapeutics.

So, Dr. Califf, in your testimony you say that the FDA is committed to continuing to use every tool in our toolbox to fight this pandemic, and I absolutely agree. As a pediatrician, I have been advocating now—we are talking years—for the use of rapid tests and masks and a multilayered approach to keep our kids and families safe and to keep our children in school, in classrooms.

And I also just want to acknowledge, Dr. Walensky, thank you for you also having that as your north star: How can we get our children into classrooms and keep them and their teachers there safely?

In fact, we did one of the first pilots in the country on using rapid tests to get kids into school.

The FDA has authorized over 30 over-the-counter tests, and I use them before I travel home to make sure I am not bringing unwanted COVID back to my family. People use them around the holidays to protect their families. And we have really come to rely on these rapid tests.

Are any of the ones that we are using today fully authorized, or do—are they all under emergency use authorization?

Dr. CALIFF. I believe all of the rapid tests that we have today are under EUA. But they will not go away, because we will have a bridging program, and they will still be available.

Ms. SCHRIER. That is fantastic. You anticipated my next——

Dr. CALIFF. I will have to check to be sure it is 100 percent.

Ms. SCHRIER. OK. I wanted to make sure that that would happen, because they are really indispensable.

I will hop to my other topic. Mr. Tabak—or Dr. Tabak, excuse me—the RADx program has been incredible. These public-private partnerships, getting accelerated treatments has been incredible.

I was wondering if you could talk about how we are going to use this and stay nimble with future threats, but just kind of a briefer answer, because I have more for you.

Dr. TABAK. Well, from the lessons learned, we know that if we could create centers that are ready to take very rapidly the problem, find a solution, and then scale it up, that we could make a big difference in any future pandemic.

Ms. SCHRIER. That public-private partnership has really been incredible. And I appreciate the work in all of these institutions: CDC, ASPR, BARDA.

I—we have already seen with COVID that, as the virus has changed, some of our therapeutics are no longer useful, like some of the monoclonal antibodies. And we know from our experience with TB and with HIV that we may get to the point where what we need are drug cocktails, essentially. You don't just use one therapeutic, in order to evade all of the mutations and changes in a virus and them getting around therapeutics. We may need to use several at once.

There is not a lot of incentive for drug companies to do that testing. And I was wondering if you could talk about what is happening at the NIH to speed drug cocktails.

Dr. TABAK. In the active program, which is a public-private partnership consortium between government agencies and industry, we have, in fact, used that as an incubator for these types of mix-and-match, if you will, types of approaches. And we have been very pleased for a number of our industry colleagues who have come forward and have been willing, you know, to engage in this sort of conversation. So I think that is the direction that we will have to proceed in the future.

Ms. SCHRIER. That is fantastic. And frankly, they will have more of a guarantee of a long market life if they figure out how to make theirs more effective in a cocktail.

Last question, Dr. Califf, I know there has been a lot of discussion about whether vaccines are still useful even if they are not perfect at preventing the disease or perfect at preventing transmission. I just wanted to give you an opportunity to set the record straight on your perception of the importance of vaccines.

Dr. CALIFF. First of all, let me just speak to the transmission issue, which has been discussed very much today. It is true that the vaccines are not sterilizing. And Dr. Bucshon, I think, was careful in using that word.

What we have, though, is a modest prevention, like a 50 percent prevention of the risk of getting infected if you're up to date on your vaccination. And that is very important for frontline workers of all types to stay healthy, for children not to infect their grandparents who may be at risk.

But the most important thing, I think, is if you're up to date—you've gotten your bivalent now, which is what that means—your risk of dying if you get infected is reduced by 80 percent. And if you get an antiviral that is recommended by the FDA, if you get infected and you're high risk, you have another 80 percent reduction. Now, you have to do contingent probability, so what that means is your risk of dying is very low if you get both.

So, you know, I am a cardiologist, so I am used to life and death. This is like the most important thing one can do today to keep from dying that is very remediable, free. There are side effects to vaccines. We all know that. But they are far overwhelmed by the benefits that occur.

Ms. SCHRIER. Thank you. As a pediatrician, I fully concur with the importance of vaccines.

I yield back.

Mr. GRIFFITH. The gentlelady yields back. Now I recognize the gentleman from Pennsylvania, Dr. Joyce.

Mr. JOYCE. Thank you, Mr. Chairman. I would like to address the CMS vaccine mandates, because I think we recognize that it has caused a cascade of problems, including workforce shortages throughout the United States on all levels.

OSHA also released a mandate November 5th, which has been held up in the courts and then subsequently withdrawn. Dr. Walensky, was the CDC consulted in issuing these mandates?

Dr. WALENSKY. The CDC provides information regarding the safety and effectiveness of vaccines and has provided the information that says that those vaccines are very safe, very effective in preventing severe disease and death, as Dr. Califf just said, as well as preventing some symptomatic disease—not as good as severe disease and death, but about 50 percent protection against symptomatic disease, even during the Delta and Omicron era.

Mr. JOYCE. Did OSHA specifically reach out to you or your teams before issuing these mandates?

Dr. WALENSKY. We provide our recommendation—or our scientific guidance within an interagency process that works across different agencies.

Mr. JOYCE. Dr. Walensky, we are both Johns Hopkins-trained physicians. We are both parents.

Head Start has a vaccination mandate that is in place. Did the CDC provide data about COVID–19 risk to Head Start-aged populations?

Dr. WALENSKY. I—CDC continues to provide recommendations and information, science-based information, on the vaccine safety and effectiveness in children and in adults.

Mr. JOYCE. In earlier testimony you stated that the vaccine mandates with COVID–19 have resulted in decreased routine pediatric immunizations. Is this is not correct?

Dr. WALENSKY. I am not—I would have to go back to the record. I am not sure I stated it exactly in that way.

Mr. JOYCE. Do you feel that, with the potential of decreased routine childhood immunizations to measles, to mumps, to rubella, do you feel the continuation of the Head Start vaccine mandates will put at risk these children, or actually have their parents consider whether or not they should continue in these Head Start programs?

Dr. WALENSKY. What I can tell you is that vaccines save lives. That is true in our routine vaccination for pediatrics. It is true in COVID–19. It is true in influenza. And I think we should do everything that we can to promote vaccination, because it saves lives for all of these different infectious threats.

Mr. JOYCE. I feel that we are subjecting certain populations to more risks than when we recognize that parents are not immunizing their children with vaccine mandates, which we recognize are not necessarily effective, particularly in pediatric populations.

I would like to pivot and talk about the end of the COVID public health emergency. Unwinding the public health emergency will eventually reset the health system back to what was in place before the pandemic, with some exceptions, unfortunately. And it really is unfortunate. I do not feel that we will restore in our public health agencies the credence that is so necessary at any time soon.

Dr. Califf, as a followup from my September 2022 letter with explicit steps, what explicit steps is the FDA taking or will the FDA take to continue to move forward on COVID–19 therapeutics, specifically therapeutics that so many patients continue to need, patients who are immunocompromised, from—whether that is from underlying disease, or patients who are immunocompromised because they are in the middle of a cancer therapy, patients who are exposed to many different types of infectious disease but particularly to COVID–19?

Dr. CALIFF. Well, let's talk about the technical aspects first. And I appreciate the question, because millions of immunocompromised people, as you know, in the United States, they deserve special protection.

We have now the ability to make therapeutic antibodies, as you well know, in addition. The first step is get vaccinated, be up to date on your vaccination, make sure, if you get infected, that you get a potent antiviral. Those are available, they are effective in immunocompromised patients, as well as other people.

Mr. JOYCE. My time is limited. Please allow me to interrupt. So the therapeutic antibodies, are they effective against the current strains that we see with COVID–19?

Dr. CALIFF. None of the ones currently available are effective against——

Mr. JOYCE. So we are talking about what is going to be available. If we recognize that the immunotherapies are not for you, are not effective against the current strains, what do we have to offer these patients?

Dr. CALIFF. Oh, I think the way to think about this now is that the technology has gotten so advanced, there is like a library of therapeutic antibodies. Don't be surprised if you see some that were old and didn't work against old strains now, with the new variants, actually becoming active against them. So those are constantly being tested.

But we also need to work with the industry to figure out a way to make it worth their while to continue to work in this field, because what they are looking at is they make a therapeutic antibody, 3 months later there is a new variant and there is no longer a market for it.

One of the real keys to Operation Warp Speed and to what came after was the government infusing money that took the risk away for the industry, for being active to use all their capabilities. So we do have work to do there, but——

Mr. JOYCE. I think——

Dr. CALIFF [continuing]. The technology is——

Mr. JOYCE. I think my time has expired. I think we have a lot of work to continue to do.

And thank you, Mr. Chairman. I yield back.

Mr. GRIFFITH. The gentleman yields back. I now recognize the gentlelady from Massachusetts, Mrs. Trahan.

Mrs. TRAHAN. Thank you. Thank you to our chairs and our ranking members for holding a hearing on the Federal response to COVID–19.

I want to thank our witnesses today for, you know, your testimony, for your patience, certainly for your leadership as we navigated the most deadly pandemic of our generation.

The U.S. has made tremendous progress in our fight against COVID–19. As many of my colleagues have already said today, the Biden administration stood up the largest free vaccination program in U.S. history, delivered hundreds of millions of free at-home tests to households, and passed the historic American Rescue Plan, which put money in the pockets of financially strained Americans and enabled schools to reopen safely for our kids.

COVID has required an all-of-government response that tested the Federal Government's public health system capacity, including testing and vaccine development, supply chain capabilities, treatment and medical responses, and workforce readiness.

It is critically important now more than ever to take our lessons learned from COVID to better equip our preparedness and response systems so that we are never caught flat-footed again. For this reason, I will be introducing a bill in the coming weeks that funds a Disease X Medical Countermeasures program at BARDA for unknown viral threats with pandemic potential. Current funding constraints at BARDA only allow the agency to go so far. With much of BARDA's MCM development work focused on a defined list of chemical, biological, radiological, and nuclear threat agents as well as influenza, we may not be prepared to develop and manufacture at scale future drugs and vaccines against unknown viral threats that can lead to a devastating pandemic.

The Disease X Act will help BARDA to fully focus on their full list of priorities, including increased focus on emerging infectious diseases. That said, BARDA played a critical role in our response to COVID. With a decade of investments and platform technologies under flexible agreements, BARDA was able to pivot to develop COVID–19 MCMs at a rapid pace.

Dr. Califf, as you know, Congress passed many provisions from the Prevent Pandemics Act as part of the 2023 omnibus funding bill that was just signed into law. One of these provisions creates a platform technology designation program at FDA to support the development and review of new treatments and countermeasures that use adaptable technologies that can be used in more than one drug or biological product for novel public health threats. We saw how powerful the mRNA platform was for the COVID–19 vaccine, and now other applications of this platform are being explored.

So, Dr. Califf, how will this new regulatory designation for platform technologies potentially lead to faster development of vaccines and therapeutics for currently unknown emerging infectious diseases in the future?

And how does FDA plan to implement this new designation?

Dr. CALIFF. Well, you know, mRNA is the example, as Dr. Tabak already stated. When you've got a platform that can be used for multiple different therapeutics, it's a wonderful thing. But it doesn't happen overnight. So if you wait until you're in a crisis, you can't then develop the platform. This happens over years to decades. So working with our partners at NIH, BARDA, ARPA–H, I wouldn't be surprised if it has a critical role to play here.

We want this to happen so that, when there is a need, the platform is available and multiple therapeutics can be developed.

Mrs. TRAHAN. Thank you. And as mentioned previously, provisions from the Prevent Pandemics Act were recently signed into law. While I am pleased many of these provisions have been enacted, this cannot be the end of our work to strengthen our preparedness and our response infrastructure.

So, Dr. Walensky, what are some of the capabilities to detect and monitor emerging infectious diseases at CDC included in the Prevent Pandemics Act, and what additional authorities and resources are needed to prevent and respond to future pandemics?

Dr. WALENSKY. Thank you. Yes, so through PREVENT we were able to receive OTA, other transaction authority, but we were unable to receive the data authorities that we need, the workforce authorities that we need.

From a workforce standpoint, our ability to rapidly respond if we are going to be a response-based agency, which we are working—we are, and—but we have never had to at this size, scale, and scope. If we are going to be able to be—to respond to this size, scale, and scope, as was required over these last 3 years, we need to have the authorities that other response-based agencies do: workforce hiring authorities, danger pay, overtime, as well as our data authorities.

It took us 6 months to receive data use agreements from 100 different jurisdictions early in the pandemic in order to be able to see the data. Similarly, through the mpox challenges over the summer, we had the same challenges in not having to be able to see the data. If you can't see the data, you can't act on the data. And that is true at CDC, but also back at the local level. We would like to give those data back to the local level so they can respond as well. Thank you.

Mrs. TRAHAN. Great. Thank you so much.

I yield.

Mr. GRIFFITH. The gentlelady yields back. I now recognize the gentlelady from Tennessee.

Mrs. HARSHBARGER. Hey.

Mr. GRIFFITH. Mrs. Harshbarger.

Mrs. HARSHBARGER. Thank you, Mr. Chairman. Thank you, Mr. Chairman. Thank you to the witnesses for being here today.

I want to talk to you, Dr. Walensky. According to Twitter files reported by David Zweig on December 23rd, the Biden administration was working with Twitter to flag anything that conflicted or differed from CDC guidance as misinformation. Dr. Walensky, were you or your staff in meetings, phone calls, or virtual meetings with the Biden White House administration officials and Twitter? And that is a yes-or-no.

Dr. WALENSKY. Thank you for the question. There is pending litigation on that, so I am not going to get into the specifics on that today. Thank you.

Mrs. HARSHBARGER. Oh. What about Facebook and Instagram?

Dr. WALENSKY. Similar.

Mrs. HARSHBARGER. Giving—given reporting the CDC was consulted frequently, and at times daily, and on giving recommendations on what content to flag as fake or misleading on Twitter,

Facebook, and Instagram, how many staff did you have dedicated to working with technology companies?

Dr. WALENSKY. Again, there is pending litigation on that, so I am not free to comment right now.

Mrs. HARSHBARGER. Was there any centralized guidance from you about what staff should relay as fake or misleading?

Dr. WALENSKY. Pending litigation, regrets.

Mrs. HARSHBARGER. Well, Dr. Walensky, when there are numerous examples of individuals being flagged as misleading for referencing peer-reviewed studies, posting CDC's own data, or their own opinions as experts being called into question merely because it differs from your scientific perspective, that is just unacceptable.

And let me ask you, Dr. Califf. Let me go back to a question. Will the FDA commit to provide transparency for the raw data used to make key decisions during the course of the pandemic on vaccines and treatments?

And specifically, will the FDA commit to releasing all data on complications in phase four monitoring to allow for outside analysis, yes or no?

Dr. CALIFF. We are committed to transparency on the information that we are collecting in our vaccine follow-up.

Mrs. HARSHBARGER. OK. All data?

And I am asking you that because there was a FOIA request for Pfizer COVID–19 vaccine safety data. And from what we read, it said that it would take the FDA 75 years at 500 pages a year to get that 329,000 pages of data that the FOIA request asks for.

Dr. CALIFF. Well, I will have to get back to you on that specific number. I am not familiar with the exact number. But we will do everything we can to make sure people are informed about vaccine safety.

Mrs. HARSHBARGER. Yes, that would be very pertinent, since these vaccines are going out to the public, these boosters are going out to the public. And I don't understand. It said in the article there were 10 employees that were requested to review that data or FOIA request.

And how many employees did the FDA employ, how many do you have, do you know?

Dr. CALIFF. We have 18,000 employees in total.

Mrs. HARSHBARGER. Eighteen thousand employees, but there's 10 that are put on FOIA requests. And at that rate, at 329,000 pages and the FDA saying that they could only do 500 pages a day, it would take 75 years. But if you would, get back with me on that.

And I have some other questions about CPG guidances and how they are construed as law, but I will put that in writing for you.

Let me see. I have got a little bit of time left, and I have another question, if I can go—if I can find it. And it is about another recent health concern.

On October 31st, 2022, the Republican leadership of this committee sent a letter to the NIH raising concerns and questions about a monkey pox, or an mpox, viral enhancement experiment being conducted at the NIAID. This experiment involves transferring the more lethal version of the mpox virus, which has about a 10 percent mortality rate in unvaccinated people, with the less lethal but more transmissible mpox virus circulating in the U.S.

Now, the less transmissible mpox virus has a mortality rate of less than 1 percent, and the more lethal virus is classified as a Federal select agent. It appears that the project is reasonably anticipated to yield a lab-generated mpox virus that is 1,000 times more lethal in mice than mpox virus currently circulating in humans.

The NIH has refused to respond to the committee's letter. And as Chairman Griffith mentioned, in stark contrast the committee asked very similar questions to Boston University about its recent experience involving SARS–CoV–2, and the folks at Boston University were very forthcoming. And because they told us exactly what they were doing and why they were doing it, we are confident they are acting appropriately.

And I will have followup questions for you, Mr. Tabak, about, since you haven't responded, why haven't you responded, and what are you hiding? Did you fail to select —to follow select agent regulations?

And did the NIH fail to follow its own guidelines and policies like it did with the EcoHealth grant?

Dr. TABAK. The experiments that you are referencing were—did follow all the select agent guidelines. It was conducted in our intramural program. It was approved back in 2015. What they did was they replaced genes in the more virulent——

Mrs. HARSHBARGER. Well, you can—I know my time is up, and I know we are on a schedule, but if you would, follow up in writing with me.

And I do have some other questions for Dr. Walensky about that——

Mr. GRIFFITH. I think we are still waiting to find out what level lab that is in too. But OK——

Mrs. HARSHBARGER. Yes.

Mr. GRIFFITH. We will get that in writing later. I now recognize——

Mrs. HARSHBARGER. Thank you.

Mr. GRIFFITH [continuing]. Representative Tonko of New York for his 5 minutes.

Mr. TONKO. Thank you, Mr. Chair. The allegation that NIH-funded research in China led to the release of COVID–19 from a lab has been routinely debunked.

I ask unanimous consent to submit a document for the record published by NIH demonstrating that SARS–CoV–2 and the types of viruses studied with NIH funding are too genetically distant to be directly related.

We all share interest in biosecurity, but we should make decisions, obviously, based on facts.

Mr. GRIFFITH. I am happy to recognize—or to admit that without objection. I would just note that, with a huge hole in the data, how do we know?

Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. TONKO. Thank you, Mr. Chair.

As scientists learned more about the virus that causes COVID–19 and the best approaches to keeping us all safe, it was important that decisions made about public health guidance and investments

evolved alongside it. This means that information and guidance were revised to keep up with our growing understanding of the virus. And despite criticisms of those changes, it is in the best interest of the Nation to ensure that the public is armed with the best information that we have at the time.

So, Dr. Califf, as we have discussed, vaccination is our best shot at keeping the American public safe and healthy. Observing how the virus itself changed over time led to the development of new vaccines like the bivalent booster to target new variants of SARS–CoV–2. Why is it important for FDA's regulation of biologics and vaccines to be responsive to emerging science about SARS–CoV–2?

Dr. CALIFF. Well, I think the emergence of these new variants is proof of principle right there. And if we didn't have all the research going on to look at the variants, to produce them in laboratories, to test whether it is therapeutic antibodies or vaccines, we couldn't keep up, and we would lose the effectiveness of our vaccinations over time.

So just like with flu vaccines that are updated every year, we are going to need to update our COVID vaccines in the same—not exactly the same, but in a similar way.

Mr. TONKO. I appreciate that. And Dr. Califf, how does new scientific information from the study of an infectious disease allow FDA to better determine the safety and efficacy of new vaccines or treatments and evaluate if they are ready to be publicly deployed?

Dr. CALIFF. Now, here I would stress two types of information. One is biological information coming from laboratories, both those that are funded at NIH and what industry is doing and the community of universities around the world. It's the only way to keep up and to know that the vaccine that you're proposing actually has activity against the specific variant.

But the second kind that Dr. Walensky has talked about over and over, in the end, the true test of anything the FDA does is what the effect is in the intact human being. We need an ethical deal. You think about yourself or me. When I get sick, I hope that a lot of other people have volunteered their data so that I will get the right treatment, because my doctor will know.

We have had some discussion about this. Doctors are smart. I am one. I think I am pretty smart. But I am a lot smarter if I have the evidence. So I call a doctor alone eminence-based medicine. A doctor armed with evidence is evidence-based medicine. It is much better. It will only work if we volunteer our data and participate in research.

Mr. TONKO. I hear the evidence-based argument.

Dr. Walensky, I know that reopening schools safely was a priority for you and the Biden administration from day one. So can you explain CDC's approach to using public health data to provide schools the guidance they need for teachers, school staff, and children to return to in-person learning?

Dr. WALENSKY. Absolutely. So we—as we create our guidance—and as you know, this was a priority for me—46 percent of schools initially opened, 63 percent within months. And then, by the new—by the fall, it was up to 95 percent in terms of getting schools back open.

So we used a layered mitigation strategy. Remember, at the time there were no vaccines for children. We were vaccinating adults, but we didn't have vaccines for children. So what were the strategies that we could use? Vaccination was one of them. Masking was another. Distance at the time, when we had high levels of community transmission, was yet another.

And then we saw these ecological studies, cohort studies in States that said when these jurisdictions had masks on and these jurisdictions didn't, there was more infection in the schools when the masks were off that schools had to close because masks were off. And it was based on those kinds of studies, whether it be in Georgia or Wisconsin or Arizona or across the country, where we were able to amend our guidance in real time as those variants emerged, as Dr. Califf noted.

Mr. TONKO. Thank you very much.

And with that I yield back. Mr. Chair, I do—did have some questions for Dr. Tabak, but will get that to you in writing.

Thank you.

Mr. GRIFFITH. I thank the gentleman. The gentleman yields back. I now recognize the gentlelady, Dr. Miller-Meeks from Iowa, for her 5 minutes.

Mrs. MILLER-MEEKS. Thank you, Mr. Chair, and I thank all the witnesses who are here.

Dr. Walensky, you and I have had the opportunity and the pleasure, if you will, to receive testimony before and ask questions. I am a physician. I am also a former director of the Iowa Department of Public Health. And when it comes to trust in our agencies, if you've lost me that means there is a lot that has to be answered for, and oversight that has to be taken care of.

I have vaccinated individuals, all 24 of my counties in my district. I was vaccinated. But even now there still persists this nonrecognition of infection-acquired immunity, of herd immunity, of immunity that exists. And the purpose of a vaccine is to do what? It is to confer immunity.

So the failures of the CDC and the FDA—and I won't get into the NIH—were both administrations.

There was the first failure to—not to develop testing in an appropriate, adequate fashion for COVID–19, despite the fact that there was already a test with high specificity and sensitivity from the University of Iowa.

The failure of the CDC to use real-world evidence and data when studies from Israel or other countries showed that viral transmission still existed, despite vaccination.

The failure of the CDC and other public health organizations to acknowledge infection-acquired immunity, despite data from other countries, and that there were waning antibodies within 1 month after vaccine.

The failure to acknowledge infection-acquired immunity or natural immunity, and mandate vaccines to those who already have immunity. And I put forth a bill to mandate that all insurance companies, public and private, cover for antibody testing and T cell antibody testing to get to this point.

The failure of the CDC to acknowledge myocarditis and pericarditis in young people and still advocate for vaccines in young men

despite that risk, which, as we talked about finally last year, that there is a risk benefit that has to be considered but was not considered in these mandates.

Menstrual irregularities in young women.

I think that when you are trying to message to the public—and I can tell you, as a public health director, what I conveyed to my staff was that our credibility was the most important thing that we had in public health. And so, when we can't acknowledge what our common concepts and what my local public health individuals and officers and physicians and nurses were acknowledging back at home but we are not receiving through the CDC, has created a lack of trust in extremely important institutions.

The failure of the FDA to utilize their own advisory boards when approving vaccines, especially in certain age groups, and rushing approval in these age groups, and then their slowness to advance any therapeutics.

And what evidence can you tell me, the evidence-based research that shows 6-foot distancing is appropriate?

It is demoralizing and it is depressing that agencies that were once held in such esteem cannot translate and transfer research and evidence and respond to real-world evidence when they come up with strategies and policies. It is not just a messaging problem. It was a problem of bias within the agencies.

So I was the sole Member of Congress to advocate on Congress during the COVID–19 markups and hearings for increased funding for public health and local public health and local public health grants.

So, Dr. Walensky, currently States and localities must apply for a CDC grant funding for chronic diseases vis-a-vis different applications, submissions, and portals for each specific programing grant. Heart disease and stroke, diabetes, and 14 cancer programs, for example, all require this. These applications are burdensome. They require vast amounts of time and resources, and often States and localities must hire specific grant coordinators to handle the process.

It appears that a much simpler approach, such as the grants to local public health, would be for States to work through a block grant process, submitting one application to CDC for funding for specific chronic diseases that will meet the needs of their specific State.

Many of these entities already are operating on slim margins, which is also why, quite honestly, I found it appalling that less than one half of 1 percent of the American Rescue Plan dollars in 2021 at the height of the pandemic went to fund State and local public health workers who are on the front lines of fighting COVID–19, all with tremendously innovative policy and procedures to combat the disease.

Updating the grant structures to be more streamlined could reduce administrative burden for both States and the internal CDC review process. Plus, if we require appropriate reporting, we can ensure each State is putting the money to good use, something that should be of paramount focus, given the alarming rates of fraud and abuse within the COVID-related dollars. Has the CDC considered this structure?

Dr. WALENSKY. Yes, thank you, Dr. Miller-Meeks, and thank you for advocating for local public health, which I think is a critically important part of one of the lessons learned as part of COVID–19.

Results-based partnerships is one of the key things that we learned and—in our CDC review, in CDC Moving Forward. And part of our organizational structure has actually streamlined where our local public health departments come.

I can tell you, as part of the $3.2 billion that went out for workforce grants, it didn't just go to States, it went to States and local jurisdictions for exactly the reasons that you note.

Mrs. MILLER-MEEKS. Yes, I think currently——

Mr. GRIFFITH. The gentlelady yields back.

Mrs. MILLER-MEEKS [continuing]. Our local public health has the trust that the CDC is lacking.

Mr. GRIFFITH. The gentlelady yields back.

Mrs. MILLER-MEEKS. I yield back.

Mr. GRIFFITH. I recognize the gentleman from Maryland, Mr. Sarbanes.

Mr. SARBANES. Thank you very much, Mr. Chairman. Thanks to all of you.

I know this is part of your job, coming up here and testifying, but I just always feel guilty when you spend 3 hours here away from your primary responsibility. So thank you for your testimony.

Dr. Walensky, I was going to talk with you a little bit more about the whole data picture. I know you have answered a ton of questions already today about that, but I want to understand a little bit better where the line is, in terms of being able to build a sophisticated and as-accurate-as-it-can-be model or platform for both tracking and forecasting infectious disease, whether it is a COVID outbreak or anything else, where the line is between what you can collect through the voluntary cooperation of public health officials, private labs, et cetera, and what you can't really do without the authority to force that.

I am—as I ask you that question, I am thinking about the dashboard that Hopkins built which became a go-to place for many of us, and billions of impressions, people all over the world using that to kind of see the heat map when it came to the COVID spread across a number of different categories and measures, which—my sense is—was largely being done by rolling up publicly available data in many places, qualifying it where it needed to be qualified or disclaimed, so that people consuming it understood, you know, how much weight to give it on a particular day, but became a fairly reliable go-to picture of what was happening.

But to the extent you have signaled that you need more authority to build the kind of robust data platform and collection vehicle that you would like to see, describe maybe in a little more detail maybe an example or something of where that line is and why working with the tool kit you have right now just isn't sufficient.

Dr. WALENSKY. So I bucket it into two different areas. One is our data modernization efforts. That is building the highways. Our—can you—can your jurisdiction, your district send data to CDC in the similar way that the one next to you can send data to the CDC, and then CDC can rapidly receive it and give it back to you so you can see what is happening in the districts around you?

That is a data modernization issue. We are working on that. It is because we lacked that modernization, those data highways, that we only had 187 healthcare facilities in the country that could provide us with data electronically on COVID. We are now up to 22,000. Those resources are being put to good use, and we have numerous examples of how we have been able to use those highways for mpox reporting and many other things.

Once those highways are built—and we will need more resources to build robust highways across this country—we have another challenge, and that is do the cars drive on the highways? Right now, we only have—we only receive those data that are voluntarily reported in the absence of a public health emergency.

So you're exactly correct. The Hopkins website does data scraping, web scraping, so that they can see what is publicly available. We at CDC would like the gold standard of what is happening at the States because it is reported from the States. But we only get that voluntarily. Even today, I can't tell you how many people have been vaccinated in the hospital. We don't have data systems that can do that. We don't have authority to collect it, and it is not voluntarily reported.

So after this public health emergency is taken down, we are currently, again, working through data use agreements. We will lose data on testing. So—and we are—we will lose data on—some data on immunizations. We are working through data use agreements, but that is just one infection—that is just one infectious disease. And so that leaves us really vulnerable if we don't have reporting coming to the CDC on what is happening in influenza and what is happening in RSV and what is happening on many of these other——

Mr. SARBANES. Let me ask you on the hospital front. I mean, obviously, HHS and other agencies have leverage with respect to hospitals, based on all kinds of other engagements. Are you saying that leverage can't be used to pull data in from those places? You have to have a separate authority to do that?

Dr. WALENSKY. Well, first of all, we would have to rely on partnerships with other agencies, and that is exactly what we did through the public health emergency. And we are receiving some of those data through the public health emergency. But we don't have that authority independent of relying on those partnerships. And it is not as robust, not necessarily. The data that are collected for purposes of CMS may or may not be all of the data that we need for purposes of tracking a new outbreak.

Mr. SARBANES. OK, thank you.

I yield back.

Mr. GRIFFITH. The gentleman yields back. I now recognize the gentlelady of Florida, Mrs. Cammack.

Mrs. CAMMACK. Thank you, Mr. Chairman, and thank you to all our witnesses for appearing before us today.

First, is it Dr. "Tay-back" or "Tah-back"?

Dr. TABAK. It is "Tay-back."

Mrs. CAMMACK. "Tay-back"?

Dr. TABAK. Yes.

Mrs. CAMMACK. I appreciate that. I have heard it multiple ways said today. I want to be——

Dr. TABAK. I answer to "Hey, you." It is OK.

Mrs. CAMMACK. OK, I appreciate that. All right, Dr. Tabak, you have been with NIH since 2000. Do you believe that Stanford Medical School, Oxford, and Harvard hire "fringe medical professors"?

Dr. TABAK. It depends on the individual professor.

Mrs. CAMMACK. OK. Well, the reason that I ask is because on October 8th of 2020 you were cc'd on an email from the then-head of NIH, Dr. Francis Collins, to Dr. Anthony Fauci.

Now, I am going to refresh your memory on the contents of this email. It says, "Hi, Tony and Cliff. This proposal, citing the Great Barrington Declaration from the three fringe epidemiologists who met with the Secretary, seemed to be getting a lot of attention, and even a co-signature from Nobel Prize winner Mike Leavitt at Stanford. There needs to be a quick and devastating published takedown of its premises. I don't see anything like that online yet. Is it underway?" Signed, "Francis." Again, you were cc'd on this email.

Yes or no, Dr. Tabak, did you communicate with Dr. Collins with you about these doctors or the Great Barrington Declaration, other than when emailing Dr. Fauci?

Dr. TABAK. I have no recollection of speaking to him about that.

Mrs. CAMMACK. Yes or no, are you aware of other instances where either Dr. Collins or Dr. Fauci planned to have the media publish articles to discredit other scientists or doctors during the COVID–19 pandemic?

Dr. TABAK. I am not aware of any such instance.

Mrs. CAMMACK. Of course. Now, as deputy ethics counselor at NIH, aren't there ethical concerns about using the U.S. Government to silence scientific speech, particularly peer-reviewed speech?

When the stakes are so high, right, as they were during the height of COVID–19, shutting down economies, keeping kids in schools, increased rates of mental illness, addiction, suicide, et cetera—and now, of course, we know that the collusion between Twitter and the Biden administration has come to light—does that not concern you?

Dr. TABAK. I am unaware of any collusion. I know there is ongoing litigation——

Mrs. CAMMACK. You know what? That is good. I am glad.

Dr. TABAK. So I can't comment.

Mrs. CAMMACK. I am going to enlighten you, then.

So just a few months after that email, this email that you were cc'd on between Dr. Francis Collins and Dr. Fauci—you have records of this, and I am sure there are others—just a few months after that, Twitter was directed by the Biden administration to deplatform multiple scientific accounts, doctors, Nobel Prize winners.

They went so far as, on March 14th, 2021, in internal communications between top Twitter executives and the Biden administration, to say, "We are very angry. The Biden administration needs a push to deplatform these multiple accounts." These deplatforming of accounts were, of course, related to the Great Barrington Declaration, and they said, according to the Biden administration to Twitter, that not enough had been done to silence these doctors.

Dr. Tabak, did you provide Dr. Collins with any ethical counsel or advice on this matter?

Dr. TABAK. This is a subject of ongoing litigation, and I can't comment on anything related to the social platform.

Mrs. CAMMACK. Who else at NIH did you talk to about the Great Barrington Declaration and its authors?

Dr. TABAK. I don't recall speaking to anybody about that at NIH, quite frankly.

Mrs. CAMMACK. OK. I know I am running low on time, but I will say this. Contrary to some of the comments that have been made here today—and we are not going to get to the bottom of this in 53 seconds. But contrary to the comments of some of my colleagues today—actually, just now, apologizing to you all for appearing before this committee, saying that we are taking you away from your primary responsibility—you have a responsibility to appear before this committee, just as we have a constitutional responsibility for oversight. That is our duty to the American people. If I were you, I would clear your schedule. This will come to light.

I appreciate you all being here today. Thank you.

Mr. GRIFFITH. The gentlelady yields back, and I recognize the gentlelady from California, Ms. Barragán.

Ms. BARRAGÁN. Thank you, Mr. Chair.

I want to remind the public, because it was a—there was a comment made that there had been no hearings on COVID, but we did have a hearing in June of 2020 on the response to the COVID–19 disaster. And a lot of that, as I remember, was a disaster under the prior administration of the response, the lack of response, the lack of acknowledging the seriousness. And I remember even claims about you can inject bleach to deal with it. I mean, the misinformation and the disinformation is a huge concern because, clearly, we know it has public health impacts. And it is really unfortunate when science is not taken seriously and when the misinformation and the disinformation continues.

I want to thank you for the work that you do day in and day out. I know that your primary concern is of Americans and making sure that we are doing all we can to fight infectious diseases and noninfectious diseases.

Dr. Walensky, I want to thank you for your willingness to not just do the work but to go across this country and travel into communities, to meet constituents and meet public health officials. Thank you for coming to my own district in Watts last year to talk about the importance of awareness in vaccines, something that I believe saved millions and millions of lives, and that nobody really should have died in the numbers that we saw happen.

So let me start, Dr. Walensky, with you with a non-COVID question, really. Heart disease, diabetes, cancer, and Alzheimer's are some of the most common causes of illness, disability, and death affecting a growing number of Americans. Many chronic diseases disproportionately impact people of color, people in low-income neighborhoods, and others whose life conditions place them at increased risk for poor health, especially during infectious disease outbreaks.

Can you talk a little bit about and discuss what the CDC is doing in this space, and the important role the CDC plays in addressing noninfectious diseases?

Dr. WALENSKY. Yes, thank you so much for that. I think it is critically important to recognize our role in our infectious diseases, for sure, and in noninfectious diseases as well—so, as you know, heart disease, mental health, opioids, diabetes, cancer—in the prevention and outreach for all of those noninfectious diseases.

What I think is lost is—in the conversation and also critically important, is the intersection of the two. So those people who have the most severe outcomes from COVID–19 and continue to are those who have those chronic medical conditions. It is because we have a partnership in cardiovascular disease, we have that work ongoing, that we can have subject matter experts in both of those coming together when we have a public health threat like COVID–19.

Similarly, with Zika—devastating infectious disease for pregnant moms, maternal mortality, anencephaly in children—it is because during the Zika outbreak that we had our infectious experts and infectious disease working alongside our birth defects experts that we could rally a response so quickly.

And then, maybe the third very vivid example that I will give is in the opioid challenges that we are having now, over 100,000 deaths per year. But we have also those who have suffered from nonfatal overdoses related to injection drug use. The coincidence of opioid use and HIV and hepatitis C and endocarditis, where I have spent much of my career, is really why it is so critical that we in public health are addressing both of those together. Thank you.

Ms. BARRAGÁN. Great, thank you.

Dr. Tabak, I want to quickly get you in. Trial diversity is essential to develop effective and safe vaccines for all populations. But this is not always the case in the development of new vaccine treatment. While developing multiple COVID–19 vaccine candidates in record time, the NIH did include a diverse pool of trial participants. Dr. Tabak, how was the NIH able to achieve this, and why is it important as we think about future pandemic preparedness?

Dr. TABAK. We were able to do this first by encouraging the vaccine manufacturers to ensure that they included a diverse population.

But we also had to gain the trust of the individuals particularly from marginalized communities. And we did that by taking advantage of equities within those communities: trusted persons, pastors, pharmacists, and so forth within the community who would allow us to share information about COVID, information about vaccines and therapeutics, and, of course, the reason why it is important for all people to participate in clinical research.

Ms. BARRAGÁN. Great, thank you so much.

My time is expired; I yield back.

Mr. GRIFFITH. I thank the gentlelady. I now recognize Mr. Palmer of Alabama for 5 minutes.

Mr. PALMER. Thank you, Mr. Chairman.

I think the largest frustrations with your agency's handling of COVID is with the information released on masks and the vaccine. Up until 2022 CD guidance was used as a premise to keep children

as young as 2 years old in masks on public transportation and in the schools.

One of the things that really struck me was the video of a 2-year-old and his family being kicked off a plane because the 2-year-old wouldn't wear a mask. I have three kids. I remember them being 2. And that would have been a challenge, if the kid didn't want to wear the mask.

Randomized controlled trials are described as the gold standard for producing robust evidence for public health guidance. Randomized controlled trials, otherwise known as RCTs, could have provided strong data about the effectiveness or ineffectiveness of forcing children to wear masks in the classroom.

Mr. Tabak, are you familiar with the Cochrane Review on masking that was recently published?

Dr. TABAK. I am peripherally aware of that. But, of course, this is in the expertise of the CDC Director. I would defer to her.

Mr. PALMER. OK. Dr. Walensky, are you familiar with that?

Dr. WALENSKY. I am familiar with that. Thank you.

Mr. PALMER. And you are also then aware that the study basically said that it really didn't make much difference, even if you wore an N95, whether——

Dr. WALENSKY. Yes, I——

Mr. PALMER [continuing]. For influenza or COVID.

Dr. WALENSKY. I would love to address that Cochrane Review; I know it well.

So Cochrane Review looked at randomized controlled trials related to COVID–19, but other respiratory viruses. Of course, COVID–19 is different because it has presymptomatic transmission rather than postsymptomatic—rather than alone post-asymptomatic transmission.

One of the limitations of that study, in addition to the fact that it included randomized trials from before COVID–19, was that—and it stated in the study—is that people actually had limited uptake of using masks. So, of course, randomized trials that look at mask use but people are not wearing them, are going to have——

Mr. PALMER. For the record, it was 9 studies in over 276,000 people. That is a pretty——

Dr. WALENSKY. But if they don't take—uptake the intervention, then it is not going to prove working.

It is also the case that our masking guidance was very much related on cohort studies and many other studies. Randomization, as you can imagine, of a mask versus no-mask approach——

Mr. PALMER. Well, let me ask you this.

Dr. WALENSKY [continuing]. During the height of the COVID–19 pandemic would have been a challenge.

Mr. PALMER. All right. But once the CDC imposes this mandate—and public pressure forced you to lift it—how many randomized controlled trials—and I will go back to Mr. Tabak, or Dr. Tabak—did the NIH fund concerning the effectiveness of children masking in the classroom setting?

Dr. TABAK. I am not aware of any.

Mr. PALMER. So you didn't do any?

Dr. TABAK. I am not aware of any. I would have to check to make sure that——

Mr. PALMER. You know, that is part of the problem with this is that I had doctors who spent years in medicine telling me that the masks were not effective, and yet these were being forced on people. They were forced on schoolkids.

And, you know, when you combine—particularly young kids, we are seeing the devastating impact that it had on their educational attainment. And it kind of surprises me that the NIH, CDC didn't do any followup testing, even while this was going on to determine the effectiveness of this and the impact it was going to have on kids.

Dr. WALENSKY. Yes, I appreciate—you know, in order to do a randomized clinical trial you need to actually have equipoise in the question. And ultimately, what would happen—what happened is that there were so many studies that demonstrated time and time again in the height of COVID transmission that masks were working to prevent transmission that I am not sure anybody would have proposed a clinical trial because, in fact, there wasn't equipoise to the question anymore.

Mr. PALMER. Well, let me ask you this. It was—Dr. Walensky, it was reported by Bloomberg, Fox that CDC altered its guidance for public schools numerous times after getting influenced, pressured, scolded by the teachers unions. And you said that the teachers did not need to be vaccinated to reopen the schools, and the teachers unions pushed back. And Jen Psaki was forced to say that you were talking in your personal capacity. Is that true?

Dr. WALENSKY. I was very motivated as I came in to get our schools open, and I think that was very clear, and it was very successful in our efforts.

I had been working on the front lines of healthcare and had seen that we were able to safely bring healthcare workers into the hospital, treating COVID patients. So I did see that——

Mr. PALMER. She said you were speaking in your personal capacity. How do you differentiate between your personal capacity and——

Dr. WALENSKY. I—no——

Mr. PALMER [continuing]. Your professional capacity?

Dr. WALENSKY. First, as I said that, which I believe was on February 3rd, I said it from an official CDC capacity. And I believe Jen Psaki—I can't speak to her comments, but I was definitely in my CDC capacity when the comments were made.

And in fact, we reopened schools——

Mr. PALMER. All I want to know is——

Mr. GRIFFITH. Hang on.

Mr. PALMER [continuing]. In the last seconds that I have got here is——

Mr. GRIFFITH. Your time is up, Mr.——

Mr. PALMER [continuing]. You took input from the unions——

Mr. GRIFFITH. Mr. Palmer, your time is up.

Mr. PALMER [continuing]. But did you take input from the parents?

Dr. WALENSKY. Actually, we did outreach to over 50 organizations, including parent organizations and superintendent organizations, as well as teachers organizations. So we did a wide scope of outreach for that guidance. Thank you.

Mr. GRIFFITH. The gentleman yields back. He can follow up with written questions. Now I recognize the gentleman from Indiana, Mr. Pence.

Mr. PENCE. Thank you, Chairs McMorris Rodgers, Griffith, and Guthrie, and Ranking Members Pallone, Castor, and Eshoo, for holding this hearing. And thank you to the witnesses today. I appreciate you being here.

I do not have a medical background, so I am going to go off the reservation a little bit, Mr. Chairman.

At the onset of the pandemic, the Trump-Pence administration acted quickly to respond to the impacts on our healthcare system and build a long-term strategy to develop innovative solutions and save lives, which you all continued when you came into your jobs.

Hoosiers and all Americans were fortunate for the work of the Trump-Pence administration to advance a historic White House Coronavirus Task Force, which resulted in the development of world-leading vaccines and therapeutics.

As a shameless point of personal privilege, Mr. Chair, I would like to thank my brother, Michael, the Vice President of the United States, for his humble leadership. I would like to thank him for his wisdom. I would like to thank him for the countless hours he put in standing up the Coronavirus Task Force. And most importantly, as I have listened to the testimony and the questions today, I would like to thank him for his clear and transparent communications to the American public and among your organizations.

And maybe—I don't want to lecture to you, some people do, that is not my style—but maybe a little more communication on your part over the last couple of years would have given people more of a sense of confidence, which—I have heard a number of my peers today say there is a confidence deficit, and something that—difficult to earn, easily lost. And that seems to be what has happened across the country. I know my constituents feel that way for what you all, all three of your organizations, are doing.

What is your thought? Do you think you have communicated adequately over the last 2 years?

And I will start with you, Dr. Tabak.

Dr. TABAK. There is always room for improvement, and we continue to work at that.

Dr. WALENSKY. Similarly, as part of CDC Moving Forward, communications is a key aspect. We need to do more risk communications, overhaul our website. Those are things that we are actively engaged in for exactly the reasons of lessons learned.

Dr. CALIFF. I would completely agree. We need to continue to work on it.

I wasn't here the first 2 years, so I had a chance to observe it on the outside.

I would also point out we have a new thing with the onslaught of misinformation, which is very much hurting the confidence of the public, often completely misdirected, and raises a number of difficult questions that none of us really anywhere were prepared to deal with. The vastness of the internet, the complexity of the information is something that we are all going to have to work on dealing with appropriately.

Mr. PENCE. Well, sure. Thank you. You know, I am really proud of my brother, the former Vice President, because he got ahead of all this. The internet existed back then, as well. Misinformation allegedly was out there, the Russian hoax being an example.

But I would encourage you all, then, if you should get out and talk, if you should communicate with the things you have done or plan on doing, get ahead of the communication. I know the American people and the people in the Indiana 6th District would very much appreciate it.

With that I yield back.

Mr. GRIFFITH. I thank the gentleman, he yields back. I now recognize the gentleman from Texas, Mr. Crenshaw, for his 5 minutes. And he will be our last witness.

Mr. CRENSHAW. All right. Thank you, Mr. Chairman.

Mr. GRIFFITH. Questioner.

Mr. CRENSHAW. And thank you to my friend from Indiana for making that point. Maybe I will expound upon it slightly, which is—I agree wholeheartedly.

You know, the point of this is not to just get engagement on social media and get a good clip out of it and bash you guys over the head. The goal is to, indeed, bring back trust into our public health institutions and help you understand the perception of many Americans.

Only about 40 percent believe that our public health institutions are ready for the next pandemic and that they trust them. That is a glaring statistic. We are seeing declining vaccination rates for children. That is a glaring statistic as well.

And I would definitely recommend that the overall communication goal should not to be speaking in these absolutist terms, which has long been a problem, especially with people like Dr. Fauci when he was clearly wrong, when it is clearly a nuanced discussion. And that makes people skeptical, and you get discredited as a result.

Dr. Walensky, I want to bring up a very specific example of this. As you know, the CDC's Advisory Committee on Immunization Practices held its annual meeting to review the CDC's immunization schedules last fall. These schedules—child, adolescent, and adult—consist of a list of vaccines that the CDC recommends for individualsS based on their age group.

Now, historically, they have relied on—or States have relied on ACIP's recommendations when determining vaccines, what vaccines will be required for schools and childcare settings. Obviously, that makes sense, especially for childhood diseases that are uniquely transmissible in that specific group. And of course, many of these vaccines do mitigate transmission.

The question I have is in October of 2022 the advisory committee broke public health norms by deciding to add the COVID–19 vaccine, including those under emergency use authorization, to the childhood immunization schedule. That includes the bivalent booster shots. Now, obviously, they are not a mandate, but they, of course, are largely followed.

So, I mean, how do you view the cost benefit of scheduling brandnew bivalent booster shots for this age group, considering the children are at a very low risk from COVID–19, 75 percent of children

have already caught the virus, and the vaccine is known to do pretty little to prevent transmission in this age group?

Dr. WALENSKY. I am really grateful that you ask that question, so I can correct the record here so that everybody understands.

First of all, we have had 2,000 pediatric deaths from COVID–19. It is the number-one respiratory and infectious killer. That was just published last week in JAMA. So less infected, less deadly than to an 80-year-old but still deadly for a pediatric infection.

The important thing, I think, that is really—that we need to recognize is the reason that ACIP recommended and CDC put forward getting the COVID–19 vaccine on the pediatric schedule is not—it was only because it would—it was the only way it could be covered in our vaccines for children program. It was the only way that our uninsured children would be able to have access to the vaccines. That was the reason to put it on the schedule. It can't be eligible for vaccines for children program for—to be available to the uninsured unless it is on that schedule. That was the reason to put it there.

Thank you for allowing me to correct that.

Mr. CRENSHAW. OK. I want to move to the FDA and kind of a different subject. And the subject is this.

I—we are going to have a lot more hearings like this, where we need to fix this problem, where we have innovators throughout the United States who want to save people's lives and the FDA crushes their dreams and crushes their potential. Their investors pull out, they have no chance of getting through the burdensome clinical trial process that the FDA imposes upon them, nor can they even communicate with anyone at the FDA to figure out what they even need to do. It is a glaring problem.

To give you a couple of examples just out of the Houston area, scientists at Baylor College of Medicine spearheaded a low-cost, easy-to-make vaccine, Corbevax, that is already aiding in the global fight against COVID–19, and we can't get it through here.

Researchers at Texas A&M Health and University of Texas MD Anderson Cancer Center in Houston are testing PUL–042. It is an inhaled therapeutic. They can't get that through, either.

I could go on and on on non-COVID-related, very obvious treatments for—and biomedical devices that they can't even get a call back from the FDA.

What are you guys doing to fix this? Because people are dying and not getting treatment they need, while innovators around the country are trying to fix that, and the FDA is stopping them.

Dr. CALIFF. I will say we could always do better, but let me just say I have been on all sides of this fence. I have been an inventor, I have worked on companies recently, you know, before my nomination. I have worked in universities. We lead the world in innovation. We lead the world in new companies. We are doing better than any other country.

I completely disagree with your characterization of this, but, of course, we always could do better.

Mr. CRENSHAW. No, we lead the world in innovation. That is different than saying that our FDA is helping with that——

Dr. CALIFF. We lead the world in translating ideas into——

Mr. CRENSHAW [continuing]. And not inhibiting it.

Dr. CALIFF [continuing]. Therapies that are effective for us and for the rest of the world, by far. And as far as I know, no one in the world disagrees with that characterization.

Mr. CRENSHAW. Well, I mean, does the European Medicines Agency, are they just the Wild West? I mean, are they just approving things willy nilly? Is that how you view them?

I mean, why not work with them, when——

Dr. CALIFF. I am good friends with my EMA colleagues, and I have gotten products through the EMA and the FDA. The EMA is a great organization.

We lead the world in innovation——

Mr. GRIFFITH. The gentleman's time——

Dr. CALIFF [continuing]. And successful companies.

Mr. CRENSHAW. Thank you, Chairman, and I respectfully request we focus on that particular problem on a different hearing. Thank you.

Mr. GRIFFITH. I suspect we will. Thank you very much.

Let me thank the witnesses. It has been a long hearing. We appreciate you taking the hard questions. We will have followup questions, I am sure. But seeing that there are no further Members wishing to ask questions, I thank you all for being here.

That being said, before adjourning, I ask unanimous consent to insert into the record the documents included on the staff hearing documents list.

Without objection, that will be the order.

[The information appears at the conclusion of the hearing.]

Mr. GRIFFITH. All right. That being said, pursuant to committee rules, I remind Members—that would be you and me, Cathy.

Mrs. RODGERS. OK.

Mr. GRIFFITH. I remind Members that they have 10 business days to submit additional questions for the record, and I ask the witnesses to submit their response within 10 business days upon receipt of the questions.

As you know, several people didn't get through their questions and said they were going to provide you all with written questions. We would appreciate those being answered.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:54 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Strategic Preparedness and Response

Testimony before the
House Energy and Commerce Committee

Hearing Titled
"The Federal Response to COVID-19"

Dawn O'Connell
Assistant Secretary for Preparedness and Response

February 8, 2023

Chairs McMorris Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and distinguished members of the Committee, it is an honor to appear before you today to discuss the work of the Administration for Strategic Preparedness and Response (ASPR) in supporting the ongoing COVID-19 response, the lessons we have learned, and how we will apply those moving forward.

ASPR plays a unique role in the nation's public health ecosystem. Our mission is to help the country prepare for, respond to, and recover from public health emergencies and disasters whether man-made or naturally occurring. Our mission manifests itself in several ways but most often it is in the development, procurement, stockpiling, and distribution of the needed tools to respond to any given threat. We have done this most recently in the ongoing COVID-19 response; the mpox response; the Ebola Sudan response in Uganda; and the response to the surge in respiratory illnesses across the country this winter. In each of these we have applied lessons learned and innovations developed along the way.

COVID-19 Response

As we enter the fourth year of the COVID-19 response, ASPR continues to play a lead role, in partnership with CDC, in the development, procurement and distribution of vaccines, therapeutics, and tests. While the initial Operation Warp Speed partnership with the Department of Defense (DOD) ended in December 2021, much of this work continues within ASPR. The Biomedical Advanced Research and Development Authority (BARDA) supports the advanced research and development of vaccines, therapeutics, and diagnostic candidates and the HHS Coordination Operations Response Element (HCORE) manages the ongoing procurement and distribution of the vaccines and therapeutics.

In partnership with CDC, ASPR has helped develop and deliver over 953 million doses of vaccine and 21.6 million treatment courses to date to protect the American people from COVID-19. BARDA alone has awarded contracts for the development of 81 medical countermeasure projects to support the COVID-19 response. These contract awards are listed on medicalcountermeasures.gov in detail and include 18 therapeutics, 59 diagnostics, and seven vaccine candidates. Meanwhile, HCORE has supported, in partnership with CDC, the distribution of vaccines to 106,000 locations and therapeutics to over 64,000 locations nationwide.

ASPR continues to support access to COVID-19 tests. ASPR has invested over $8 billion in domestic test manufacturers to accelerate production of rapid tests and expand manufacturing capacity. In January 2022, President Biden announced a plan to make one billion free at-home tests available to the American people and mail them directly to their homes via COVIDTests.gov. Since this effort began in January 2022, ASPR, in partnership with the U.S. Postal Service, has delivered more than 720 million at-home tests, including the Ellume test to support low-vision and blind citizens, to homes across the country.

As the acute phase of the COVID-19 response effort winds down, the Department of Health and Human Services (HHS) is working with commercial partners to transition the development and

distribution of vaccines and therapeutics to the private sector. Timelines regarding commercialization are different for each product and depend on several factors including the products' regulatory status and the manufacturers' ability to manufacture enough product for nationwide distribution. As we work through these and other issues our aim is to provide a smooth transition for each product as it enters the commercial market. One monoclonal antibody therapy produced by Eli Lilly made available under Emergency Use Authorization authorities transitioned from USG-directed distribution to traditional commercial distribution channels in August 2022.

Over the course of the COVID-19 response, the Strategic National Stockpile (SNS) has worked to backstop the medical supply needs of states, Tribal nations, territories and large metropolitan areas at an accelerated pace. Since the beginning of the pandemic, the SNS has deployed more than 610 million items to aid the national response including personal protective equipment, ventilators, Federal Medical Stations, and pharmaceuticals.

In the summer and fall of 2021 the United States saw a surge of COVID-19 cases and hospitalizations related to the Delta variant. Using medical materiel procured during an earlier stage of the pandemic, SNS responded to this uptick in cases by rapidly deploying ventilators and High Flow Nasal Cannulas (HFNC) to 18 states. Additionally, starting in January 2022, SNS began deploying National Institute for Occupational Safety & Health (NIOSH)-certified N95 respirators to the American public. These respirators were available for pick-up at retail pharmacies and community health centers nationwide. In total more than 282 million N95 respirators were distributed through this program.

As of January 19, 2023, the SNS has utilized approximately $11.5 billion from COVID-19 supplemental appropriations provided by Congress to restock its inventory. It currently has: 531 million N95 respirators (42 times pre-pandemic levels); 207 million surgical and procedure face masks (6.7 times pre-pandemic levels); 12.2 million face shields (2 times pre-pandemic levels); 47.4 million gowns and coveralls (10 times pre-pandemic levels); 4.8 billion gloves (285 times pre-pandemic levels); and 158,000 ventilators (10 times pre-pandemic levels).

While replenishing the SNS is essential, it is also critical to address the root cause of the strain in supply chains witnessed throughout the pandemic. I am working to integrate and organize supply chain situational awareness and industrial analysis, domestic industrial base expansion, and supply chain logistics into a new office within ASPR. Bringing these pieces together will strengthen our industry partnerships and support our work to establish and maintain resilient public health and medical supply chains.

Throughout the COVID-19 response, ASPR has leveraged the authorities delegated to the Secretary under the Defense Production Act (DPA) 70 times, including by granting 54 priority ratings for United States Government (USG) contracts for health resources, 10 priority ratings for USG contracts for industrial expansion, six priority ratings for non-USG contracts to support the production of resins for both diagnostics and infusion pumps, and the manufacture of closed suction catheters for treatment of patients with COVID-19—all to ensure private sector partners

making life-saving products are able to acquire the raw materials, components, and products requisite to deliver for the response.

ASPR is also equipping the domestic public health industrial base to secure and develop its manufacturing capacity, retool and expand industry machinery, scale production facilities, train a skilled workforce, and ultimately infuse the supply chain and marketplace with products the United States needs to contain future pandemic waves. ASPR is doing this through targeted investments in domestic manufacturing of such critical supplies as gloves, gowns, and N95 masks.

As ASPR has executed its COVID-19 response priorities, we have learned critical lessons and innovations that we are now applying to all response-related activities.

Mpox and Other Responses

In addition to the COVID-19 response, ASPR supported several other public health responses during 2022. These included both the domestic mpox response and the Ebola Sudan virus outbreak in Uganda, as well as the winter surge of respiratory viral illnesses like RSV and flu – for which ASPR mobilized to ensure sufficient supply of Tamiflu and clinical personnel in local jurisdictions. Our work for all of these efforts benefited from the lessons we learned during COVID-19.

For example, in mpox we adjusted the vaccine and therapeutics ordering and distribution platforms to reflect key learnings from COVID-19. These vaccines and therapeutics, unlike those in the COVID-19 response, are being provided by the SNS—rather than the manufacturers themselves. To increase the efficiency of the SNS' ordering system we moved from a paper process to a more sophisticated digital process. As we digitized the ordering system, we opted to use a program that allowed states to order both vaccines and therapeutics from the same system rather than using separate, non-interoperable systems as they have had to do in the COVID-19 response. Using this multi-platform ordering system is a step towards modernizing our public health infrastructure for the current response and for future responses.

In the mpox response we have also expanded the number of sites to which the SNS delivers to better serve our healthcare partners. At the start of the outbreak, the SNS was only able to deliver to five sites in each jurisdiction, resulting in the jurisdiction having to forward distribute the products to their hospitals and vaccination clinics. While such a system is more than enough for the high-consequence large-scale chemical, biological, radiological, nuclear, and explosive events that the SNS plans for, there was increased burden on the jurisdictions in this nationwide mpox response. After seeing the advantage of multiple distribution sites in the COVID-19 vaccine and therapeutics effort and hearing jurisdictions' preference for this direct distribution capability, the SNS contracted with a commercial medical distribution vendor that leveraged its existing distribution capabilities and was able to rapidly reach a diverse set of requestors and recipients to create a distribution network for mpox that was similar to that used in COVID-19. These are just two examples of the lessons we have learned from one response and applied them to another.

Strengthening ASPR for Future Responses

As an organization, ASPR continuously evaluates best practices and calibrates our responses to ensure we are fully meeting our mission and doing so in a way that allows us to move quickly and decisively against a range of complex threats. As we move out of the acute phase of the COVID-19 response, I have begun looking at our response capabilities and evaluating what additional authorities and structure changes we might need to improve our work going forward.

For example, early in the pandemic HHS could not move contracts as quickly and flexibly as it needed to in order to keep up with pace of the pandemic. ASPR entered into a relationship with DOD to take on some of the necessary procurements. Our agreement with DOD to provide these services ends at the end of fiscal year 2023 and we need to be ready to take over that work internally. To match the speed and flexibility of DOD's contracting capabilities for future outbreaks ASPR needs additional acquisitions authorities—such as expanded Other Transaction Authority and streamlined acquisition authorities to enhance the speed of contracting and access innovative products and vendors.

Throughout the response, filling critical workforce gaps across the organization has been a challenge. Similar to our reliance on DOD for contracting support, we relied heavily on FEMA and the Coast Guard to bolster our limited staff. Having additional hiring flexibilities would go a long way towards ensuring that we are able to quickly scale up our responses when necessary. ASPR must have the appropriate authorities to prepare for, respond to, and recover from whatever comes next—no matter what that might be. We look forward to working with Congress to explore options to strengthen our workforce capacity.

These are just some examples of additional authorities ASPR could benefit from in future emergency and disaster responses. I look forward to further collaboration with you and your staff as you consider these and other potential authorities for ASPR in the upcoming reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) this Congress.

As for structure, we will soon implement a reorganization that both fully incorporates our new capabilities and creates additional accountability in existing programs. This will strengthen our ability to prepare for and respond to whatever comes next. The following are key elements of the upcoming reorganization: (1) two new programs that were launched during the COVID-19 response will become stand-alone offices directly reporting to the ASPR: H-CORE and the Office of Industrial Base Management/Supply Chain; (2) one program that has increased significantly in budget and mandate will become its own stand-alone office directly reporting to the ASPR: the Strategic National Stockpile; and (3) to better coordinate and align ASPR's external engagement and policy work across the organization, several components are moving into the Immediate Office of the ASPR. These include Legislative, Communications, External Affairs, Policy, Strategy and Requirements. Each of these changes will improve line-of-sight and accountability as well as strengthen ASPR's ability to meet its mission on behalf of the American people.

Conclusion

Thank you again for inviting me to testify before you on efforts within ASPR to support the COVID-19 response, lessons learned, and thoughts for the next iteration of PAHPA. I look forward to answering your questions and working with you and your staff as we move forward in the 118th Congress.

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Cochrane Database of Systematic Reviews 2023, Issue 1. Art. No.: CD006207.
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[Intervention Review]

Physical interventions to interrupt or reduce the spread of respiratory viruses

Tom Jefferson[1], Liz Dooley[2], Eliana Ferroni[3], Lubna A Al-Ansary[4], Mieke L van Driel[5,6], Ghada A Bawazeer[7], Mark A Jones[2], Tammy C Hoffmann[2], Justin Clark[2], Elaine M Beller[2], Paul P Glasziou[2], John M Conly[8,9,10]

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ABSTRACT

Background

Viral epidemics or pandemics of acute respiratory infections (ARIs) pose a global threat. Examples are influenza (H1N1) caused by the H1N1pdm09 virus in 2009, severe acute respiratory syndrome (SARS) in 2003, and coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in 2019. Antiviral drugs and vaccines may be insufficient to prevent their spread. This is an update of a Cochrane Review last published in 2020. We include results from studies from the current COVID-19 pandemic.

Objectives

To assess the effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses.

Search methods

We searched CENTRAL, PubMed, Embase, CINAHL, and two trials registers in October 2022, with backwards and forwards citation analysis on the new studies.

Selection criteria

We included randomised controlled trials (RCTs) and cluster-RCTs investigating physical interventions (screening at entry ports, isolation, quarantine, physical distancing, personal protection, hand hygiene, face masks, glasses, and gargling) to prevent respiratory virus transmission.

Data collection and analysis

We used standard Cochrane methodological procedures.

Main results

We included 11 new RCTs and cluster-RCTs (610,872 participants) in this update, bringing the total number of RCTs to 78. Six of the new trials were conducted during the COVID-19 pandemic; two from Mexico, and one each from Denmark, Bangladesh, England, and Norway. We identified four ongoing studies, of which one is completed, but unreported, evaluating masks concurrent with the COVID-19 pandemic.

Many studies were conducted during non-epidemic influenza periods. Several were conducted during the 2009 H1N1 influenza pandemic, and others in epidemic influenza seasons up to 2016. Therefore, many studies were conducted in the context of lower respiratory viral circulation and transmission compared to COVID-19. The included studies were conducted in heterogeneous settings, ranging from suburban schools to hospital wards in high-income countries; crowded inner city settings in low-income countries; and an immigrant neighbourhood in a high-income country. Adherence with interventions was low in many studies.

The risk of bias for the RCTs and cluster-RCTs was mostly high or unclear.

Medical/surgical masks compared to no masks

We included 12 trials (10 cluster-RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and 10 in the community). Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials, 276,917 participants; moderate-certainty evidence. 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 (RR 1.01, 95% CI 0.72 to 1.42; 6 trials, 13,919 participants; moderate-certainty evidence). Harms were rarely measured and poorly reported (very low-certainty evidence).

N95/P2 respirators compared to medical/surgical masks

We pooled trials comparing N95/P2 respirators with medical/surgical masks (four in healthcare settings and one in a household setting). We are very uncertain on the effects of N95/P2 respirators compared with medical/surgical masks on the outcome of clinical respiratory illness (RR 0.70, 95% CI 0.45 to 1.10; 3 trials, 7779 participants; very low-certainty evidence). N95/P2 respirators compared with medical/surgical masks may be effective for ILI (RR 0.82, 95% CI 0.66 to 1.03; 5 trials, 8407 participants; low-certainty evidence). Evidence is limited by imprecision and heterogeneity for these subjective outcomes. The use of a N95/P2 respirators compared to medical/surgical masks probably makes little or no difference for the objective and more precise outcome of laboratory-confirmed influenza infection (RR 1.10, 95% CI 0.90 to 1.34; 5 trials, 8407 participants; moderate-certainty evidence). Restricting pooling to healthcare workers made no difference to the overall findings. Harms were poorly measured and reported, but discomfort wearing medical/surgical masks or N95/P2 respirators was mentioned in several studies (very low-certainty evidence).

One previously reported ongoing RCT has now been published and observed that medical/surgical masks were non-inferior to N95 respirators in a large study of 1009 healthcare workers in four countries providing direct care to COVID-19 patients.

Hand hygiene compared to control

Nineteen trials compared hand hygiene interventions with controls with sufficient data to include in meta-analyses. Settings included schools, childcare centres and homes. Comparing hand hygiene interventions with controls (i.e. no intervention), there was a 14% relative reduction in the number of people with ARIs in the hand hygiene group (RR 0.86, 95% CI 0.81 to 0.90; 9 trials, 52,105 participants; moderate-certainty evidence), suggesting a probable benefit. In absolute terms this benefit would result in a reduction from 380 events per 1000 people to 327 per 1000 people (95% CI 308 to 342). When considering the more strictly defined outcomes of ILI and laboratory-confirmed influenza, the estimates of effect for ILI (RR 0.94, 95% CI 0.81 to 1.09; 11 trials, 34,503 participants; low-certainty evidence), and laboratory-confirmed influenza (RR 0.91, 95% CI 0.63 to 1.30; 8 trials, 8332 participants; low-certainty evidence), suggest the intervention made little or no difference. We pooled 19 trials (71, 210 participants) for the composite outcome of ARI or ILI or influenza, with each study only contributing once and the most comprehensive outcome reported. Pooled data showed that hand hygiene may be beneficial with an 11% relative reduction of respiratory illness (RR 0.89, 95% CI 0.83 to 0.94; low-certainty evidence), but with high heterogeneity. In absolute terms this benefit would result in a reduction from 200 events per 1000 people to 178 per 1000 people (95% CI 166 to 188). Few trials measured and reported harms (very low-certainty evidence).

We found no RCTs on gowns and gloves, face shields, or screening at entry ports.

Authors' conclusions

The high risk of bias in the trials, variation in outcome measurement, and relatively low adherence with the interventions during the studies hampers drawing firm conclusions. There were additional RCTs during the pandemic related to physical interventions but a relative paucity given the importance of the question of masking and its relative effectiveness and the concomitant measures of mask adherence which would be highly relevant to the measurement of effectiveness, especially in the elderly and in young children.

There is uncertainty about the effects of face masks. The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different from the observed estimate of the effect. The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use

of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. Hand hygiene is likely to modestly reduce the burden of respiratory illness, and although this effect was also present when ILI and laboratory-confirmed influenza were analysed separately, it was not found to be a significant difference for the latter two outcomes. Harms associated with physical interventions were under-investigated.

There is a need for large, well-designed RCTs addressing the effectiveness of many of these interventions in multiple settings and populations, as well as the impact of adherence on effectiveness, especially in those most at risk of ARIs.

PLAIN LANGUAGE SUMMARY

Do physical measures such as hand-washing or wearing masks stop or slow down the spread of respiratory viruses?

Key messages
We are uncertain whether wearing masks or N95/P2 respirators helps to slow the spread of respiratory viruses based on the studies we assessed.

Hand hygiene programmes may help to slow the spread of respiratory viruses.

How do respiratory viruses spread?
Respiratory viruses are viruses that infect the cells in your airways: nose, throat, and lungs. These infections can cause serious problems and affect normal breathing. They can cause flu (influenza), severe acute respiratory syndrome (SARS), and COVID-19.

People infected with a respiratory virus spread virus particles into the air when they cough or sneeze. Other people become infected if they come into contact with these virus particles in the air or on surfaces on which they land. Respiratory viruses can spread quickly through a community, through populations and countries (causing epidemics), and around the world (causing pandemics).

Physical measures to try to prevent respiratory viruses spreading between people include:

· washing hands often;

· not touching your eyes, nose, or mouth;

· sneezing or coughing into your elbow;

· wiping surfaces with disinfectant;

· wearing masks, eye protection, gloves, and protective gowns;

· avoiding contact with other people (isolation or quarantine);

· keeping a certain distance away from other people (distancing); and

· examining people entering a country for signs of infection (screening).

What did we want to find out?
We wanted to find out whether physical measures stop or slow the spread of respiratory viruses from well-controlled studies in which one intervention is compared to another, known as randomised controlled trials.

What did we do?
We searched for randomised controlled studies that looked at physical measures to stop people acquiring a respiratory virus infection.

We were interested in how many people in the studies caught a respiratory virus infection, and whether the physical measures had any unwanted effects.

What did we find?
We identified 78 relevant studies. They took place in low-, middle-, and high-income countries worldwide: in hospitals, schools, homes, offices, childcare centres, and communities during non-epidemic influenza periods, the global H1N1 influenza pandemic in 2009, epidemic influenza seasons up to 2016, and during the COVID-19 pandemic. We identified five ongoing, unpublished studies; two of them evaluate masks in COVID-19. Five trials were funded by government and pharmaceutical companies, and nine trials were funded by pharmaceutical companies.

No studies looked at face shields, gowns and gloves, or screening people when they entered a country.

We assessed the effects of:

· medical or surgical masks;

· N95/P2 respirators (close-fitting masks that filter the air breathed in, more commonly used by healthcare workers than the general public); and

· hand hygiene (hand-washing and using hand sanitiser).

We obtained the following results:

Medical or surgical masks

Ten studies took place in the community, and two studies in healthcare workers. Compared with wearing no mask in the community studies only, wearing a mask may make little to no difference in how many people caught a flu-like illness/COVID-like illness (9 studies; 276,917 people); and probably makes little or no difference in how many people have flu/COVID confirmed by a laboratory test (6 studies; 13,919 people). Unwanted effects were rarely reported; discomfort was mentioned.

N95/P2 respirators

Four studies were in healthcare workers, and one small study was in the community. Compared with wearing medical or surgical masks, wearing N95/P2 respirators probably makes little to no difference in how many people have confirmed flu (5 studies; 8407 people); and may make little to no difference in how many people catch a flu-like illness (5 studies; 8407 people), or respiratory illness (3 studies; 7799 people). Unwanted effects were not well-reported; discomfort was mentioned.

Hand hygiene

Following a hand hygiene programme may reduce the number of people who catch a respiratory or flu-like illness, or have confirmed flu, compared with people not following such a programme (19 studies; 71,210 people), although this effect was not confirmed as statistically significant reduction when ILI and laboratory-confirmed ILI were analysed separately. Few studies measured unwanted effects; skin irritation in people using hand sanitiser was mentioned.

What are the limitations of the evidence?
Our confidence in these results is generally low to moderate for the subjective outcomes related to respiratory illness, but moderate for the more precisely defined laboratory-confirmed respiratory virus infection, related to masks and N95/P2 respirators. The results might change when further evidence becomes available. Relatively low numbers of people followed the guidance about wearing masks or about hand hygiene, which may have affected the results of the studies.

How up to date is this evidence?
We included evidence published up to October 2022.

The panel was supposed to improve efficiency at the NIH. It hasn't even met for 7 years

By Lev Facher May 9, 2022
Reprints

WASHINGTON — An oversight board tasked with making the National Institutes of Health more efficient and more effective mysteriously stopped meeting seven years ago, according to a STAT review of agency records — and its members don't know why.

The group, which Congress created in 2006, was intended to serve as a sounding board for the NIH director, providing periodic feedback and recommendations aimed at improving the government's largest science agency. But it hasn't met since the summer of 2015, and several prominent researchers whom the NIH website still lists as board members appear confused as to whether the group still exists.

"There wasn't any notification that we weren't going to meet again — it was just that the meetings stopped getting called," said Nancy Andrews, a board member and the former dean of the Duke University School of Medicine.

"I had the sense that we were asking questions in areas that they didn't really want to get into, and I suppose Francis in particular didn't really want us working on," Andrews said, referring to Francis Collins, the longtime NIH director who stepped down at the end of 2021 after over a decade leading the agency.

The de facto disappearance of the NIH's Scientific Management Review Board (SMRB), critics charge, is emblematic of the agency's broader reluctance to accept criticism and to modernize. Some science policy experts have charged lately that the NIH operates too

slowly, that it funds research too conservatively, and that its bureaucratic structure is cumbersome and unwieldy.

Now more than ever, the critics said, the NIH needs its outside advisers. The $42 billion research agency is currently in a period of major transition. The science community is waiting for President Biden to name Collins' successor; Anthony Fauci, the agency's quasi-celebrity and top infectious diseases researcher, has begun to hint at retirement; and top agency officials are working to establish ARPA-H, a new research arm aimed at developing transformative new technologies.

"The fact that the SMRB has basically gone dormant is a lost opportunity," said Stuart Buck, the founder of the Good Science Project, a new organization aimed at making government-funded science more efficient and transparent. "Hopefully a new NIH director will make this a higher priority."

In a statement, an NIH spokeswoman told STAT that the review board "currently does not have an active charge and is administratively inactive." The agency recommended that the committee be terminated during the Trump administration, she said. But its status is still in flux, according to a federal website, and her statement did not account for the committee's inactivity between 2015 and 2019.

Related: NIH's identity crisis: The pandemic and the search for a new leader leave at a crossroads

Lawmakers created the review board as part of the NIH Reform Act, a bill lawmakers passed overwhelmingly in 2006 that established several new committees meant to analyze its performance. The SMRB, as they described it, would consist of a combination of NIH institute directors, the NIH director, and outside appointees selected by the health secretary.

The group would be required to issue a sweeping report about the NIH's organizational structure every seven years, and its recommendations would be binding unless the NIH director issued a formal objection.

The NIH website describes the panel as one of the "main advisory boards to the NIH director" — it was meant to help give the agency and its leadership the kind of expert advice and counsel that Congress doesn't always offer, despite having a similar oversight capacity. Lawmakers, happy to fund medical research initiatives, have largely ignored the agency's brushes with controversy over the last decade.

The group did meet regularly between 2009 and 2015. It established a handful of working groups to examine some of the broader organizational questions the agency faced back in the mid 2000s, and issued a number of reports on topics ranging from the NIH's long-critiqued peer review process to high schoolers' engagement in the biomedical sciences.

Related: Biden's high-stakes biomedical science agency ARPA-H will be part of the NIH — but there's a twist

It's not clear, however, how much impact the group had when it was meeting regularly.

In 2010, the group voted 12-3 to recommend a major bureaucratic change: merging the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, two NIH institutes focused on alcohol addiction and drug addiction, respectively, into a single institute focused on addiction more broadly.

Yet in 2012, Collins rejected the change — a high-profile rebuke of one of the panel's most concrete recommendations. The institutes remain separate.

The panel's last public meeting was in 2015.

The NIH's website still maintains a roster of SMRB members. But many of the names, titles, and employers are years out of date: The physicist Roderic Pettigrew, for instance, is listed as a member even though he stepped down as director of the National Institute of Biomedical Imaging and Bioengineering in 2017.

Gilbert Omenn, a University of Michigan genomics and cancer researcher, referred to the group as an "excellent committee" in a brief phone interview, and said he believed his term had expired. He is still listed on the website.

Most other board members did not respond to STAT's requests for comment.

It's not as though there aren't plenty of topics that the NIH could use advice on.
In the years since the panel's last meeting, the NIH has been dogged with a handful of minor and major controversies. The Trump administration, for example, reignited a decades-old debate in 2019 by ordering the agency to stop using human fetal tissue that scientists argued were necessary for key experiments. There are perennial concerns about the potential conflicts of interest that arise from research partnerships between the NIH and private companies, including the alcohol industry and the NFL. There are almost always critics of the agency's reliance on animal testing.

The NIH has also been criticized more broadly for its bureaucratic structure and the perceived shortcomings of the peer-review system it uses to award tens of billions of dollars to researchers across the country.

The review board is perfectly positioned to address those issues, Buck said, making its absence all the more costly.

"Any well-functioning organization will regularly think about questions like, 'What is our overall strategy? Are we achieving it? Is there anything we're doing that isn't working very well, and are there any new activities/divisions that we need to launch?'" he said. "The SMRB was intended to help Congress, HHS, and NIH have those regular conversations about how NIH is doing."

NIH's habit of ignoring feedback from outside research experts extends far beyond the mysterious disappearance of the SMRB, said Robert Cook-Deegan, an Arizona State professor and founding director of Duke's Center for Genome Ethics, Law, and Policy.

"About every 10 years, the National Academies [of Sciences, Engineering, and Medicine] are asked to review NIH, and they make recommendations, most of which are ignored," he said. The agency's "large, inertial, and ponderous bureaucracy," he added, is "not terribly open to criticism as a whole."

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New Report Confirms U.S. Life Expectancy has Declined to Lowest Level Since 1996

For Immediate Release: December 22, 2022

Contact: CDC, National Center for Health Statistics, Office of Communication (301) 458-4800
E-mail: paoquery@cdc.gov

U.S. Life Expectancy decreased in 2021 for the second consecutive year, according to final mortality data released today. The drop was primarily due to increases in COVID-19 and drug overdose deaths. The data are featured in two new reports from CDC's National Center for Health Statistics (NCHS).

"Mortality in the United States: 2021" features the first public release of final mortality data for 2021, and the report documents that there were 3,464,231 total deaths in the United States during 2021 — 80,502 more than the total reported in 2020.

The death rate for the entire U.S. population increased by 5.3% from 835.4 deaths per 100,000 population in 2020 to 879.7 in 2021. As a result, life expectancy at birth for the U.S. population decreased from 77 years in 2020 to 76.4 years in 2021.

The 10 leading causes of death in 2021 were largely unchanged from 2020, except chronic liver disease and cirrhosis became the 9th leading cause of death in 2021 while influenza and pneumonia dropped from the list of 10 leading causes. Heart disease remained the leading cause of death in the United States, followed by cancer and COVID-19.

A second report released today, "Drug Overdose Deaths in the United States, 2001-2021," showed that overdose deaths, which account for more than a third of all accidental deaths in the United States, have risen five-fold over the past two decades. The official number of drug overdose deaths among residents in the United States for 2021 was 106,699, nearly 16% higher than the 91,799 deaths in 2020.

Other Findings:

- The drug overdose death rate was 32.4 overdose deaths per 100,000 in 2021, higher than 28.3 in 2020.
- The rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) increased 22% from 17.8 in 2020 to 21.8 in 2021.
- From 2020 to 2021, the rate of drug overdose deaths involving cocaine increased 22% (from 6.0 to 7.3) and the rate for deaths involving psychostimulants with abuse potential (drugs such as methamphetamine) increased 33% (from 7.5 to 10.0).
- The rate of drug overdose deaths involving heroin decreased 32% from 4.1 in 2020 to 2.8 in 2021.

REPORTS:

Mortality in the United States: 2021
Drug Overdose Deaths in the United States, 2001-2021

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Study: U.S. Lags Behind Other Wealthy Countries in Health Outcomes

The U.S. performs worse than its wealthy peers in nearly every major measure of health and well-being measured in a recent study, despite spending far more on health care.

By Elliott Davis Jr.

Feb. 1, 2023

Save Comment

Nurse assistants prepare a room at Providence St. Joseph Hospital in Orange, Calif., on April 14, 2022. The U.S. leads 12 other members of the Organization for Economic Cooperation and Development in just about every category of negative health outcomes studied in a report released by The Commonwealth Fund on Jan. 31, 2023. (PHOTO BY PAUL BERSEBACH/MEDIANEWS GROUP/ORANGE COUNTY REGISTER VIA GETTY IMAGES)

Americans have the lowest life expectancy at birth and the highest avoidable death rates when compared to their peer countries, despite the U.S. spending far more on health care, according to a study released Tuesday.

after enduring several years of the COVID-19 pandemic. The U.S. leads 12 other members of the Organization for Economic Cooperation and Development, a forum of 38 wealthy countries, in just about every category of negative health outcomes studied by the foundation, from assault death rate to infant and maternal mortality.

[**READ:** These Are the Top 25 COVID Hot Spots in the U.S.]

This is in spite of the U.S. being an outlier when it comes to health care spending. For example, the country spent nearly 18% of its gross domestic product on health care in 2021, according to The Commonwealth Fund. The next closest spender was Germany at just under 13%, while the OECD average was 9.6%. America's total health care spending is close to twice that of Germany and at least three times the amount spent by the countries at the bottom of the list (Japan, New Zealand and South Korea).

Because the U.S. is the only high-income country that doesn't guarantee health coverage, it is also the only country studied where voluntary health insurance spending is higher than government or compulsory health insurance spending, The Commonwealth Fund authors note.

These findings make the state of health in the country all the more concerning, at least in relative terms. The U.S.'s life expectancy at birth – 77 – is close to three years below the OECD average, and is marred by ever-present racial and ethnic disparities. America's maternal and infant mortality rates are much higher than those of fellow wealthy countries like Canada and New Zealand. South Korea has by far the highest suicide rate per 100,000, but the U.S. still ranks third, with a rate that is above the OECD average.

7.4 per 100,000 is more than five times that of the next closest competitor. The country similarly sets itself apart from others internationally when it comes to gun ownership and firearm-related deaths, according to other sources, including the nonpartisan data center USAFacts.

[**MORE:** Report: Hawaii Has the Strongest Health System in the U.S.]

The Commonwealth Fund recommends that U.S. policymakers and other officials address health care affordability, cost containment and prevention. And while the results outlined in the study aren't inspiring for America, the foundation has hopes for improvement.

"Other countries have found ways to do these things well; the U.S. can as well," the authors write."

The other countries studied were Australia, Canada, France, Germany, Japan, the Netherlands, New Zealand, Norway, South Korea, Switzerland, Sweden and the United Kingdom. The Commonwealth Fund culled the most recent data available from the OECD, Our World in Data and its own 2020 International Health Policy Survey.

Join the Conversation

See Comments

Tags: health, women's health, children's health, mental health, health care, health insurance, pandemic, United States

It's Time for the Scientific Community to Admit We Were Wrong About COVID and It Cost Lives | Opinion

KEVIN BASS , *MS MD/PHD STUDENT, MEDICAL SCHOOL*

ON 1/30/23 AT 8:00 AM EST

As a medical student and researcher, I staunchly supported the efforts of the public health authorities when it came to COVID-19. I believed that the authorities responded to the largest public health crisis of our lives with compassion, diligence, and scientific expertise. I was with them when they called for lockdowns, vaccines, and boosters.

I was wrong. *We* in the scientific community were wrong. And it cost lives.

I can see now that the scientific community from the CDC to the WHO to the FDA and their representatives, repeatedly overstated the evidence and misled the public about its own views and policies, including on natural vs. artificial immunity, school closures and disease transmission, aerosol spread, mask mandates, and vaccine effectiveness and safety, especially among the young. All of these were scientific mistakes *at the time*, not in hindsight. Amazingly, some of these obfuscations continue to the present day.

But perhaps more important than any individual error was how inherently flawed the overall approach of the scientific community was,

and continues to be. It was flawed in a way that undermined its efficacy and resulted in thousands if not millions of preventable deaths.

What we did not properly appreciate is that preferences determine how scientific expertise is used, and that our preferences might be—indeed, our preferences *were*—very different from many of the people that we serve. We created policy based on *our* preferences, then justified it using data. And then we portrayed those opposing our efforts as misguided, ignorant, selfish, and evil.

We made science a team sport, and in so doing, we made it no longer science. It became us versus them, and "they" responded the only way anyone might expect them to: by resisting.

A students adjusts her facemask at St. Joseph Catholic School in La Puente, California on November 16, 2020, where pre-kindergarten to Second Grade students in need of special services returned to the classroom today for in-person instruction. - The campus is the second Catholic school in Los Angeles County to receive a waiver approval to reopen as the coronavirus pandemic rages on. The US surpassed 11 million coronavirus cases Sunday, adding one million new cases in less than a week, according to a tally by Johns Hopkins University.FREDERIC J. BROWN / AFP

We excluded important parts of the population from policy development and castigated critics, which meant that we deployed a monolithic response across an exceptionally diverse nation, forged a society more fractured than ever, and exacerbated longstanding heath and economic disparities.

Our emotional response and ingrained partisanship prevented us from seeing the full impact of our actions on the people we are supposed to serve. We systematically minimized the downsides of the interventions we imposed—imposed without the input, consent, and recognition of those forced to live with them. In so doing, we violated the autonomy of those who would be most negatively impacted by our policies: the poor, the working class, small business owners, Blacks and Latinos, and children. These populations were overlooked because they were made invisible to us by their systematic exclusion from the dominant, corporatized media machine that presumed omniscience.

Most of us did not speak up in support of alternative views, and many of us tried to suppress them. When strong scientific voices like world-renowned Stanford professors John Ioannidis, Jay Bhattacharya, and Scott Atlas, or University of California San Francisco professors Vinay Prasad and Monica Gandhi, sounded the alarm on behalf of vulnerable communities, they faced severe censure by relentless mobs of critics and detractors in the scientific community—often not

on the basis of fact but solely on the basis of differences in scientific opinion.

Fact Check: Does Project Veritas video show Pfizer is mutating COVID?

When former President Trump pointed out the downsides of intervention, he was dismissed publicly as a buffoon. And when Dr. Antony Fauci opposed Trump and became the hero of the public health community, we gave him our support to do and say what he wanted, even when he was wrong.

Trump was not remotely perfect, nor were the academic critics of consensus policy. But the scorn that we laid on them was a disaster for public trust in the pandemic response. Our approach alienated large segments of the population from what should have been a national, collaborative project.

And we paid the price. The rage of the those marginalized by the expert class exploded onto and dominated social media. Lacking the scientific lexicon to express their disagreement, many dissidents turned to conspiracy theories and a cottage industry of scientific contortionists to make their case against the expert class consensus that dominated the pandemic mainstream. Labeling this speech "misinformation" and blaming it on "scientific illiteracy" and "ignorance," the government conspired with Big Tech to aggressively

suppress it, erasing the valid political concerns of the government's opponents.

And this despite the fact that pandemic policy was created by a razor-thin sliver of American society who anointed themselves to preside over the working class—members of academia, government, medicine, journalism, tech, and public health, who are highly educated and privileged. From the comfort of their privilege, this elite prizes paternalism, as opposed to average Americans who laud self-reliance and whose daily lives routinely demand that they reckon with risk. That many of our leaders neglected to consider the lived experience of those across the class divide is unconscionable.

Incomprehensible to us due to this class divide, we severely judged lockdown critics as lazy, backwards, even evil. We dismissed as "grifters" those who represented their interests. We believed "misinformation" energized the ignorant, and we refused to accept that such people simply had a different, *valid* point of view.

We crafted policy for the people without consulting them. If our public health officials had led with less hubris, the course of the pandemic in the United States might have had a very different outcome, with far fewer lost lives.

Instead, we have witnessed a massive and ongoing loss of life in America due to distrust of vaccines and the healthcare system; a

massive concentration in wealth by already wealthy elites; a rise in suicides and gun violence especially among the poor; a near-doubling of the rate of depression and anxiety disorders especially among the young; a catastrophic loss of educational attainment among already disadvantaged children; and among those most vulnerable, a massive loss of trust in healthcare, science, scientific authorities, and political leaders more broadly.

COVID: China spread an "experiment the likes of which none of us have seen"

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COVID: China spread an "experiment the likes of which none of us have seen"

My motivation for writing this is simple: It's clear to me that for public trust to be restored in science, scientists should publicly discuss what went right and what went wrong during the pandemic, and where we could have done better.

It's OK to be wrong and admit where one was wrong and what one learned. That's a central part of the way science works. Yet I fear that many are too entrenched in groupthink—and too afraid to publicly take responsibility—to do this.

Solving these problems in the long term requires a greater commitment to pluralism and tolerance in our institutions, including the inclusion of critical if unpopular voices.

Intellectual elitism, credentialism, and classism must end. Restoring trust in public health—and our democracy—depends on it.

https://www.bloomberg.com/news/articles/2021-12-21/cdc-public-health-data-failures-mean-u-s-lacks-whole-picture-on-covid?leadSource=uverify%20wall#xj4y7vzkg

Data Failures Keep the CDC From Seeing the Whole Picture on Covid

Bloomberg
December 21, 2021

A year into the Covid-19 vaccination campaign, the U.S. government still faces data shortcomings that cloud its vision of who's getting vaccinated and at what rate The record-time development of the shots was a (mostly) American triumph. Now vaccines are plentiful in the U.S. and offer meaningful protection for those who get them. But in another way the U.S. has lagged. America's public-health authorities have struggled to monitor the rollout of vaccines and to track data on how effective they are. The most recent example: The Centers for Disease Control and Prevention has been overcounting the number of Americans who've received at least one dose of vaccine. The agency's data are far off from what many states have been reporting on their own, meaning there are millions more unvaccinated than its numbers show. That issue followed another a few weeks earlier. After the U.S. cleared Covid shots for kids age 5 to 11 at the start of November, it took the CDC almost three weeks to publish data on how many children had been vaccinated. In the meantime, an impatient White House started its own ad hoc data collection effort, assembling vaccination numbers for the age cohort from states and vaccine providers, according to people familiar with the matter.

Those problems are just the latest. In late spring the U.S. stopped counting many vaccine breakthrough cases, information that was critical for deciding how and when to roll out boosters. And the government still lacks complete data on the race and ethnicity of vaccine recipients, despite the Biden administration making demographic equity a cornerstone of its rollout.

After two years of rising case counts and more than 800,000 deaths, there's broad agreement that U.S. public-health systems need an overhaul, just as the Sept. 11 attacks and the 2008 financial crisis paved the way for national security and banking reforms, respectively. The push is being led by influential persons in public health and in Congress who aim to better prepare the government for the next infectious-disease threat the world will confront. The slow-to-arrive kids data felt like deja vu. I'm one of the people who run the Bloomberg Vaccine Tracker, our newsroom effort to tally every Covid vaccine going into arms around the world. When we began the project in December 2020, our team of journalists would reach out to states and foreign governments each day and produce a tally of how many doses had been administered. It was

laborious, complex work, but we figured the CDC and the World Health Organization would quickly put us out of business. That didn't happen.

The CDC took months to catch up to data that was being published independently by states. Entities such as the WHO didn't have real-time access to data on vaccinations and ended up relying for several months on third-party sources for information, according to a person familiar with the organization's efforts. The situation was an echo of the first year of the pandemic, when nongovernment sources such as the Covid Tracking Project and Johns Hopkins University were the go-to resource for data on the virus. Robert Redfield, director of the CDC during the Trump administration, said the agency's inability to provide seemingly basic information on the virus bothered him. "I was quite embarrassed that everybody quotes Johns Hopkins and Bloomberg", he says." Why aren't they quoting CDC?"

There's no obvious reason the data on child immunizations should have been difficult to collect or disseminate. The vaccines were cleared for use in children on Nov. 2; a few days later a handful of states began publishing their own numbers. And for months the CDC had been putting out detailed data on the ages of people who've been vaccinated. But a little over two weeks after the shots were cleared, there were still no numbers from the CDC. Instead, the White House announced its own tally: 2.6 million 5- to 11-year-olds had gotten a dose.

When the agency eventually published its own data, there were several discrepancies between its statistics and what states were reporting. A White House official, expressing frustration, described the CDC's child vaccine data at the time as "useless" since it was several days behind reality on the ground.

In a statement, the CDC said that it's working with states, local jurisdictions, and the health system to improve and speed the flow of data but that the huge variety of sources could create slowness and errors.

"While CDC data provides a wide-angle lens to look at vaccination across the country, we know that states and local health departments have a wealth of information and have always referred reporters there for the most up to date data", the agency said.

It added that the vaccination data for 5- to 11-year-olds presented challenges because of a new dose amount and new vaccine providers. The agency said that while it worked to get its own data up and running, it helped in the effort to model a national number.

In many ways the CDC's ability to gather and publish timely numbers on the pandemic has improved. The agency now has a website rich with statistics, providing an invaluable resource for the public, researchers, and policymakers.

But the delayed child vaccine data and the miscount of millions of vaccinated people are only the latest data problems from the agency. In late spring the CDC stopped collecting information on

mild breakthrough infections; just as the delta variant was beginning to spread widely. It had to rely on Israeli government data for information on how quickly the effectiveness of vaccines was waning and the need for booster shots. And the government has race and ethnicity data for only about 70% of vaccinations, even though states have published such data on their own, covering more than 90% of shots.

Being slow to produce information in the middle of a health emergency isn't just a pandemic problem. Redfield recalls an episode from April 2018, the month after he took over the agency. He'd almost lost one of his children to a drug overdose, from cocaine laced with fentanyl, and he wanted a report on the opioid epidemic "I got a wonderful briefing", Redfield says. "And afterwards I asked the simple question, when was the data through? And they said, 'Through March 2015'. And I said, 'But it's April 2018'". He adds: "When I became CDC director, I was excited about making an impact on the human condition and public health. I didn't realize I was becoming a medical historian."

In Congress, Senators Richard Burr, a North Carolina Republican, and Patty Murray, a Washington Democrat, are drafting legislation to make broad changes at the agency. The pair, who lead the U.S. Senate Committee on Health, Education, Labor and Pensions, hope to introduce a bill after Congress finishes dealing with the Biden administration's Build Back Better package.

A key part of any new law will be increasing funding for the CDC or rethinking how it spends existing dollars, along with how much of its budget should be funneled to state public-health departments. The lawmakers also want to overhaul the way health data gets collected and reported. Among some legislators, former agency heads such as Redfield, and state public-health officials, there's also talk that the culture needs to change. One often-heard criticism is that the agency is too academic. It has tended to "agonize over having perfect, clean data," Burr said at a Nov. 4 hearing with current CDC Director Rochelle Walensky. "By the time we get their data, it's too late."

Another White House official, who spoke anonymously because they're not authorized to comment publicly on such matters, says there's a sense that while the CDC is a useful center of knowledge, it's not "operational,"; meaning it's not capable of mounting an on-the-ground response. Those types of tasks (such as executing quarantines, ramping up testing capacity, or running disease surveillance) might be better handled by another part of the government.

Walensky has said she's working to make changes at the agency, whose a little over 10,000 employees are based mostly in Atlanta. "One of the things I think we've done since I've been here is try and understand what are the questions people are going to be asking a month from now or two months from now,"; she said at an event hosted by the *Atlantic* in September.

The agency now gets faster updates on vaccine effectiveness from studies it's commissioned, for example. Walensky, the former chief of the Division of Infectious Diseases at Massachusetts

General Hospital, also set up a unit to focus on disease forecasting. The new Center for Forecasting and Outbreak Analytics is meant to give the agency better information on future threats and is being led by people hired from outside the agency - an effort to get around the CDC's too-academic culture, according to a person familiar with the effort.

Redfield says a CDC overhaul will require a substantial investment, anywhere from $25 billion to $50 billion: "This is not some hundred million here, a hundred million there."; As recently as a few years ago, he says, the agency was still getting reports from some local agencies by fax. "We've never given the American public the public-health system that it needs; more importantly, that it deserves."

The problems aren't just at the federal level. In January 2021, as the U.S. vaccine rollout was getting under way, public-health officials in California saw something that worried them. Despite months of planning, the state's numbers were lagging. It didn't make sense. Health workers in the field were saying immunizations were moving quickly. But according to the data, California was slower than other states in administering the still-meager supplies of vaccines being shipped by the federal government.

So officials began to investigate. The culprit, it turned out, wasn't vaccine hesitancy or bottlenecks at hospitals. It was a button. On one of the computer programs the state was using to feed records into a central database, the "submit"; button was buried at the bottom of the screen and easy to miss. A message went out to vaccinators: Hit "submit."; Within days the numbers began to turn around.

It was a face-palming oversight with serious repercussions. One of California's biggest health-care systems, Sutter Health, had been focusing those early vaccinations on older, vulnerable people. Supplies were tight, and Sutter quickly used up what it had. But the state wasn't sending more - and doses were being delayed. "The state thought they had vaccine, but they didn't," says Paul Markovich, chief executive officer of Blue Shield of California, the health insurer that would end up being brought in to take over management of the state's vaccine program. He says there were "a number of glitches"; in the state systems that could have caused the problem. "We had people who were 80-plus years old not getting their second shot,"; he says. A Sutter Health representative confirmed that the system had briefly paused first-dose appointments and also second-dose appointments. "When you have the most virulent virus we have seen in a century tearing its way through your population, it's critical that you get the people who are the highest risk,"; says Markovich. "You're potentially costing people their lives, because the vaccine is not going to the people it should."

CDC Centers for Disease Control and Prevention

Contact Tracing for COVID-19

Updated Feb. 10, 2022

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CDC is reviewing this page to align with updated guidance.

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- Changes made to reflect updated guidance for isolation and quarantine.

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COVID-19

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Close contact evaluation and monitoring priorities

In jurisdictions with testing capacity, symptomatic and asymptomatic close contacts to patients with confirmed and probable COVID-19 should be evaluated and monitored. For areas with insufficient testing support and/or limited public health resources, the following evaluation and monitoring hierarchy (Box 4) and the case investigation and contact tracing prioritization recommendations can be used to help guide prioritization. The hierarchy is based on the assumption that if close contacts listed in Priority 1 *become infected,* they could potentially expose many people, those at higher risk for severe disease, or critical infrastructure workers. If close contacts in Priority 2 *become infected,* they may be at higher risk for severe disease, so prompt notification, monitoring, and linkage to needed medical and support services is important.

When prioritizing close contacts to evaluate and monitor, jurisdictions should be guided by the local characteristics of disease transmission, demographics, and public health and healthcare system capacity. Some states require mandatory testing for specific circumstances. Local decisions depend on local guidance and circumstances.

The Washington Post

The inside story of how Trump's denial, mismanagement and magical thinking led to the pandemic's dark winter

By Yasmeen Abutaleb, Ashley Parker, Josh Dawsey and Philip Rucker
Dec. 19, 2020

As the number of coronavirus cases ticked upward in mid-November — worse than the frightening days of spring and ahead of an expected surge after families congregated for Thanksgiving — four doctors on President Trump's task force decided to stage an intervention.

After their warnings had gone largely unheeded for months in the dormant West Wing, Deborah Birx, Anthony S. Fauci, Stephen Hahn and Robert Redfield together sounded new alarms, cautioning of a dark winter to come without dramatic action to slow community spread.

White House Chief of Staff Mark Meadows, among the many Trump aides who were infected with the virus this fall, was taken aback, according to three senior administration officials with knowledge of the discussions. He told the doctors he did not believe their troubling data assessment. And he accused them of outlining problems without prescribing solutions.

The doctors explained that the solutions were simple and had long been clear — among them, to leverage the power of the presidential bully pulpit to persuade all Americans to wear masks, especially the legions of Trump supporters refusing to do so, and to dramatically expand testing.

"It was something that we were almost repetitively saying whenever we would get into the Situation Room," said Fauci, who directs the National Institute of Allergy and Infectious Diseases. "Whenever we got the opportunity to say, 'This is really going to be a problem because the baseline of infections was really quite high to begin with, so you had a lot of community spread.' "

On Nov. 19, hours after the Centers for Disease Control and Prevention advised against Thanksgiving travel, Vice President Pence, who chairs the coronavirus task force, agreed to hold a full news conference with some of the doctors — something they had not done since the summer. But much to the doctors' dismay, Pence did not forcefully implore people to wear masks, nor did the administration take meaningful action on testing.

As for the president, he did not appear at all.

Trump went days without mentioning the pandemic other than to celebrate progress on vaccines. The president by then had abdicated his responsibility to manage the public health crisis and instead used his megaphone almost exclusively to spread misinformation in a failed attempt to overturn the results of the election he lost to President-elect Joe Biden.

“I think he’s just done with covid,” said one of Trump’s closest advisers who, like many others interviewed for this story, spoke on the condition of anonymity to candidly discuss internal deliberations and operations. “I think he put it on a timetable and he’s done with covid. . . . It just exceeded the amount of time he gave it.”

Now, a month later, the number of coronavirus cases in the United States is reaching records daily. The nation’s death count is rising steadily as well, this past week surpassing 300,000 — a total that had seemed unfathomable earlier this year. The dark winter is here, hospitalizations risk breaching capacities, and health professionals predict it will get worse before it gets better.

The miraculous arrival of a coronavirus vaccine this past week marks the first glimmer of hope amid a pandemic that for 10 months has ravaged the country, decimated its economy and fundamentally altered social interactions.

Yet that triumph of scientific ingenuity and bureaucratic efficiency does not conceal the difficult truth, that the virus has caused proportionately more infections and deaths in the United States than in most other developed nations — a result, experts say, of a dysfunctional federal response led by a president perpetually in denial.

“We were always going to have spread in the fall and the winter, but it didn’t have to be nearly this bad,” said Scott Gottlieb, a former FDA commissioner in the Trump administration. “We could have done better galvanizing collective action, getting more adherence to masks. The idea that we had this national debate on the question of whether masks infringed on your liberty was deeply unfortunate. It put us in a bad position.”

Maryland Gov. Larry Hogan, one of the few Republican elected officials who have criticized Trump’s handling of the pandemic, said many in the administration are working hard to control the alarming November-to-December surge, but not the man at the top.

“My concern was, in the worst part of the battle, the general was missing in action,” Hogan said of the recent surge.

The story of how America arrived at this final season of devastation, with the reported death toll some days surpassing 3,000 people — a new 9/11 day after day — is based on interviews over the past month with 48 senior administration officials, government health professionals, outside presidential advisers and other people briefed on the inner workings of the federal response.

The catastrophe began with Trump's initial refusal to take seriously the threat of a once-in-a-century pandemic. But, as officials detailed, it has been compounded over time by a host of damaging presidential traits — his skepticism of science, impatience with health restrictions, prioritization of personal politics over public safety, undisciplined communications, chaotic management style, indulgence of conspiracies, proclivity toward magical thinking, allowance of turf wars and flagrant disregard for the well-being of those around him.

"There isn't a single light-switch moment where the government has screwed up and we're going down the wrong path," said Kyle McGowan, who resigned in August as chief of staff at the CDC under Redfield, the center's director. "It was a series of multiple decisions that showed a lack of desire to listen to the actual scientists and also a lack of leadership in general, and that put us on this progression of where we're at today."

'Words matter'

Trump's defenders say the president and his administration deserve credit not only for Operation Warp Speed — the public-private initiative to develop, test and now distribute vaccines — but also for their work early on to address a shortage of ventilators, ease supply-chain delays for personal protective equipment and set guidelines for businesses and other gathering places to reopen after the March and April shutdowns.

They also point to Trump's decision in late January to restrict travel from China, where the virus originated. And they say they're not sure what Trump should have done differently.

"President Trump has led a historic, whole-of-America coronavirus response — resulting in 100,000 ventilators procured, an abundance of critical PPE sourced for our frontline heroes, the largest testing regime in the world, groundbreaking treatments, and a safe and effective vaccine in record time with another to be approved in the coming days," White House spokeswoman Sarah Matthews said in a statement. She went on to attribute the success of vaccines to Trump's "bold and innovative leadership."

Still, the administration's overall response is likely to be scrutinized for years to come as a case study in crisis mismanagement. At the heart of the problem, experts say, have been Trump's scrambled and faulty communications.

"Words matter a lot, and what we have here is a failure to communicate — and worse than that, the effective communication of policies, of myths, of confusion about masks, about hydroxychloroquine, about vaccines, about closures, about testing," said Tom Frieden, a former CDC director in the Obama administration. "It's stunning."

Trump's repeated downplaying of the virus, coupled with his equivocations about masks, created an opening for reckless behavior that contributed to a significant increase in infections and deaths, experts said.

“The central and most important thing we needed was national leadership from the president to be able to really lead with empathy,” said Anita Cicero, deputy director of the Johns Hopkins Center for Health Security. “It seemed much more focused on the administration as the lead character, rather than communities in need.”

A hallmark of the response has been the secrecy of some in the White House, including Meadows, whom other officials described as outright hostile in his denial of the virus and punitive toward colleagues who sought to follow public health guidelines or be transparent.

As the virus spread wildly among White House staff this fall, Meadows sought to conceal some cases from becoming public — including, at first, his own — and instructed at least one fellow adviser who sought to disclose an infection not to.

In addition, Meadows threatened to fire White House Medical Unit doctors, who fall below the chief of staff in the chain of command, if they helped release information about new infections, according to one official. Ben Williamson, an aide to Meadows, said it was “false” that the chief of staff ever threatened to terminate doctors.

Meadows argued internally, according to this official, that the White House was “under no obligation to tell the press or the public that Joe Schmo who works in the White House has tested positive.”

Despite shunning recommended protocols internally, Trump aides speak with pride about the actions they took on the pandemic and are incredulous that their work has been so widely panned.

One senior administration official involved in the response said what was accomplished in less than a year — from producing and distributing protective gear to creating vaccines — is nothing short of remarkable. But, this official acknowledged, “The way it was messaged, unfortunately, was flawed.”

A second senior administration official said, “I’m not clear on what Trump should have done different, but put me in the camp of, well, something, because it has not been a success.”

Olivia Troye, a former Pence adviser and task force aide who resigned in the summer and campaigned against Trump’s reelection, said the nation’s trauma is a result of the president’s mismanagement of the crisis early on, and is being prolonged by his disinterest in it now.

“I would love to say that I’m shocked, but I’m not,” Troye said. “This is in keeping with everything he has been.” She added: “People are still dying every day. There’s thousands of cases every day and yet he won’t do the right thing. . . . To see a sitting president directly refuse to help during a crisis is just flabbergasting to me.”

Paul A. Offit, who is director of the Vaccine Education Center at Children's Hospital of Philadelphia, a professor of vaccinology at the University of Pennsylvania and a member of the FDA's vaccine advisory council, said of Trump: "He's a salesman, but this is something he can't sell. So he just gave up. He gave up on trying to sell people something that was unsellable."

On Friday morning, in a tableau orchestrated to provide hope to a beleaguered nation, Pence and second lady Karen Pence received the Pfizer vaccine — a needle in his left shoulder as they sat beneath a sign that read, "SAFE and EFFECTIVE," broadcast live on national television.

Trump was nowhere to be seen.

'It was whack-a-mole'

Tucker Carlson arrived at Trump's private Mar-a-Lago Club the first Saturday in March, before cities started shutting down, on an urgent mission: to convey to the president the seriousness of the coronavirus threat.

Carlson's message was simple but pointed. He warned the president that the virus was real, that people he knew were going to get it, that the country might have already missed the point at which they could control it and, as he later told Vanity Fair, that "this could be really bad."

But Carlson and the president ultimately talked past one another, said a person familiar with the conversation. Carlson told Trump he could lose the election because of the virus, and Trump argued that the virus was less deadly than people were claiming.

The scene at Mar-a-Lago that weekend underscored the concerns. Far from taking any precautions, Trump that Saturday dined with Brazilian President Jair Bolsonaro and his delegation — several of whom later tested positive for the virus — while Donald Trump Jr.'s girlfriend, Kimberly Guilfoyle, threw herself a lavish 51st birthday party at the club. The next day, Trump hosted a fundraising brunch with about 900 attendees.

As the country began to shut down in March, Trump and his administration found themselves in the early throes of denial and dysfunction. Despite the warnings of Carlson and others, Trump continued to downplay the severity of the virus, and turf wars and unclear chains of command roiled the administration's fledgling response.

Public health advisers and other administration officials were left scrambling — scattershot, and with little clear direction — to recoup time squandered.

Jared Kushner, the president's son-in-law and senior adviser who had spent the early days of 2020 focused on other challenges in his overly large portfolio — including a Middle East peace plan and overseeing Trump's reelection campaign — turned his attention to the virus.

Kushner's allies and even some of his critics say he was effective in helping cut through bureaucracy — ensuring, for instance, that states eventually had as many ventilators as they needed. A text or call to Kushner could yield a clear response or directive in just minutes, said one senior administration official, and shortly after Pence was appointed head of the coronavirus task force his chief of staff, Marc Short, enlisted Kushner's help to streamline resources and speed up response times.

But the help Kushner provided was often ad hoc rather than part of a long-term strategy, according to people familiar with his role.

"It was entirely tactical troubleshooting and, to be fair, it was pretty successful, with the ventilators and this and that, but it was whack-a-mole," said an outside Republican in frequent touch with the White House.

Part of Kushner's coronavirus management approach was an ambitious effort to bring in a cadre of young consultants from the private sector as volunteers. The group was dismissively referred to as the "Slim Suit" crowd.

"[Kushner] is like, 'I'm going to bring in my data and we're going to MBA this to death and make it work,' " one senior administration official said.

But problems quickly emerged with Kushner's team of volunteers. The group was not issued government laptops or emails, forcing them to use their personal Gmail addresses — a practice that often hindered their efforts to procure personal protective equipment from companies that were understandably skeptical of inquiries coming from nongovernment email accounts. The volunteers in charge of PPE procurement also did not know the Food and Drug Administration requirements for importing the protective equipment, and found themselves spending unnecessary time Googling basic questions and calling the FDA for guidance.

Max Kennedy Jr., a senior associate at a private growth equity firm when he joined Kushner's effort as a volunteer, was so alarmed by what he witnessed that he initially filed an anonymous whistleblower report.

Among his complaints was a culture that prioritized tips and leads from VIPs, which consumed an inordinate amount of the volunteers' time and energy. Kennedy wrote in his report that Jeanine Pirro, a Trump booster who hosts a Fox News show, "repeatedly called and emailed until 100,000 masks were sent to a particular hospital she favored. No checks were completed to ensure that the hospital was in particular need of PPE."

Kennedy, a lifelong Democrat and a grandson of Robert F. Kennedy, later revealed his identity and, in an interview with The Washington Post, described a group of smart and earnest volunteers who were, at best, out of their depth and, at worst, asked to do things they felt uncomfortable doing.

Kennedy said that Brad Smith, the director of the Center for Medicare and Medicaid Innovation and a friend of Kushner, asked him and another volunteer to make a

coronavirus model for 2020 that specifically projected a low casualty count. When Kennedy noted that he had no training in epidemiology and had never modeled a virus before, he recalled, Smith told him that it was just like making a financial model. The other models made by the health experts, Smith explained, were "too catastrophic."

"'They think 250,000 people could die and I want this model to show that fewer than 100,000 people will die in the worst-case scenario,' " Kennedy said Smith told him. "He gave us the numbers he wanted it to say."

Kennedy and the other volunteer refused to make the model. But he said the incident left him discomfited.

"[Smith] said, 'Look around. Does it look like 250,000 people are going to die? I don't think so,' " Kennedy recounted. "And I remember thinking it was a weird thing to say because we were surrounded by military officers in the [Federal Emergency Management Agency] basement and it did look like a lot of people might die."

In an emailed statement, Smith denied asking Kennedy and a fellow volunteer to create a low fatality model.

"The only model I asked the team to build in the three weeks Max volunteered was a model to project PPE needs through July 2020," Smith said. "To calculate PPE needs, the model used hospitalizations and deaths as inputs. The mean version of the model assumed 169,000 deaths by July 2020 and the worst case version of the model assumed 312,000 deaths by July 2020. According to the CDC, there were approximately 160,000 deaths as of July 30, so the model's assumptions proved to be very accurate."

There were other problems too. Kushner's initiative to stand up drive-through testing sites nationwide at retail stores such as CVS, Target and Walgreens, for instance, may have been a good idea in theory but almost instantly raised concerns. Government officials asked Kushner and his team whether they had fully considered the logistical and supply issues behind setting up the sites — including swabs and reagents for tests, and protective equipment for the clinicians administering them.

Kushner's team responded that they had it covered, but it quickly became clear they did not. At a time when health-care workers were using garbage bags as gowns and reusing N95 masks because of severe shortages, roughly 30 percent of "key supplies," including masks, in the national stockpile of emergency medical equipment went toward Kushner's testing effort, according to an internal March planning document obtained by The Post and confirmed by one current and one former administration official.

Though Kushner had initially promised thousands of testing sites, only 78 materialized, the document said, and the national stockpile was used to supply more than half of those.

"The knock against Jared has always been that he's a dilettante who will dabble in this and dabble in that without doing the homework or really engaging in a long-term,

sustained, committed way, but will be there to claim credit if things go well and disappear if things go poorly," a former senior administration official said. "And this is another example of that."

By the summer, Trump had grown angry with Kushner over problems with testing, said current and former administration officials — a rare conflict between the president and his son-in-law.

Matthews defended Kushner's testing initiative, saying there are now more than 6,000 retail testing sites and that the federal government has established more than 500 temporary surge testing sites in 17 states over the past 10 months.

At the beginning of the outbreak, the United States failed to deploy a coronavirus diagnostic test across the country so state and local officials could quickly detect and trace confirmed cases. And while the administration eventually scaled up testing considerably — more than 1.5 million tests a day are now being conducted — it still has not developed a national testing strategy. Even as more tests have become available, experts said, there have rarely been enough for the scale of the pandemic.

"Compared to other countries, the biggest mistake we made was in testing," said Katrina Armstrong, a physician and chief of Massachusetts General Hospital who has been treating coronavirus patients. "It's not even a hard test, and we whiffed it. There should be central leadership bringing everything together. For the clinical side, not having access to testing early on and through the summer was the biggest tragedy of what got us here."

The best chance to control an outbreak is at the very beginning. But U.S. officials squandered that opportunity in February for two key reasons. The first was the CDC's failure to deploy a working coronavirus test, and the second was the task force's almost singular focus on repatriating Americans from China and cruise ships, rather than on preparing the United States for an inevitable outbreak.

A review of task force agendas from that time demonstrates a disproportionate focus on cruise ships, masks and other bureaucratic and logistical issues, rather than on more practical public health steps such as testing, contact tracing and targeted efforts to prevent the virus's spread. That allowed the virus to spread undetected for all of February, several officials and experts said, as it seeded itself in New York, Washington state, California, New Orleans and other populous areas. And from then on, the country was perpetually behind the virus.

Kennedy said his experience volunteering in the White House left him disillusioned.

"I don't think this has to be a politicized crisis," Kennedy said. "This pandemic is incredibly tragic and, as someone who was in the room, it was very clear it wasn't taken seriously. It was well understood what measures could be taken to save lives, to reduce the severity of the pandemic, and the administration and Jared Kushner made an active choice not to pursue those actions."

‘A loser message’

As the virus began to rage across the United States, some of the nation’s health officials had a novel idea. Face coverings were emerging as one of the simplest tools available to control the contagion’s spread. So Robert Kadlec, the assistant secretary for preparedness and response at the Department of Health and Human Services, called Jerry Cook, an executive at the cotton clothing giant Hanes, on March 13 to discuss producing enough masks to send to every American household, according to two senior administration officials.

Cook pulled together a number of underwear makers, including Fruit of the Loom, SanMar, Beverly Knits and Delta Apparel, to figure out how to redirect their manufacturing operations to manufacture 650 million three-ply cotton masks — enough to send a packet of five to each household. The masks would bear an HHS logo, contain a microbiocide that would kill the virus, and say: “Do your part, help stop the spread.”

A command group at FEMA unanimously approved the plan, and the task force doctors did as well. Birx, the White House coronavirus response coordinator, saw the white prototypes and asked if they could be made in a neutral tone.

But when Kadlec’s boss, HHS Secretary Alex Azar, began to pitch it at a White House task force meeting in March, there was sharp dissent. Several on the task force generally did not have much confidence in Kadlec, and a senior administration official said his plan was half-baked and that he was unable to answer basic questions, like how much the effort would cost or how they would deliver all the masks.

Short abruptly stopped the conversation and told Pence the idea wasn’t ready and was being pulled off the agenda. Other officials complained that the masks looked like underwear, according to three current and former senior administration officials. Peter T. Gaynor, the FEMA administrator, compared them to jockstraps.

Then there was the issue of logistics. For months leading up to the pandemic, Trump had been attacking the U.S. Postal Service and airing grievances over its business relationship with Amazon. Some aides surmised that, for Trump, a private-public partnership involving the Postal Service as the distributor would be a nonstarter.

The mail-a-mask plan was killed. The Office of Management and Budget tried to cancel the contracts with the underwear makers, but the masks still were produced and distributed to health clinics, religious groups and states that requested them. Hanes did not respond to a request for comment.

Kadlec was so frustrated that he decided his time as preparedness and response chief was no longer best spent on preparing and responding, so he focused instead on vaccines and therapeutics.

Skepticism of masks became a hallmark of the Trump administration’s pandemic response. On April 3, when the CDC recommended that all Americans wear masks,

Trump announced that he would not do so because he could not envision himself sitting behind the Resolute Desk with his face covered as he greeted visiting dignitaries. The president stressed that mask-wearing was "voluntary," effectively permitting his legions of followers to disregard the CDC's recommendation.

In the months that followed, Trump was only seen wearing a mask on rare occasions, instead following the advice of Stephen Miller, Johnny McEntee, Derek Lyons and other trusted aides to think of masks as a cultural wedge issue.

Pence covered his face with somewhat more regularity than the president, but after forgoing a mask during an April 28 visit to the Mayo Clinic in Minnesota, he drew a public rebuke from the hospital's leaders. Short then yelled at a hospital official over it, a person with knowledge of the visit said.

"What the Trump administration has managed to do is they accomplished — remarkably — a very high-tech solution, which is developing a vaccine, but they completely failed at the low-tech solution, which is masking and social distancing, and they put people at risk," Offit said.

Trump did not imagine the coronavirus would consume the fourth year of his presidency. When he established a task force in January, he assumed it would not last long and that the crisis would subside relatively quickly, according to two officials with knowledge of the situation. These officials said the president selected Pence, the favorite of then-acting White House chief of staff Mick Mulvaney, for chair of the task force over Gottlieb and former New Jersey governor Chris Christie.

In retrospect, according to a senior administration official, Trump's biggest political miscalculation was basing the task force in the White House. "Once you put it in the Situation Room, the president owns every failure, leak, whatever, whereas this could have been an Azar, Redfield, Hahn problem," this official said.

In the early weeks, Pence was the frontman at daily coronavirus news conferences. He provided top-line updates, including case and death counts, before turning it over to Fauci, Birx and other health professionals. Short advised the vice president against detailing such dire statistics, but Pence insisted, believing he was obligated to share such facts with the public, according to another official with knowledge of these discussions.

Over time, however, Trump decided he wanted to be the face of the government's response, so he took over Pence's role at the briefings. A number of Republican senators privately counseled the president to let the doctors be out front, according to a senior Republican congressional official, but "Trump just couldn't let someone else get all that attention."

Trump's performances were riddled with misinformation, contradictions and indecorous boasts, while also predicting miracles and promoting cure-all therapeutics. Trump often said he was trying to be a "cheerleader" for the country, and a senior

administration official explained that the president has said he drew lessons from Norman Vincent Peale's "The Power of Positive Thinking."

"What he's saying there is, 'I'm going to will the economy to success through mass psychology. We're going to tell the country things are going great and it's going to be a self-fulfilling prophecy,' " this official said of Trump.

But there were consequences for Trump's often too-rosy takes. Hogan — who as chairman of the National Governors Association helped lead regular meetings among governors and task force members, sometimes including Trump — said there was "a huge disconnect" between what was agreed to by Pence and members of the task force and what the president told the public.

"We would have a great meeting that might have lasted an hour or two with all the top folks focused on the virus, and then the president would have one of those rambling press conferences that went on maybe an hour too long and he said the opposite of what others in the administration told us that day," Hogan recalled.

The Maryland governor, one of the rare Republicans who seemed unafraid to challenge Trump, said he directly confronted the president in some of these sessions about what was not working.

"I pushed back very hard when there was no testing program and there was no availability of basic supplies, like swabs and tubes and testing agents and ventilators," Hogan said. "There were a few times the president bristled when I wasn't saying everything was great. . . . One time the president said on a call, 'You're not being very nice to me.' I said, 'No, Mr. President, I'm always nice. I'm just telling you what the governors see.' "

The White House also made governors' jobs more difficult by interfering at the CDC, which was forced to water down reopening guidelines for businesses, schools, restaurants and other facilities after a cadre of White House and administration officials weighed in with suggestions that were not based on science.

By late spring — after he infamously suggested people ingest bleach to cure themselves of the virus — Trump stopped appearing at coronavirus briefings. Meadows is among those credited with pulling the plug.

"He felt it was a loser message," said one senior administration official with knowledge of Meadows's thinking. "So why message on covid?"

'A MAGA perspective'

Scott Atlas found himself in Trump's orbit the way so many do: through the television screen.

A neuroradiologist with no infectious-disease or public health background, Atlas joined the coronavirus response team in August as a special government employee, after a few senior Trump advisers — Kushner, McEntee and Hope Hicks — were impressed by his appearances on cable news.

Atlas began working out of Kushner's office suite, and quickly scored a blue badge — the most coveted level of White House access — and a spot on the coronavirus task force. Though many were skeptical of him, the vice president's team felt that if Atlas was going to be part of the virus response, then he needed to be a full-fledged member of the effort, said two people familiar with the decision.

Atlas pushed a controversial "herd immunity" strategy — of letting the virus spread freely among the young and healthy — and clashed with others on the task force, many of whom described him as combative and condescending. He lorded his seemingly unfettered access to the president over the group and, as one senior adviser said, "The science just got totally perverted with Scott in the room."

Atlas, who resigned Nov. 30, defended his advice to Trump as "based on the best available science and data at the time" and said he sought to reduce both the virus spread and what he called "structural harms." In a lengthy emailed statement, Atlas denied much of The Post's reporting about his work in the administration, including that he had described those with the coronavirus in derisive or demeaning terms.

"I am very disappointed to see more totally false statements and patently absurd lies about me," Atlas said. "Although I don't intend to weigh-in on every false and defamatory story or allow myself to be endlessly used as a political piñata, I firmly deny the false accusations that, as a special advisor to the President, I advocated for 'herd immunity' via letting the infection spread as a scientific approach to the pandemic. Nothing could be further from the truth."

Even those inclined to be sympathetic to Atlas's coronavirus theory — that the virus mainly affected the most vulnerable, who were the only ones who truly needed protection — found his personal manner off-putting, said one senior administration official. And privately, Atlas often argued his case more crudely, bluntly saying coronavirus was a disease that only affected the overweight, the diabetic and the elderly, the other adviser said.

But Trump liked Atlas — and the shoddy science he was peddling seemingly bolstered the president's optimism. Atlas's appeal to Trump, this adviser explained, was that he "had a doctor title but a MAGA perspective," referring to Trump's "Make America Great Again" slogan.

Atlas's presence, however, frustrated much of the rest of the group, especially the public health experts who feared he was undermining their hard-fought efforts to keep the public safe.

“If you ever wanted to spread confusion and give license to the people in the cities and states who did not want to abide by any of the public health measures, you gave them license to do it,” Fauci said. “They could say, ‘Look, this guy who’s a well-respected Stanford person who the president seems to like is saying this thing; why should we listen to Fauci?’ I think he was disruptive to what Birx and I were trying to do.”

The addition of Atlas to the coronavirus task force was just the latest iteration of the infighting that had plagued the virus response all along. He clashed with the other doctors, but especially with Birx.

One early dispute was over testing. At the time, the president was pushing to move away from the widespread testing recommended by health experts and toward more narrow surveillance testing in vulnerable communities. Atlas and Birx fought over the issue in the Oval Office, with Birx — who was backed up by Redfield — advising that widespread testing was the best way to catch new cases, a senior administration official said.

In August, the CDC put out revised testing guidelines that were more in line with Atlas’s view than Birx’s, only to walk them back after a public outcry.

During another task force meeting, Atlas argued that it would be reasonable to consider substantially fewer mitigation efforts, allowing people to become infected. Instead, Atlas said, officials should focus their efforts on protecting those in nursing homes. Birx retorted that the vulnerable were not only in nursing homes, prompting agreement by other doctors in the group.

“Dr. Scott Atlas has caused people to lose their lives because he stood at the White House podium and told people masks may not work and he told people we should get over it and build up herd immunity,” said McGowan, the former CDC chief of staff. “He’s telling the world lies from a bully pulpit, from a position of power, and I believe people died because of that.”

Some of Trump’s advisers tried to convey to the president how much his reelection might hinge on the pandemic. Being seen as a responsible, empathetic leader in a moment of crisis, they explained, would buoy his chances of victory.

For instance, internal campaign data from pollster Tony Fabrizio found that in July, just 40 percent of voters approved of Trump’s handling of the virus and 58 percent disapproved, a deficit of 18 percentage points. Among independents, the gap grew to 30 percentage points, according to a senior campaign adviser.

According to an internal polling memo obtained by The Post, more than 70 percent of voters in target states supported “mandatory masks at least indoors when in public, and even a majority of Republicans support this.”

Though Republicans were not keen on the idea of an executive order for mask-wearing, they were less opposed to an order that applied only indoors, the internal polling found. And, as one of the slides reviewed by The Post read, “Voters favor mask-wearing while

keeping the economy open," and also favor Trump "issuing an executive order mandating the use of masks in public places."

Given those findings, Fabrizio, Kushner, then-campaign manager Brad Parscale and others urged Trump to model good behavior by wearing a mask, and to encourage his supporters to do so as well, several Trump advisers said. But the president was unreceptive, as was Meadows.

"He was of the opinion that it would hurt his base," the senior campaign adviser said. "He listened and it just didn't move him. The argument just didn't move him."

The president and some on his team were also increasingly frustrated with Fauci, who frequently appeared in the media offering what they viewed as an overly alarmist public health message. "Fauci was probably Joe Biden's most effective campaign surrogate on the trail in 2020," said Jason Miller, a senior campaign adviser.

Trump aides added that there also was little pushback to the idea of Trump resuming large rallies — without social distancing or mask requirements. The few advisers who did counsel caution were largely ignored, with allies arguing that rallies were key to the president's brand and that the raucous events also helped improve his mood.

"My attitude was, how are voters going to take us seriously that we're taking this seriously if we're doing things where the perception is we're putting people at risk?" the senior adviser said. "It surely undermines."

'We're in trouble'

As summer turned to fall, Birx — whose calming guidance and elegant scarves had inspired online memes — found herself silenced and increasingly minimized in the coronavirus response.

Atlas succeeded in sidelining her from Trump's immediate orbit. Her national television appearances all but vanished. She traveled to dozens of states and had unfiltered conversations with governors and local officials, but was denied the time she wanted with the president to keep him abreast of the facts. And her warnings fell on deaf ears inside the West Wing.

"She would circulate her daily report, and more often than not, there would be no responses from anyone on the email," a senior administration official recalled. "I remember there were times where she would flag something massive, like, we are within weeks of a massive remdesivir shortage, and no one would reply."

Birx met either in person or virtually with Fauci and other doctors on the task force at least once a week to discuss the science and support each other as they were being ignored at the White House. They plotted alternative ways to get their messages to the public, including through Birx's travels to states.

But Birx was undermined there, too. After she advised Florida's political leaders in August to close bars and restrict indoor dining, Atlas visited the state and contradicted her. Atlas told Gov. Ron DeSantis (R) and other local leaders to focus less on widespread testing and instead to direct their efforts to opening the economy back up and opening schools, according to two senior administration officials.

As it became clear the pandemic was worsening and the country was headed for a disastrous winter, Atlas dismissed Birx's projections in task force meetings and in private discussions with Trump and Pence. This pushed Birx to be more outspoken, especially in the reports she and her small team put together, some of which took on a grim tone, officials said.

"It was almost like she wanted to make sure she had a paper trail saying, 'I, too, think we're in trouble,' " another senior administration official said. "It was a combination of events that pushed her to change her tune and be much more realistic about the seriousness of what was going on."

The rise in cases and deaths in November coincided with a drop in visibility from Trump and Pence. Following the Nov. 3 election, the two went many days without public appearances. Whenever the president did speak or weigh in on Twitter, it was usually about his desire to overturn the election results, not about the worsening pandemic.

As for Pence, one consistent criticism was his reluctance to deliver tough news and dire coronavirus statistics to the president. As one former senior administration official put it, "He knows, like everybody else knows, that covid is the last thing Trump wants to hear about or see anybody making news about. If not touting Operation Warp Speed, it's the topic that shall not be spoken of." A senior administration official and Pence ally, however, said Pence always shared the daily reality with Trump but, as a perpetual optimist, often did so with a positive spin.

The president and vice president did make a couple of appearances to tout vaccine breakthroughs. But much to the frustration of health officials, they did little to leverage their influence with the 74 million Americans who had just voted for them to persuade people to make sacrifices to stop the spread.

"There are tens of millions of people who fundamentally don't have the same perception of reality when it comes to the virus," Frieden said. "There are always going to be people who are suspicious and paranoid and believe in UFOs or whatever, but because we're not on the same page on covid, it's very hard to get people to act together."

The week before Thanksgiving, health officials fanned out to plead with Americans not to travel over the holiday. Fauci practically begged people in an appearance on ABC's "Good Morning America" to stay home and not interact with people outside their immediate household.

But even America's most famous doctor, one with an approval rating well north of Trump's, was unconvincing to many. More than 3 million people were screened at U.S.

airports in a three-day period just before Thanksgiving, according to the Transportation Security Administration. AAA projected that an additional 48 million people would travel by car around the holiday.

That nonchalance about spreading the virus carried this month into the White House, where Trump and first lady Melania Trump hosted a traditional series of elaborate holiday parties.

Night after night, the Trumps had party guests congregate inside the White House residence to mix, mingle and hear the president speak — each clinking of champagne flutes a potential superspreader moment.

“Here, you have Fauci and Birx saying: wear a mask, keep your distance, avoid congregate settings and indoor crowds, particularly indoors,” a senior administration official said. “And then you have these events at the White House where nobody is wearing a mask, they’re having an event inside and then coming outside, if there ever was a complete confusion of messages.”

Pence and second lady Karen Pence also hosted holiday parties at the Naval Observatory, where pictures from one such event earlier this month showed hundreds of guests mingling mostly maskless underneath an enclosed tent. Even Pence himself, the head of the coronavirus task force, did not wear a mask.

Members of military bands, servers and others were forced to work and exposed for hours to guests who were not wearing masks, officials said.

At least one worker who got infected never heard from anyone in the White House about the illness. They were replaced for the next party.

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https://www.washingtonpost.com/graphics/2020/politics/trump-covid-pandemic-dark-winter/

The Washington Post
Democracy Dies in Darkness

ECONOMIC POLICY

GOP opposition leaves covid aid in peril as White House warns of surge

Billions of dollars remain stalled as the Biden administration warns it needs more money for tests, therapeutics and vaccines

By Tony Romm

May 11, 2022 at 9:14 a.m. EDT

A bipartisan push in Congress to adopt another round of coronavirus aid is in fresh political peril, as Republicans continue to block Democrats from swiftly approving as much as the Biden administration believes is necessary to prepare for an expected new surge.

Five days after federal health officials warned a new wave could infect 100 million people, lawmakers still find themselves struggling to overcome familiar partisan divides. There appears to be no immediate pathway in the Senate for a long-stalled agreement to spend $10 billion to boost the availability of tests, therapeutics and vaccines nationwide.

For weeks, the White House has sounded urgent alarms about the need for more aid, arguing it has already committed most of its existing public health dollars to specific uses. Some key federal initiatives even have run out of cash, leading the administration to slow purchases of critical supplies while shuttering a program that had provided free testing to uninsured Americans.

But those dire pleas have failed to resolve the logjam, as Republicans have held up the covid aid package as part of an unrelated immigration dispute. GOP lawmakers again this week have insisted they will not allow the Senate to proceed unless Democrats first permit a vote on amendments, especially a proposal to preserve restrictions on migrants crossing the U.S.-Mexican border.

"It's very simple: If the White House goes to [Majority Leader Charles E. Schumer] and says, 'We'd like to get a vote on this, let the Republicans and Democrats each have amendments,' it'll be voted on and passed," said Sen. Mitt Romney (R-Utah), the chief GOP negotiator for the $10 billion bipartisan deal. "It's being held up for political purposes only."

Some Democrats had hoped to dodge the stalemate by linking the covid aid to a fast-moving measure to provide roughly $40 billion in new assistance to Ukraine. But the White House asked Congress to separate the two issues on Monday, and Senate Minority Leader Mitch McConnell (R-Ky.) said a day later that he had urged President Biden to split them apart so the covid standoff did not delay the humanitarian support. The House passed the Ukraine aid bill on Tuesday evening.

The chain of events left Democrats scrambling to devise a new approach for the covid funding and bolster preparations for the virus — more than two years into the pandemic that has vexed policymakers at every turn.

"We are looking for every way to get a vote on it," said Sen. Chris Van Hollen (D-Md.), a top lawmaker on the Senate Appropriations Committee. "This is an urgent matter."

The clock is ticking in the eyes of the Biden administration. The president's top advisers on pandemic response delivered their latest sobering assessment Friday: They projected the United States is likely to see another significant uptick in infections and deaths, cresting perhaps in the fall and winter, from a newer, faster-spreading version of the omicron variant that's already circulating domestically.

In doing so, the administration also reaffirmed Tuesday that it is running out of funds to respond effectively in the event of a rapid decline. White House press secretary Jen Psaki outlined the potential doomsday scenarios to reporters at her daily briefing: The United States may struggle to maintain its supply of tests, for example, or "lose out to other countries on promising new treatments," she said.

"We don't want to sugarcoat it: We need more money. We don't have a Plan B here," she said.

The administration initially sought more than twice as much money, requesting $22.5 billion in March to restock dwindling federal supplies, though top officials noted at the time they were likely to need even more than that in the months to come. But Republicans questioned the need for more spending, arguing Congress had already adopted about $6 trillion in response to the pandemic.

The GOP first whittled down the amount, then insisted that any new coronavirus funding must be fully paid for, a rarity for emergency spending measures. Democrats couldn't come up with a deal that worked for both sides, and an effort to pass $16 billion in new aid collapsed in March.

Working with Romney, Senate Democrats then agreed on $10 billion that would largely be redirected from existing coronavirus aid programs. But even that scaled-back approach met Republican objections, as GOP lawmakers set their sights on trying force a vote on immigration policy. They targeted Biden's decision to resume allowing migrants from Mexico to seek asylum, which former president Donald Trump had barred in the name of public health. The GOP push scuttled any hopes of resolving the dispute by early April. Adding to the headaches, some Senate Democrats — including those who are vulnerable in this year's elections — seemed inclined to join with Republicans in a vote that might have delivered a public rebuke to Biden.

After agreeing to split the coronavirus aid from the Ukraine assistance, Democrats found themselves struggling again to overcome GOP objections. Schumer and his allies cannot act in the narrowly divided Senate without the help of Republicans, some of whom on Tuesday questioned if another burst of covid cash is even necessary.

"If you're going to do anything, you're going to need to find it ... in money we've already appropriated for it," said Sen. Mike Braun (R-Ind.), explaining that Republicans' approach stems in part from a belief the virus has become "endemic and manageable."

The work is set to start in the House, where Rep. Rosa L. DeLauro (D-Conn.), the leader of the Appropriations Committee, is readying a new aid package — one that might add money and scope to the Senate's initial $10 billion bipartisan plan. Democrats have weighed whether it is possible to tack on aid that would help distribute vaccines to nations in need, according to a person familiar with the matter, who requested anonymity to describe private talks.

Lawmakers in both parties have previously supported such spending, which can help prevent the incubation of new variants, and the Biden administration tried to fund the idea in its initial March request. Speaking to reporters late Tuesday, House Speaker Nancy Pelosi (D-Calif.) signaled it remains a top issue for her caucus. "We're overdue on passing the covid relief, and that is of the highest priority for us, at home and again globally as well ," she said.

But the House push could add to its overall cost, potentially upsetting the delicate if imperiled deal in the Senate. Some Democrats in the chamber, meanwhile, acknowledged that $10 billion is probably insufficient in the first place.

"We're open to expand it," Senate Majority Whip Richard J. Durbin (D-Ill.) told reporters.

But Democrats face an uphill battle in selling an even larger aid package to skeptical fiscal hawks in the Republican Party. Asked about the discussions to expand the price tag beyond $10 billion, Romney said Tuesday: "Nope, we've got a deal at ten, let's get it done."

Other Republicans said they wouldn't back down on immigration. Speaking to reporters at his weekly news conference, McConnell pointed to the "bipartisan demand" for the Senate to reinstate the border restrictions, adding about the coronavirus aid package: "That's the context in which that vote ought to occur."

Schumer, however, has declined to commit to a vote on a such an amendment. At his own news conference this week, the Democratic leader maintained the Senate would wait to see what the House could pass once they dispatched with Ukraine aid.

Schumer then pointed a finger at his GOP foes, blasting them for months of obstruction. “The bottom line is very simple,” he said. “Our Republican friends should not be blocking covid legislation.”

A federal court could decide imminently on a challenge to Biden’s rollback of the rules, known as Title 42. Privately, many Democrats grouse that Republicans are likely to raise additional objections, slowing down needed coronavirus aid. And that is to say nothing of the complicated politics of immigration, as GOP leaders look to seize on the stalled aid package in election year — hoping to force Democrats to cast a vote on a sensitive political issue in blatant defiance of the president.

“I sympathize with them,” Durbin said, expressing some anxiety that the debate might come down to the border issue. “Schumer has tried to get us into a circumstance where [the vote doesn’t happen]. There’s some things he just can’t achieve.”

The New York Times | https://www.nytimes.com/2020/12/31/us/politics/trump-coronavirus.html

Trump's Focus as the Pandemic Raged: What Would It Mean for Him?

President Trump missed his chance to show that he could rise to the moment in the final chapter of his presidency and meet the defining challenge of his tenure.

By Michael D. Shear, Maggie Haberman, Noah Weiland, Sharon LaFraniere and Mark Mazzetti

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WASHINGTON — It was a warm summer Wednesday, Election Day was looming and President Trump was even angrier than usual at the relentless focus on the coronavirus pandemic.

"You're killing me! This whole thing is! We've got all the damn cases," Mr. Trump yelled at Jared Kushner, his son-in-law and senior adviser, during a gathering of top aides in the Oval Office on Aug. 19. "I want to do what Mexico does. They don't give you a test till you get to the emergency room and you're vomiting."

Mexico's record in fighting the virus was hardly one for the United States to emulate. But the president had long seen testing not as a vital way to track and contain the pandemic but as a mechanism for making him look bad by driving up the number of known cases.

And on that day he was especially furious after being informed by Dr. Francis S. Collins, the head of the National Institutes of Health, that it would be days before the government could give emergency approval to the use of convalescent plasma as a treatment, something Mr. Trump was eager to promote as a personal victory going into the Republican National Convention the following week.

"They're Democrats! They're against me!" he said, convinced that the government's top doctors and scientists were conspiring to undermine him. "They want to wait!"

Throughout late summer and fall, in the heat of a re-election campaign that he would go on to lose, and in the face of mounting evidence of a surge in infections and deaths far worse than in the spring, Mr. Trump's management of the crisis — unsteady, unscientific and colored by politics all year — was in effect reduced to a single question: What would it mean for him?

The result, according to interviews with more than two dozen current and former administration officials and others in contact with the White House, was a lose-lose situation. Mr. Trump not only ended up soundly defeated by Joseph R. Biden Jr., but missed his chance to show that he could rise to the moment in the final chapter of his presidency and meet the defining challenge of his tenure.

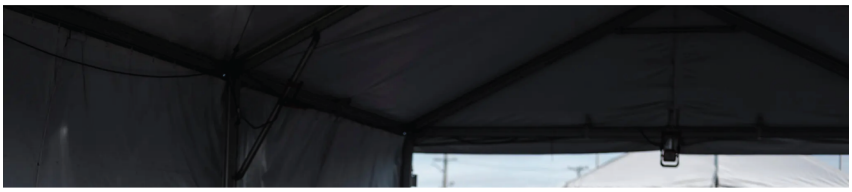
Efforts by his aides to persuade him to promote mask wearing, among the simplest and most effective ways to curb the spread of the disease, were derailed by his conviction that his political base would rebel against anything that would smack of limiting their personal freedom. Even his own campaign's polling data to the contrary could not sway him.

His explicit demand for a vaccine by Election Day — a push that came to a head in a contentious Oval Office meeting with top health aides in late September — became a misguided substitute for warning the nation that failure to adhere to social distancing and other mitigation efforts would contribute to a slow-rolling disaster this winter.

His concern? That the man he called "Sleepy Joe" Biden, who was leading him in the polls, would get credit for a vaccine, not him.

The government's public health experts were all but silenced by the arrival in August of Dr. Scott W. Atlas, the Stanford professor of neuroradiology recruited after appearances on Fox News.

With Dr. Deborah L. Birx, the coordinator of the White House virus task force, losing influence and often on the road, Dr. Atlas became the sole doctor Mr. Trump listened to. His theories, some of which scientists viewed as bordering on the crackpot, were exactly what the president wanted to hear: The virus is overblown, the number of deaths is exaggerated, testing is overrated, lockdowns do more harm than good.



The president has long seen testing not as a vital way to track and contain the pandemic but as a mechanism for making him look bad by driving up the number of known cases. William DeShazer for The New York Times

Weeks after his own recovery, he would still complain about the nation's preoccupation with the pandemic.

"All you hear is Covid, Covid, Covid, Covid, Covid, Covid, Covid, Covid, Covid, Covid, Covid," Mr. Trump said at one campaign stop, uttering the word 11 times.

In the end he could not escape it.

Supporters of Mr. Trump outside Walter Reed National Military Medical Center, where he was treated for the coronavirus, in October. He largely rejected aides' efforts to use his bout with the illness to demonstrate a new compassion. Oliver Contreras for The New York Times

'The Base Will Revolt'

By late July, new cases were at record highs, defying Mr. Trump's predictions through the spring that the virus was under control, and deaths were spiking to alarming levels. Herman Cain, a 2012 Republican presidential candidate, died from the coronavirus; the previous month he had attended a Trump rally without a mask.

With the pandemic defining the campaign despite Mr. Trump's efforts to make it about law and order, Tony Fabrizio, the president's main pollster, came to the Oval Office for a meeting in the middle of the summer prepared to make a surprising case: that mask wearing was acceptable even among Mr. Trump's supporters.

Arrayed in front of the Resolute Desk, Mr. Trump's advisers listened as Mr. Fabrizio presented the numbers. According to his research, some of which was reported by The Washington Post, voters believed the pandemic was bad and getting worse, they were more concerned about getting sick than about the virus's effects on their personal financial situation, the president's approval rating on handling the pandemic had hit new lows and a little more than half the country did not think he was taking the situation seriously.

But what set off debate that day was Mr. Fabrizio's finding that more than 70 percent of voters in the states being targeted by the campaign supported mandatory mask wearing in public, at least indoors, including a majority of Republicans.

Mr. Kushner, who along with Hope Hicks, another top adviser, had been trying for months to convince Mr. Trump that masks could be portrayed as the key to regaining freedom to go safely to a restaurant or a sporting event, called embracing mask-wearing a "no-brainer."

Mr. Kushner had some reason for optimism. Mr. Trump had agreed to wear one not long before for a visit to Walter Reed National Military Medical Center, after finding one he believed he looked good in: dark blue, with a presidential seal.

But Mark Meadows, the White House chief of staff — backed up by other aides including Stephen Miller — said the politics for Mr. Trump would be devastating.

"The base will revolt," Mr. Meadows said, adding that he was not sure Mr. Trump could legally make it happen in any case.

The president removed his mask upon arriving at the White House on Oct. 5, after being hospitalized with Covid-19. He was rarely seen wearing one again. Anna Moneymaker for The New York Times

That was all Mr. Trump needed to hear. “I’m not doing a mask mandate,” he concluded.

Aside from when he was sick, he was rarely seen in a mask again.

The president had other opportunities to show leadership rather than put his political fortunes first.

After he recovered from his bout with the virus, some of his top aides, including Mr. Kushner and Jason Miller, a senior campaign strategist, thought the illness offered an opportunity to demonstrate the kind of compassion and resolve about the pandemic’s toll that Mr. Trump had so far failed to show.

When Mr. Trump returned from the hospital, his communications aides, with the help of Ivanka Trump, his daughter, urged him to deliver a national address in which he would say: “I had it. It was tough, it kicked my ass, but we’re going to get through it.”

He refused, choosing instead to address a boisterous campaign rally for himself from the balcony of the White House overlooking the South Lawn.

Mr. Trump never came around to the idea that he had a responsibility to be a role model, much less that his leadership role might require him to publicly acknowledge hard truths about the virus — or even to stop insisting that the issue was not a rampaging pandemic but too much testing.

Alex M. Azar II, the health and human services secretary, briefed the president this fall on a Japanese study documenting the effectiveness of face masks, telling him: “We have the proof. They work.” But the president resisted, criticizing Mr. Kushner for pushing them and again blaming too much testing — an area Mr. Kushner had been helping to oversee — for his problems.

“I’m going to lose,” Mr. Trump told Mr. Kushner during debate preparations. “And it’s going to be your fault, because of the testing.”

Mr. Morgenstern, the White House spokesman, said that exchange between the president and Mr. Kushner “never happened.”

Mr. Azar, who was sometimes one of the few people wearing a mask at White House events, privately bemoaned what he called a political, anti-mask culture set by Mr. Trump. At White House Christmas parties, Mr. Azar asked maskless guests to back away from him.

Dr. Stephen M. Hahn, center, the commissioner of the Food and Drug Administration, Dr. Deborah L. Birx, the coordinator of the White House virus task force, and Alex M. Azar II, the secretary of health and human services, in the Oval Office in May. Conflicts on the president's team only intensified as the year went on. Erin Schaff/The New York Times

Divisions and Disagreements

The decision to run the government's response out of the West Wing was made in the early days of the pandemic. The idea was to break down barriers between disparate agencies, assemble public health expertise and encourage quick and coordinated decision-making.

It did not work out like that, and by fall the consequences were clear.

Mr. Trump had always tolerated if not encouraged clashes among subordinates, a tendency that in this case led only to policy paralysis, confusion about who was in charge and a lack of a clear, consistent message about how to reduce the risks from the pandemic.

Keeping decision-making power close to him was another Trump trait, but in this case it also elevated the myriad choices facing the administration to the presidential level, bogging the process down in infighting, raising the political stakes and encouraging aides to jockey for favor with Mr. Trump.

The result at times was a systemwide failure that extended well beyond the president.

"What we needed was a coordinated response that involved contributions from multiple agencies," said Dr. Scott Gottlieb, who was commissioner of the Food and Drug Administration for the first two years of the Trump administration.

"Someone needed to pull that all together early," he said. "It wasn't the job of the White House, either. This needed to happen closer to the agencies. That didn't happen on testing, or on a whole lot of other things."

The relationship between Mr. Azar and Dr. Stephen M. Hahn, the commissioner of the Food and Drug Administration, grew increasingly tense; by early November, they were communicating only by text and in meetings.

Dr. Birx had lost the clout she enjoyed early on in the crisis and spent much of the summer and fall on the road counseling governors and state health officials.

Mr. Meadows was at odds with almost everyone as he sought to impose the president's will on scientists and public health professionals. In conversations with top health officials, Mr. Meadows would rail against regulatory "bureaucrats" he thought were more interested in process than outcome.

Some of the doctors on the task force, including Dr. Anthony S. Fauci and Dr. Robert R. Redfield, were reluctant to show up in person at the White House, worried that the disdain there for mask wearing and social distancing would leave them at risk of infection.

Vice President Mike Pence was nominally in charge of the task force but was so cautious about getting crosswise with Mr. Trump as they battled for re-election that, in public at least, he became nearly invisible.

The debates inside the White House increasingly revolved around Dr. Atlas, who had no formal training in infectious diseases but whose views — which Mr. Trump saw him deliver on Fox News — appealed to the president's belief that the crisis was overblown.

Dr. Scott W. Atlas, the Stanford professor of neuroradiology recruited after appearances on Fox News, became the sole doctor Mr. Trump listened to. Anna Moneymaker for The New York Times

His arrival at 1600 Pennsylvania Avenue was itself something of a mystery. Some aides said he was discovered by Kayleigh McEnany, the White House press secretary. Others said John McEntee, the president's personnel chief, had been Googling for a Trump-friendly doctor who would be loyal.

Marc Short, Mr. Pence's chief of staff, opposed hiring Dr. Atlas. But once the president and his team brought him in, Mr. Short insisted that Dr. Atlas have a seat at the task force table, hoping to avoid having him become yet another internal — and destructive — critic.

Once inside, Dr. Atlas used the perch of a West Wing office to shape the response. During a meeting in early fall, Dr. Atlas asserted that college students were at no risk from the virus. We should let them go back to school, he said. It's not a problem.

Dr. Birx exploded. What aspect of the fact that you can be asymptomatic and still spread it do you not understand? she demanded. You might not die, but you can give it to somebody who can die from it. She was livid.

"Your strategy is literally going to cost us lives," she yelled at Dr. Atlas. She attacked Dr. Atlas's ideas in daily emails she sent to senior officials. And she was mindful of a pact she had made with Dr. Hahn, Dr. Fauci and Dr. Redfield even before Dr. Atlas came on board: They would stick together if one of them was fired for doing what they considered the right thing.

Health officials often had a hard time finding an audience in the upper reaches of the West Wing. In a mid-November task force meeting, they issued a dire warning to Mr. Meadows about the looming surge in cases set to devastate the country. Mr. Meadows demanded data to back up their claim.

One outcome of the meeting was a Nov. 19 news conference on the virus's dire threat, the first in many weeks. But while Mr. Pence, who led the briefing, often urged Americans to "do their part" to slow the spread of the virus, he never directly challenged Mr. Trump's hesitancy on masks and social distancing. At the briefing, he said that "decision making at the local level" was key, continuing a long pattern of the administration seeking to push responsibility to the states.

Mr. Azar had been cut out of key decision-making as early as February, when Mr. Pence took over the task force. Mr. Azar would complain to his associates that Mr. Pence's staff and task force members went around him to issue orders to his subordinates.

On tenterhooks about his job status, Mr. Azar found an opening that offered a kind of redemption, steering his attention through the summer and fall to Operation Warp Speed, the government's effort to support rapid development of a vaccine, lavishing praise on Mr. Trump and crediting him for nearly every advance.

Behind the scenes, Mr. Azar portrayed Dr. Hahn to the White House as a flailing manager — a complaint he also voiced about Dr. Redfield. In late September, he told the White House he was willing to fire Dr. Hahn, according to officials familiar with the offer.

For their part, Dr. Hahn, Dr. Redfield, Dr. Birx and other senior health officials saw Mr. Azar as crushing the morale of the agencies he oversaw as he sought to escape blame for a worsening crisis and to strengthen his own image publicly and with the White House.

Health officials on the task force several times took their complaints about Mr. Azar to Mr. Pence's office, hoping for an intervention.

Caitlin B. Oakley, a spokeswoman for Mr. Azar, said he had "always stood up for balanced, scientific, public health information and insisted that science and data drive the decisions."

Once eager to visit the White House, Dr. Hahn became disillusioned with what he saw as its efforts to politicize the work of the Food and Drug Administration, and he eventually shied away from task force meetings, fearing his statements there would leak.

If there was a bureaucratic winner in this West Wing cage match, it was Dr. Atlas.

He told Mr. Trump that the right way to think about the virus was how much "excess mortality" there was above what would have been expected without a pandemic.

Mr. Trump seized on the idea, often telling aides that the real number of dead was no more than 10,000 people.

As of Thursday, 342,577 Americans had died from the pandemic.

Two coronavirus vaccines arrived at sites across the country this month. Mr. Trump was furious that a successful vaccine was not announced until after the election. Bryan Anselm for The New York Times

Trump vs. Vaccine Regulators

In an Oval Office meeting with senior health officials on Sept. 24, the president made explicit what he had long implied: He wanted a vaccine before the election, according to three people who witnessed his demand.

Pfizer's chief executive had been encouraging the belief that the company could deliver initial results by late October. But Mr. Trump's aides tried in vain to make clear that they could not completely control the timing.

Dr. Fauci and Dr. Hahn reminded West Wing officials that a company's vaccine trial results were a "black box," impossible to see until an independent monitoring board revealed them. A vaccine that did not go through the usual, rigorous government approval process would be a "Pyrrhic victory," Mr. Azar told them. It would be a shot no one would take.

Dr. Moncef Slaoui, the scientific leader of Operation Warp Speed, said the president never asked him to deliver a vaccine on a specific timetable. But he said Mr. Trump sometimes complained in meetings that "it was not going to happen before the election and it will be 'Sleepy Joe'" who would ultimately get credit.

In late October, science and regulations worked against Mr. Trump's waning hopes for pre-Election Day good news. At the F.D.A., scientists had refined the standards for authorizing a vaccine for emergency use. And at Pfizer, executives realized that the agency was unlikely to authorize its vaccine on the basis of so few Covid-19 cases among its clinical trial volunteers.

They decided to wait for more data, a delay of up to a week.

When Pfizer announced on Nov. 9 — two days after Mr. Biden clinched his victory — that its vaccine was a stunning success, Mr. Trump was furious. He lashed out at the company, Dr. Hahn and the F.D.A., accusing "deep state regulators" of conspiring with Pfizer to slow approval until after the election.

The president's frustration with the pace of regulatory action would continue into December, as the F.D.A. went through a time-consuming process of evaluating Pfizer's data and then that of a second vaccine maker, Moderna.

On Dec. 11, Mr. Meadows exploded during a morning call with Dr. Hahn and Dr. Peter Marks, the agency's top vaccine regulator. He accused Dr. Hahn of mismanagement and suggested he resign, then slammed down the phone. That night, the F.D.A. authorized the Pfizer vaccine.

In the weeks that followed, Mr. Pence, Mr. Azar, Dr. Fauci and other health officials rolled up their sleeves to be vaccinated for the cameras.

Mr. Trump, who after contracting Covid-19 had declared himself immune, has not announced plans to be vaccinated.

Michael D. Shear, Noah Weiland, Sharon LaFraniere and Mark Mazzetti reported from Washington, and Maggie Haberman from New York. Katie Thomas contributed reporting from Chicago.

The New York Times | https://www.nytimes.com/2020/04/24/us/politics/trump-inject-disinfectant-bleach-coronavirus.html

Trump's Suggestion That Disinfectants Could Be Used to Treat Coronavirus Prompts Aggressive Pushback

Responding to the criticism from public health officials around the country, the president said he was playing a trick on reporters.

By Katie Rogers, Christine Hauser, Alan Yuhas and Maggie Haberman

April 24, 2020 6 MIN READ

WASHINGTON — In Maryland, so many callers flooded a health hotline with questions that the state's Emergency Management Agency had to issue a warning that "under no circumstances" should any disinfectant be taken to treat the coronavirus. In Washington State, officials urged people not to consume laundry detergent capsules. Across the country on Friday, health professionals sounded the alarm.

Injecting bleach or highly concentrated rubbing alcohol "causes massive organ damage and the blood cells in the body to basically burst," Dr. Diane P. Calello, the medical director of the New Jersey Poison Information and Education System, said in an interview. "It can definitely be a fatal event."

Even the makers of Clorox and Lysol pleaded with Americans not to inject or ingest their products.

The frantic reaction was prompted by President Trump's suggestion on Thursday at a White House briefing that an "injection inside" the human body with a disinfectant like bleach or isopropyl alcohol could help combat the virus.

"And then I see the disinfectant, where it knocks it out in a minute," Mr. Trump said after a presentation from William N. Bryan, an acting under secretary for science at the Department of Homeland Security, detailed the virus's possible susceptibility to bleach and alcohol.

"One minute," the president said. "And is there a way we can do something like that, by injection inside or almost a cleaning? Because you see it gets in the lungs and it does a tremendous number on the lungs. So it would be interesting to check that."

Dr. Deborah L. Birx, the White House's coronavirus response coordinator, was sitting to the side in the White House briefing room, blinking hard and looking at the floor as he spoke. Later, Mr. Trump asked her if she knew about "the heat and the light" as a potential cure.

"Not as a treatment," Dr. Birx said, adding, "I haven't seen heat or light —" before the president cut her off.

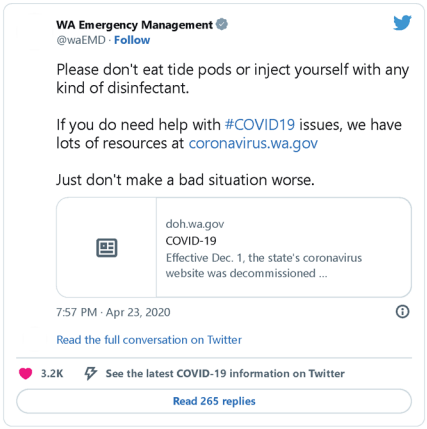
Mr. Trump's remarks caused an immediate uproar, and the White House spent much of Friday trying to walk them back. Also Friday, the Food and Drug Administration warned that hydroxychloroquine and chloroquine, two drugs that the president has repeatedly recommended in treating the coronavirus, can cause dangerous abnormalities in heart rhythm in coronavirus patients and has resulted in some deaths.

The F.D.A. said the drugs should be used only in clinical trials or hospitals where patients can be closely monitored for heart problems.

"Leave it to the media to irresponsibly take President Trump out of context and run with negative headlines," Kayleigh McEnany, the new White House press secretary, said in a statement criticizing the coverage of Thursday night's briefing.

But the president later undermined her argument by insisting that his question to Mr. Bryan in fact had been an elaborate prank that he had engineered to trick reporters.

"I was asking a question sarcastically to reporters like you just to see what would happen," Mr. Trump said on Friday to journalists gathered in the Oval Office. The president said he had posed his theory on cleaning the body with disinfectant "in the form of a sarcastic question to a reporter," which also was not true — he had said it unprompted to Mr. Bryan.



With more questions likely at the Friday briefing, Vice President Mike Pence, the head of the White House coronavirus task force, abruptly ended it shortly after it began.

Several White House officials said they shared the view that Mr. Trump had been taken out of context, even as they acknowledged that his comments were problematic. They noted that the president had later directed the same comments to Dr. Birx, and suggested them as a course of study, as opposed to a recommendation of a course of action for the American public.

But they acknowledged that Mr. Trump's delivery was too sloppy for a president in the middle of managing the response to a pandemic that has killed over 45,000 Americans. Some said it was one of the worst days in one of the worst weeks of his presidency.

Others inside the administration raised questions about why Mr. Bryan, whose background is not in health or science, had been invited to deliver a presentation. Mr. Bryan, whose expertise is in energy infrastructure and security, is serving in an acting capacity as the head of the department's science and technology directorate.

Mr. Bryan served 17 years in the Army, followed by yearslong stints as a civil servant at the Defense and Energy Departments. The latter role led to a whistle-blower complaint accusing him, in part, of manipulating government policy to further his personal financial interests, and then lying to Congress about those interests.

The United States Office of Special Counsel, a federal agency that investigates whistle-blower complaints, asked the Energy Department last year to investigate the accusations against Mr. Bryan. In January, the Senate returned his nomination to the White House.

Mr. Bryan was invited by the vice president's office to coronavirus task force meetings on Wednesday and Thursday to talk about a study that his department had done relating to heat and the conditions in which the coronavirus can thrive or be dampened. On Thursday, Mr. Bryan presented a graphic to the room, according to four people briefed on the events.

Mr. Pence's advisers wanted Mr. Bryan to brief the news media on his findings, but several West Wing staff members objected, partly because they were concerned the information had not been verified.

Before Mr. Bryan took the lectern in the White House Briefing Room, Dr. Birx and Dr. Anthony S. Fauci, a member of the coronavirus task force, made a few revisions to his presentation, officials said.

As he listened to Mr. Bryan, the president became increasingly excited, and also felt the need to demonstrate his own understanding of science, according to three of the advisers. So Mr. Trump went ahead with his theories about the chemicals.

Later in the briefing, Phil Rucker, a reporter for The Washington Post, asked the president why he had had that discussion because "people tuning into these briefings, they want to get information and guidance and want to know what to do — they're not looking for a rumor."

"Hey, Phil," he responded. "I'm the president, and you're fake news."

The backlash was swift. A host of corporations, doctors and government officials quickly stepped forward to issue an identical warning: Cleaning products are extremely dangerous to ingest — potentially deadly — and no one should do so.

Speaker Nancy Pelosi ridiculed Mr. Trump's comments as she criticized his priorities for coronavirus relief. "The president is asking people to inject Lysol into their lungs," she said, calling it an indication that "Republicans reject science."

And Joseph R. Biden Jr., the presumptive Democratic presidential nominee, added his own criticism.

"I can't believe I have to say this," Mr. Biden posted on Twitter on Friday afternoon, "but please don't drink bleach."

Dr. Jerome M. Adams, the surgeon general, also issued a warning through his Twitter feed — the closest he has come so far to walking back the president's words.

"A reminder to all Americans- PLEASE always talk to your health provider first before administering any treatment/ medication to yourself or a loved one," Dr. Adams said. "Your safety is paramount, and doctors and nurses are have years of training to recommend what's safe and effective."

Mr. Trump's hopeful comments about disinfectant use coincided with an alarming rise in accidents with household cleaning products in recent weeks, according to doctors who monitor activity at poison call centers. On Monday, the Centers for Disease Control and Prevention reported a growing number of calls to poison control centers and a significant increase in accidental exposures to household cleaners and disinfectants.

The F.D.A. has moved to tamp down on merchants online that have encouraged the ingestion of products made with disinfectants and cleaning agents, including chlorine dioxide, a compound commonly used as a bleach. The products have found favor with conspiracy theorists and fringe activists online who peddle chlorine dioxide as "Magical Mineral Solution," or M.M.S.

One such activist, Mark Grenon, claimed after the president's briefing that "Trump has got the M.M.S. and all the info," according to The Guardian. Mr. Grenon did not reply to an email seeking comment, nor did the White House. On Friday, a person familiar with the situation said senior administration officials were not familiar with Mr. Grenon or his letter.

Social media platforms have also moved to filter out the circulation of junk science and bad information online, using disinfectants as a prime example. Last month, Mark Zuckerberg, the chief executive of Facebook, specifically mentioned a bleach "cure" as an example of "misinformation that has imminent risk of danger."

"Things like, 'You can cure this by drinking bleach,'" he said. "I mean, that's just in a different class."

A spokesman for Twitter said on Friday that the president's statements did "not violate our Covid-19 misinformation policy."

Katie Rogers reported from Washington, and Christine Hauser, Alan Yuhas and Maggie Haberman from New York. Kenneth P. Vogel and Zolan Kanno-Youngs contributed reporting from Washington, and Davey Alba from New York.

The New York Times https://www.nytimes.com/2020/03/19/us/politics/trump-coronavirus-outbreak.html

Before Virus Outbreak, a Cascade of Warnings Went Unheeded

Government exercises, including one last year, made clear that the U.S. was not ready for a pandemic like the coronavirus. But little was done.

By David E. Sanger, Eric Lipton, Eileen Sullivan and Michael Crowley

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10 MIN READ

WASHINGTON — The outbreak of the respiratory virus began in China and was quickly spread around the world by air travelers, who ran high fevers. In the United States, it was first detected in Chicago, and 47 days later, the World Health Organization declared a pandemic. By then it was too late: 110 million Americans were expected to become ill, leading to 7.7 million hospitalized and 586,000 dead.

That scenario, code-named "Crimson Contagion" and imagining an influenza pandemic, was simulated by the Trump administration's Department of Health and Human Services in a series of exercises that ran from last January to August.

The simulation's sobering results — contained in a draft report dated October 2019 that has not previously been reported — drove home just how underfunded, underprepared and uncoordinated the federal government would be for a life-or-death battle with a virus for which no treatment existed.

The draft report, marked "not to be disclosed," laid out in stark detail repeated cases of "confusion" in the exercise. Federal agencies jockeyed over who was in charge. State officials and hospitals struggled to figure out what kind of equipment was stockpiled or available. Cities and states went their own ways on school closings.

Many of the potentially deadly consequences of a failure to address the shortcomings are now playing out in all-too-real fashion across the country. And it was hardly the first warning for the nation's leaders. Three times over the past four years the U.S. government, across two administrations, had grappled in depth with what a pandemic would look like, identifying likely shortcomings and in some cases recommending specific action.

In 2016, the Obama administration produced a comprehensive report on the lessons learned by the government from battling Ebola. In January 2017, outgoing Obama administration officials ran an extensive exercise on responding to a pandemic for incoming senior officials of the Trump administration.

The full story of the Trump administration's response to the coronavirus is still playing out. Government officials, health professionals, journalists and historians will spend years looking back on the muddled messages and missed opportunities of the past three months, as President Trump moved from dismissing the coronavirus as a few cases that would soon be "under control" to his revisionist announcement on Monday that he had known all along that a pandemic was on the way.

But officials have declined to say why the administration was so slow to roll out broad testing or to move faster, as the simulations all indicated it should, to urge social distancing and school closings.

Asked at his news briefing on Thursday about the government's preparedness, Mr. Trump responded: "Nobody knew there would be a pandemic or epidemic of this proportion. Nobody has ever seen anything like this before."

The work done over the past five years, however, demonstrates that the government had considerable knowledge about the risks of a pandemic and accurately predicted the very types of problems Mr. Trump is now scrambling belatedly to address.

Crimson Contagion, the exercise conducted last year in Washington and 12 states including New York and Illinois, showed that federal agencies under Mr. Trump continued the Obama-era effort to think ahead about a pandemic.

But the planning and thinking happened many layers down in the bureaucracy. The knowledge and sense of urgency about the peril appear never to have gotten sufficient attention at the highest level of the executive branch or from Congress, leaving the nation with funding shortfalls, equipment shortages and disorganization within and among various branches and levels of government.

The October 2019 report in particular documents that officials at the Departments of Homeland Security and Health and Human Services, and even at the White House's National Security Council, were aware of the potential for a respiratory virus outbreak originating in China to spread quickly to the United States and overwhelm the nation.

"Nobody ever thought of numbers like this," Mr. Trump said on Wednesday, at a news conference.

In fact, they had.

From Ebola, Lessons Learned

Health workers entering a high-risk ward at an Ebola treatment center in 2014 in Monrovia, Liberia. The outbreak led the Obama administration to study U.S. preparedness for a pandemic. Daniel Berehulak for The New York Times

As early as the George W. Bush administration, homeland security and health officials focused on big gaps in the American response to a biological attacks and the growing risk of pandemics. The first test came in April 2009, just a few months after the start of President Barack Obama's first term. A 10-year-old California girl was diagnosed with a contagious disease that would be called swine flu or H1N1, the first flu pandemic in more than 40 years.

The Centers for Disease Control and Prevention estimates that ultimately there were about 60.8 million cases in the United States, along with 274,304 hospitalizations and 12,469 deaths associated with H1N1.

The virus turned out to be less deadly than first expected. But it was a warning shot that officials in the Obama administration said they took seriously, kicking off a planning effort that escalated in early 2014, with the outbreak of Ebola in West Africa and ensuing fear that it could spread to the United States.

Ebola was less contagious than the flu, but far more deadly. It killed 11,000 people in Africa. But it could have been far worse. The United States sent nearly 3,000 troops to Africa to help keep the disease from spreading. While the containment effort was considered a success, inside the White House, officials sensed that the United States had gotten lucky — and that the response had revealed gaps in preparedness.

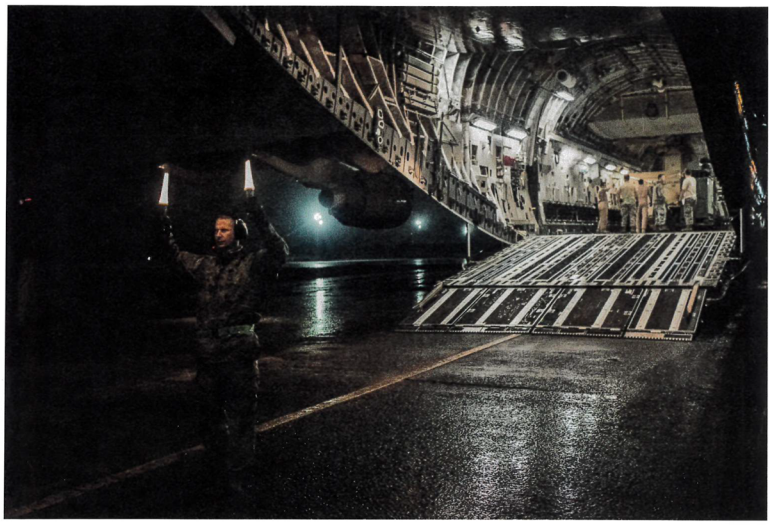
Christopher Kirchhoff, a national security aide who moved from the Pentagon to the White House to deal with the Ebola crisis, was given the job of putting together a "lessons learned" report, with input from across the government.

The weaknesses Mr. Kirchhoff identified were early warning signals of what has unfolded in the past three months.

His report concluded that the United States assumed more ability on the part of the World Health Organization than the agency actually had.

The United States had its own issues. There was no airplane in the U.S. fleet capable of evacuating an American doctor who was infected while treating patients in Liberia. The Pentagon was largely unprepared for the intervention that Mr. Obama ordered.

While the United States rapidly developed a way to screen air passengers coming into the country — borrowing from intelligence tools developed after the Sept. 11, 2001, attacks to track possible terrorists — Mr. Kirchhoff found deficiencies in even measuring how fast the virus was spreading.



The United States sent nearly 3,000 troops to Africa to help keep Ebola from spreading in 2014. Daniel Berehulak for The New York Times

On the plus side, the Obama White House had created an Ebola Task Force, run by Ron Klain, Vice President Joseph R. Biden Jr.'s former chief of staff, before a single case emerged in the United States. Congress allocated $5.4 billion in emergency funding to pay for Ebola treatment and prevention efforts in the United States and West Africa.

The money helped fund a little-known agency inside the Department of Health and Human Services in charge of preparing for future contagious disease outbreaks, the same office that in 2019 ran the Crimson Contagion exercise and other similar events in the years since.

After a man named Thomas Duncan, a Liberian citizen, became the first person given a diagnosis of Ebola on American territory in September 2014, errors resulted in the infection of two nurses and fear of a wider spread in the United States. (Mr. Duncan died, but the two nurses recovered.)

What is striking in reading Mr. Kirchhoff's account today, however, is how few of the major faults he found in the American response resulted in action — even though the report was filled with department-by-department recommendations.

There were deficiencies "in personal protective equipment use, disinfection" and "social services for those placed under quarantine."

There was confusion over travel restrictions, and the need "for a smoother sliding scale of escalation of government response, from local authorities acting on their own to local authorities acting with some federal assistance" to the full activation of the federal government.

The report concluded that "a minimum planning benchmark might be an epidemic an order of magnitude or two more difficult than that presented by the outbreak of Ebola in West Africa, with much more significant domestic spread."

But one big change did come out of the study: The creation of a dedicated office at the National Security Council to coordinate responses and raise the alarm early.

"What I learned most is that we had to stand up a global biosecurity and health directorate, and get it enshrined for the next administration," said Lisa Monaco, Mr. Obama's homeland security adviser.

Getting the Trump Team's Attention

John F. Kelly and Rex W. Tillerson were part of a high-level pandemic exercise, but both men left the administration before the Covid-19 outbreak. Al Drago for The New York Times

After Mr. Trump's election, Ms. Monaco arranged an extensive exercise for high-level incoming officials — including Rex W. Tillerson, the nominee for secretary of state; John F. Kelly, designated to become homeland security secretary; and Rick Perry, who would become energy secretary — gaming out the response to a deadly flu outbreak.

She asked Tom Bossert, who was preparing to come in as Mr. Trump's homeland security adviser, to run the event alongside her.

"We modeled a new strain of flu in the exercise precisely because it's so communicable," Ms. Monaco said. "There is no vaccine, and you would get issues like nursing homes being particularly vulnerable, shortages of ventilators."

Ms. Monaco was impressed by how seriously Mr. Bossert, her successor, appeared to take the threat, as did many of the 30 or so Trump team members who participated in the exercise, details of which were reported by Politico.

But by the time the current crisis hit, almost all of the leaders at the table — Mr. Tillerson, Mr. Kelly and Mr. Perry among them — had been fired or moved on.

In 2018, Mr. Trump's national security adviser at the time, John R. Bolton, ousted Mr. Bossert and eliminated the National Security Council directorate, folding it into an office dedicated to weapons of mass destruction in what Trump officials called a logical consolidation.

Asked about that shift on March 13, Mr. Trump told a reporter that it was "a nasty question," before adding: "I don't know anything about it." Writing on Twitter the next day, Mr. Bolton lashed out at critics who said the shift had reflected disregard for pandemic threats.

"Claims that streamlining NSC structures impaired our nation's bio defense are false," Mr. Bolton tweeted. "Global health remained a top NSC priority."

In a statement, the National Security Council said it "has directors and staff whose full-time job it is to monitor, plan for, and respond to pandemics, including an infectious disease epidemiologist and a virologist."

But in testimony to Congress last week, Dr. Anthony S. Fauci, the director of the National Institute of Allergy and Infectious Diseases, suggested that ending the stand-alone directorate was ill-advised. "It would be nice if the office was still there," he said.

On Feb. 10, nearly three weeks after the first coronavirus case was diagnosed in the United States, Mr. Trump submitted a 2021 budget proposal that called for a $693.3 million reduction in funding for the C.D.C., or about 9 percent, although there was a modest increase for the division that combats global pandemics.

'Crimson Contagion'

A health worker at a drive-through testing center for the coronavirus on Thursday in Arlington, Va. Erin Schaff/The New York Times

The Crimson Contagion planning exercise run last year by the Department of Health and Human Services involved officials from 12 states and at least a dozen federal agencies. They included the Pentagon, the Department of Veterans Affairs and the National Security Council. Groups like the American Red Cross and American Nurses Association were invited to join, as were health insurance companies and major hospitals like the Mayo Clinic.

The war game-like exercise was overseen by Robert P. Kadlec, a former Air Force physician who has spent decades focused on biodefense issues. After stints on the Bush administration's Homeland Security Council and the staff of the Senate Intelligence Committee, he was appointed assistant secretary of Health and Human Services for Preparedness and Response.

"He recognized early that we have a big problem and we needed much bigger budgets to prepare," said Richard Danzig, the secretary of the Navy in the Clinton administration, who had worked with Mr. Kadlec.

The exercise played out in four separate stages, starting in January 2019.

The events were supposedly unspooling in real time — with the worst-case scenario underway as of Aug. 13, 2019 — when, according to the script, 12,100 cases had already been reported in the United States, with the largest number in Chicago, which had 1,400.

The fictional outbreak involved a pandemic flu, which the Department of Health and Human Services says was "very different than the novel coronavirus." The staged outbreak had started when a group of 35 tourists visiting China were infected and then flew home to Australia, Kuwait, Malaysia, Thailand, Britain and Spain, as well as to the United States, with some developing respiratory symptoms and fevers en route.

A 52-year-old man from Chicago, who was on the tour, had "low energy and a dry cough" upon his return home. His 17-year-old son on that same day went out to a large public event in Chicago, and the chain of illnesses in the United States started.

Many of the moments during the tabletop exercise are now chillingly familiar.

In the fictional pandemic, as the virus spread quickly across the United States, the C.D.C. issued guidelines for social distancing, and many employees were told to work from home.

But federal and state officials struggled to identify which employees were essential and what equipment was needed to effectively work from home.

There also was confusion over how to handle school children. The C.D.C. recommended that states delay school openings — the exercise took place toward the end of the summer. But some school districts decided to go ahead with the start of school while others followed the federal advice, causing the same types of confusion and discrepancies that have marked the response to the coronavirus.

The exercise from last year then went on to predict how the situation on the ground in the United States would worsen as the weeks passed.

Confusion emerged as state governments began to turn in large numbers to Washington for help to address shortages of antiviral medications, personal protective equipment and ventilators. Then states started to submit requests to different branches of the federal government, leading to bureaucratic chaos.

Friction also emerged between the Federal Emergency Management Agency, which is traditionally in charge of disaster response, and the Department of Health and Human Services, another scenario playing out now.

But the problems were larger than bureaucratic snags. The United States, the organizers realized, did not have the means to quickly manufacture more essential medical equipment, supplies or medicines, including antiviral medications, needles, syringes, N95 respirators and ventilators, the agency concluded.

Congress was briefed in December on some of these findings, including the inability to quickly replenish certain medical supplies, given that much of the product comes from overseas.

These concerns turned more urgent at a hearing last Thursday on Capitol Hill, as lawmakers peppered officials with the Department of Health and Human Services with questions that sounded almost as if they had read the script from the fictional exercise, reflecting the shortage of respirators and protective gear.

Senator Mitt Romney, Republican of Utah, said last week that he blamed Congress and prior administrations for not increasing stockpiles of this type of equipment.

"That is an area we ought to consider making an investment in," he added, making a point, apparently unknown to him, that the administration's own simulation had made clear five months earlier.

STAT

Two new studies paint encouraging picture of Covid-19 vaccine's performance

By Helen Branswell[1] [2] Jan. 25, 2023

A child receives a dose of Pfizer's Covid-19 vaccine at an event launching school vaccinations in Los Angeles in November 2021. *FREDERIC J. BROWN/AFP via Getty Images*

Two new studies published Wednesday report good news about the updated Covid-19 vaccine, with one suggesting it is more effective than the previous monovalent vaccine and the other showing that even though it targeted an earlier strain of the SARS-CoV-2 virus, its protection is holding up against current variants.

The findings suggest the updated vaccine, which targets both the original SARS-2 virus and the Omicron subvariants BA.4 and BA.5, is performing better than some critics of the decision[4] to update the vaccine concluded, based on studies that only compared the levels of neutralizing antibodies each induced.

The first study[5], published in the New England Journal of Medicine, found the updated vaccine was significantly more effective at protecting against severe illness, hospitalization, and death from Covid than the monovalent vaccine that was previously used.

"It's clear from this study that the bivalent booster, in that short term following administration, provides additional protection above and beyond that of the monovalent," said Michael Osterholm, director of the

University of Minnesota's Center for Infectious Diseases Research and Policy. "I think that's clear and this should be a reason why we can feel confident that it was the right decision to go with the bivalent vaccine."

Anna Durbin, director of the Center for Immunization Research at the Johns Hopkins Bloomberg School of Public Health, agreed.

"I think it's pretty compelling," said Durbin. "It certainly is a big difference between the two."

The research was conducted by scientists at the University of North Carolina Gillings School of Global Public Health and the North Carolina Department of Health and Human Services, using state vaccine registry data. The senior author, Danyu Lin, said this is the first study that estimated vaccine effectiveness of the updated vaccine in comparison to the previous product. (Lin, a professor of biostatistics, spells his given name Dan-yu when he publishes in the scientific literature.)

Determining whether the bivalent vaccine is more effective than the previous single-strain version has been difficult. When it authorized the updated vaccine the Food and Drug Administration rescinded the license for the monovalent vaccine, a move that closed the door to head-to-head trials. Testing the two vaccines at the same time would have generated the best picture of how the new vaccine stacked up against the one it replaced.

Lin and his colleagues did the next best thing, comparing the vaccine effectiveness of the monovalent virus over 99 days from late May 2022 to the end of August, to the vaccine effectiveness of the bivalent vaccine over 99 days from September through late November. In the earlier period, nearly 300,000 people received a monovalent booster dose, while just over 1 million received the bivalent booster and were followed in the later period.

For people aged 12 and older who received the monovalent vaccine, the vaccine effectiveness against disease severe enough to require hospitalization was 25%. The effectiveness of the bivalent vaccine was 58.7%. Vaccine effectiveness against severe infection that resulted in hospitalization or death was 24.9% for the monovalent booster and 61.8% for bivalent booster.

Of note, two new Omicron subvariants, BQ.1 and BQ.1.1, began to circulate after the bivalent vaccine went into use. Given the bivalent vaccine targeted a different version of Omicron, that could have rendered the updated vaccine less effective.
"You would expect that will make the bivalent booster even worse, because the bivalent booster is targeting BA.4 and BA.5," Lin told STAT. Instead, the study findings suggested the updated vaccine was more effective, both against the earlier BA.5 subvariant and the BQ strains that followed.

"I think it's pretty convincing," Lin said.

The second study[8] released Wednesday looked at whether protection generated by the bivalent booster was still effective against the newest Omicron subvariants that are sweeping the country, XBB.1 and XBB.1.5. It was conducted by scientists from the Centers for Disease Prevention and Control.

They reported in the CDC journal Morbidity and Mortality Weekly Report that the bivalent vaccine's effectiveness against the XBB and XBB.1.5 strains is similar to what was seen when the BA.5 strain of the virus was circulating.

Early studies measuring neutralizing antibody responses to the new XBB subvariants raised concerns that the mutations contained in the new strains would further erode the protection generated by the vaccine. But that does not appear to be playing out in the real world, the CDC scientists suggested in a media briefing.

“So bottom line … is we did not see reduced vaccine protection against symptomatic illness for XBB and XBB.1.5, compared with those other recent BA.5 variants,” said Brendan Jackson, who currently heads CDC’s Covid response.

“Quite reassuring.”

The article looked at data from Covid tests conducted at pharmacies during the period from Dec. 1, 2022, to Jan. 13. It found that vaccine effectiveness against symptomatic infection was quite similar. For people aged 18 to 49, the effectiveness was 49% for XBB and XBB.1.5 viruses versus 52% for the BA.5 viruses. For those aged 50 to 64, the effectiveness against the XBB-related strains was 40%, compared to 43% for BA.5. And for people aged 65 and older, the effectiveness against infection by XBB and XBB.1.5 viruses was 43%, compared to 37% against the BA.5 viruses.

The estimates were calculated by comparing infections in people who had received a bivalent booster between two and three months earlier against people who had not received the updated booster.

Jackson said additional data the CDC was posting to its website on Wednesday showed that people who got the updated booster have a 13-fold reduction in the risk of death compared to people who are unvaccinated. People vaccinated with the bivalent booster had more than a two-fold reduced risk of death from Covid compared to vaccinated people who had only received monovalent vaccine.

The authors noted several possible limitations of the study, including the fact that the number of previous vaccinations and infections among participants was based on self-reported data. If there had been more infections among the participants than reported — likely, given that Covid can cause very mild and even asymptomatic illness — that could have the effect of making the vaccine look less protective than it actually is. That’s because infection also confers some protection, albeit of limited duration, against infection.

“So, if anything, these estimates that we’re publishing are probably underestimates of how well that vaccine is protecting,” said Ruth Link-Gelles, lead author of the study.

This article was updated to include the findings of the study published in the New England Journal of Medicine.

About the Author

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Shuren: FDA needs new authorities to prevent device shortages beyond public health emergencies

Regulatory News | 02 February 2023 | By Ferdous Al-Faruque

The head of the US Food and Drug Administration's (FDA) device center says he will continue to work with Congress and the medtech industry to pass legislation to prevent potential medical device shortages before a public health emergency must be declared.

CDRH Director Jeff Shuren spoke to attendees at the 2022 annual Medtech Conference in Boston, MA. (Source: Ferdous Al-Faruque)

Jeff Shuren, Center for Devices and Radiological Health (CDRH) director, spoke with *Focus* about his center's performance last year and priorities for this year.

The FDA recently published the CDRH 2022 Annual Report, which states that while the excess workload from the COVID-19 pandemic is starting to alleviate, it is still tackling pandemic-related work on top of its normal day-to-day activities.

"Although COVID-19 has been an odyssey that we are returning home from – albeit battle-scarred – we have emerged a bit wiser and more prepared for the future to ensure we are best responding to public health needs," Shuren wrote in the report.

One of the key takeaways from the pandemic, according to the report, is how vulnerable the US medical products supply chain is to trade disruptions. The crisis led to shortages in critical devices such as personal protective equipment (PPE) and ventilators needed to prevent and treat

COVID-19.

While the Coronavirus Aid, Relief, and Economic Security (CARES) Act gave the FDA new authority to require supply chain reporting from manufacturers, that authority may only be used during a public health emergency. The information the agency was able to collect under the authority allowed it to better understand and monitor the medical device supply chain and take proactive measures to prevent product shortages or at least find alternative solutions.

Despite the new authorities, Shuren said the agency needs to do better and wants the additional authority to spot a shortage before a public health emergency needs to be declared. Such authority would allow regulators to detect potential shortages even sooner.

“What's most important for the authorities [that we are seeking] is that we receive advance notice of potential shortages in circumstances outside of a public health emergency,” Shuren told *Focus*.

He acknowledged that industry is wary of being subjected to onerous reporting requirements, but he argued that the FDA’s interest is to only ask for “limited information under limited circumstances,” which is essential for regulators to take proactive steps to prevent or mitigate shortages.

“We continue to remain open to working with Congress and the industry on rational authorities that best meet the needs of patients in the least burdensome manner,” Shuren said. He added that he’s not asking to get data on all medical devices and diagnostics but rather a subset of products that the FDA deems critical to public health.

“Device shortages happen all the time and they don't respect the boundaries of a public health emergency,” Shuren said. “We think this could be crafted with minimal burden on the industry but have a significant beneficial impact on patients.”

In the latest CDRH annual report, the center noted that it has significantly reduced the backlog of reviews caused by the COVID-19 pandemic. Over the past year, it has shifted its focus to addressing the impact of new SARS-CoV-2 variants on device safety and effectiveness, developing strategies to transition existing COVID-19 devices, converting devices from emergency use authorization (EUA) to traditional marketing authorization, bolstering the supply chain, and preparing for future public health emergencies.

In 2022, CDRH authorized 765 medical devices to address COVID-19, bringing the total number of such devices authorized to address the public health emergency to 2,831. It also gave breakthrough designation to 135 devices, bringing the total to 752 devices since the breakthrough program began in 2015, according to the report.

The report also addresses FDA's work to require Philips to recall its Respironics ventilators, as well as bilevel positive airway pressure (BiPAP) and continuous positive airway pressure (CPAP) machines. It was noted that the polyester-based polyurethane (PEPUR) foam used in the devices could break down and potentially cause serious injury to patients.

After informing the company of the need to notify healthcare providers and patients about the risk of the devices, FDA determined Philips' response was inadequate, forcing the agency to take additional steps to ensure the recall notification was publicized.

As part of that effort, Shuren said that his center for the first created a CDRH Recall Response Team in CDRH's Division of Industry and Consumer Education (DICE). The group of FDA staff were tasked with ensuring patients and providers were kept abreast of the recall.

"Because we were receiving so many inquiries from patients and others, often because they felt they were not getting the answers they needed from Phillips, we had a group of individuals dedicated to responding to those inquiries," Shuren said. "This is an unusual step, and it reflects the problems that we have seen with Phillips adequately and effectively responding and communicating with the public."

POLITICO

EXCLUSIVE

Trump officials interfered with CDC reports on Covid-19

The politically appointed HHS spokesperson and his team demanded and received the right to review CDC's scientific reports to health professionals.

Former Trump campaign official Michael Caputo and his team have attempted to add caveats to the CDC's findings, including an effort to retroactively change agency reports that they said wrongly inflated the risks of Covid-19. | Mark Wilson/Getty Images

By **DAN DIAMOND**
09/11/2020 10:25 PM EDT
Updated: 09/12/2020 11:11 AM EDT

The health department's politically appointed communications aides have demanded the right to review and seek changes to the Centers for Disease Control and Prevention's weekly scientific reports charting the progress of the coronavirus pandemic, in what officials characterized as an attempt to intimidate the reports' authors and water down their communications to health professionals.

In some cases, emails from communications aides to CDC Director Robert Redfield and other senior officials openly complained that the agency's reports would undermine President Donald Trump's optimistic messages about the outbreak, according to emails reviewed by POLITICO and three people familiar with the situation.

CDC officials have fought back against the most sweeping changes, but have increasingly agreed to allow the political officials to review the reports and, in a few cases, compromised on the wording, according to three people familiar with the exchanges. The communications aides' efforts to change the language

in the CDC's reports have been constant across the summer and continued as recently as Friday afternoon.

The CDC's Morbidity and Mortality Weekly Reports are authored by career scientists and serve as the main vehicle for the agency to inform doctors, researchers and the general public about how Covid-19 is spreading and who is at risk. Such reports have historically been published with little fanfare and no political interference, said several longtime health department officials, and have been viewed as a cornerstone of the nation's public health work for decades.

But since Michael Caputo, a former Trump campaign official with no medical or scientific background, was installed in April as the Health and Human Services department's new spokesperson, there have been substantial efforts to align the reports with Trump's statements, including the president's claims that fears about the outbreak are overstated, or stop the reports altogether.

Caputo and his team have attempted to add caveats to the CDC's findings, including an effort to retroactively change agency reports that they said wrongly inflated the risks of Covid-19 and should have made clear that Americans sickened by the virus may have been infected because of their own behavior, according to the individuals familiar with the situation and emails reviewed by POLITICO.

Caputo's team also has tried to halt the release of some CDC reports, including delaying a report that addressed how doctors were prescribing hydroxychloroquine, the malaria drug favored by Trump as a coronavirus treatment despite scant evidence. The report, which was held for about a month after Caputo's team raised questions about its authors' political leanings, was finally published last week. It said that "the potential benefits of these drugs do not outweigh their risks."

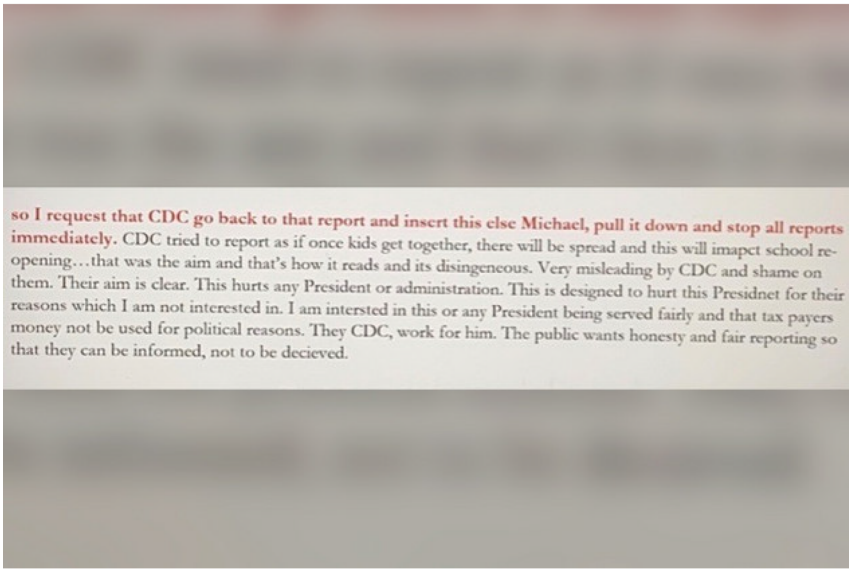
In one clash, an aide to Caputo berated CDC scientists for attempting to use the reports to "hurt the President" in an Aug. 8 email sent to CDC Director Robert Redfield and other officials that was widely circulated inside the department and obtained by POLITICO.

"CDC to me appears to be writing hit pieces on the administration," appointee Paul Alexander wrote, calling on Redfield to modify two already published reports that Alexander claimed wrongly inflated the risks of coronavirus to children and undermined Trump's push to reopen schools. "CDC tried to report as if once kids get together, there will be spread and this will impact school re-opening . . . Very misleading by CDC and shame on them. Their aim is clear."

Alexander also called on Redfield to halt all future MMWR reports until the agency modified its years-old publication process so he could personally review the entire report prior to publication, rather than a brief synopsis. Alexander, an assistant professor of health research at McMaster University near Toronto whom Caputo recruited this spring to be his scientific adviser, added that CDC needed to allow him to make line edits — and demanded an "immediate stop" to the reports in the meantime.

"The reports must be read by someone outside of CDC like myself, and we cannot allow the reporting to go on as it has been, for it is outrageous. Its lunacy," Alexander told Redfield and other officials. "Nothing to go out unless I read and agree with the findings how they CDC, wrote it and I tweak it to ensure it is fair and balanced and 'complete.'"

CDC officials have fought the efforts to retroactively change reports but have increasingly allowed Caputo and his team to review them before publication, according to the three individuals with knowledge of the situation. Caputo also helped install CDC's interim chief of staff last month, two individuals added, ensuring that Caputo himself would have more visibility into an agency that has often been at odds with HHS political officials during the pandemic.



Paul Alexander uses red type to call for inserting text and accuses CDC officials of trying to use the reports to undermine President Donald Trump. | Screenshot

Asked by POLITICO about why he and his team were demanding changes to CDC reports, Caputo praised Alexander as "an Oxford-educated epidemiologist" who specializes "in analyzing the work of other scientists," although he did not make him available for an interview.

"Dr. Alexander advises me on pandemic policy and he has been encouraged to share his opinions with other scientists. Like all scientists, his advice is heard and taken or rejected by his peers," Caputo said in a statement.

Caputo also said that HHS was appropriately reviewing the CDC's reports. "Our intention is to make sure that evidence, science-based data drives policy through this pandemic—not ulterior deep state motives in the bowels of CDC," he said.

Caputo's team has spent months clashing with scientific experts across the administration. Alexander this week tried to muzzle infectious-disease expert Anthony Fauci from speaking about the risks of the coronavirus to children, and The Washington Post reported in July that Alexander had criticized the CDC's methods and findings.

But public health experts told POLITICO that they were particularly alarmed that the CDC's reports could face political interference, praising the MMWRs as essential to fighting the pandemic.

"It's the go-to place for the public health community to get information that's scientifically vetted," said Jennifer Kates, who leads the Kaiser Family Foundation's global health work. In an interview with POLITICO, Kates rattled off nearly a dozen examples of MMWR reports that she and other researchers have relied on to determine how Covid-19 has spread and who's at highest risk, including reports on how the virus has been transmitted in nursing homes, at churches and among children.

Confirmed U.S. Cases: 7,292,422 | **U.S. Deaths:** 208,068

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"They're so important, and CDC has done so many," Kates said.

The efforts to modify the CDC reports began in earnest after a May report authored by senior CDC official Anne Schuchat, which reviewed the spread of Covid-19 in the United States and caused significant strife within the health department. HHS officials, including Secretary Alex Azar, believed that Schuchat was implying that the Trump administration moved too slowly to respond to the outbreak, said two individuals familiar with the situation.

The HHS criticism was mystifying to CDC officials, who believed that Schuchat was merely recounting the state of affairs and not rendering judgment on the response, the individuals familiar with the situation said. Schuchat has made few public appearances since authoring the report.

CDC did not respond to a request for comment about Schuchat's report and the response within the department.

The close scrutiny continued across the summer with numerous flashpoints, the individuals added, with Caputo and other HHS officials particularly bristling about a CDC report that found the coronavirus spread among young attendees at an overnight camp in Georgia. Caputo, Alexander and others claimed that the timing of the August report was a deliberate effort to undermine the president's push on children returning to schools in the fall.

Most recently, Alexander on Friday asked CDC to change its definition of "pediatric population" for a report on coronavirus-related deaths among young Americans slated for next week, according to an email that Caputo shared with POLITICO.

"[D]esignating persons aged 18-20 as 'pediatric' by the CDC is misleading," Alexander wrote, arguing that the report needed to better distinguish between Americans of different ages. "These are legal adults, albeit young."

Caputo defended his team's interventions as necessary to the coronavirus response. "Buried in this good [CDC] work are sometimes stories which seem to purposefully mislead and undermine the President's Covid response with what some scientists label as poor scholarship — and others call politics disguised in science," Caputo told POLITICO.

The battles over delaying or modifying the reports have weighed on CDC officials and been a distraction in the middle of the pandemic response, said three individuals familiar with the situation. "Dr. Redfield has pushed back on this," said one individual. "These are scientifically driven articles. He's worked to shake some of them loose."

Kates, the Kaiser Family Foundation's global health expert, defended the CDC's process as rigorous and said that there was no reason for politically appointed officials to review the work of scientists. "MMWRs are famously known for being very clear about their limitations as well as being clear for what they've found," she said.

Kates also said that the CDC reports have played an essential role in combating epidemics for decades, pointing to an MMWR posted in 1981 — the first published report on what became the HIV epidemic.

"Physicians recognized there was some kind of pattern and disseminated it around the country and the world," Kates said. "We can now see how important it was to have that publication, in that moment."

FILED UNDER: CENTERS FOR DISEASE CONTROL, DONALD TRUMP, DONALD TRUMP 2020,

POLITICO

HEALTH CARE

Attacks on Fauci grow more intense, personal and conspiratorial

Conservatives are amplifying attacks on Fauci after the release of his emails. And they're fundraising off of it too.

Reddit and Facebook lit up with a fresh round of Fauci attacks, some of which called him a war criminal. | Sarah Silbiger/AP Photo

By **NATASHA KORECKI** and **SARAH OWERMOHLE**
06/04/2021 11:00 AM EDT

For over a year, Anthony Fauci has been a bogeyman for conservatives, who have questioned his handling of the Covid-19 pandemic and accused him of quietly undermining then-President Donald Trump.

But those attacks took on a whole new level of vitriol this week, to the point that one social media analysis described it as highly misleading and at least one platform pulled down some posts, citing false content.

It all stemmed from a tranche of Fauci's emails that were published as part of a Freedom of Information Act request filed byvarious news outlets. Within hours of publication, the hashtag #FauciLeaks was trending on Twitter, accusing the nation's top infectious disease doctor of lying under oath about the origins of Covid. It became a trending topic on Facebook too, where detractors added an inaccurate and more nefarious framing that the emails were secretly "leaked" — drawing on a playbook that has worked for partisans on the right in the past, despite the fact that Fauci's publicly disclosed emails were not state secrets.

Reddit and Facebook lit up with a fresh round of Fauci attacks, some of which called him a war criminal. Sen. Rand Paul (R-Ky.), perhaps Fauci's most prominent bete noire on the Hill, quickly released Facebook ads demanding to "fire Fauci" and requesting a campaign donation.

And a round of conservatives, cherry-picking individual emails out of more than 3,000, argued that Fauci, who leads the National Institute of Allergy and Infectious Diseases, had privately supported a theory that the virus leaked from a Chinese lab and lied about masks in an effort to amass political power. Neither was true. Fauci has said he thinks it's more likely that the virus spread from animal to human but would not rule out a lab leak, and while he initially downplayed the need for masks, it was, he said, out of fear that medical professionals would lose access to them if the public began panic purchasing.

The veracity and velocity of the new attacks, nevertheless, underscored the growing intensity with which Fauci animates conservatives some five months after Trump has left office. And they raised difficult questions for political and medical professionals about how much they should push back on the anti-Fauci campaign and what the cost would be if it went ignored.

“Targeting Fauci erodes trust in scientific institutions and makes them seem partisan – just as universities are increasingly seen as partisan, the media, the bureaucracy,” said Karen Kornbluh, senior fellow and director of GMF Digital at the German Marshall Fund of the U.S. “These strategies don’t have an easy response. You try to ignore them when they’re not that widespread and even if you eventually refute them it can seem he said-she said. The best strategy — which the White House and Fauci seem to be taking — is to push ahead with an

For the White House, this has created a quandary: to defend Fauci from the incoming and risk elevating it, or to ignore it and assume it only gains traction with an audience that would never trust the Biden administration anyway.

On Thursday, White House press secretary Jen Psaki called Fauci an “undeniable asset” but said the White House would let him speak for himself. In an interview later in the day, Rob Flaherty, the White House’s digital director, would not directly comment on Fauci but said that while the White House regularly pushes back on false information it must also balance out whether its response will exacerbate false information or quash it.

Fauci declined to comment for this piece.

Career government officials don't often become political lightning rods. But Fauci's role, the crisis in which he has operated, and the flow of information on social media, has created the perfect conditions for just that. A mild-mannered infectious disease specialist who has earned the admiration of Republican and Democratic presidents alike, Fauci is prone to bluntness. That has served him well as someone communicating to the public about complex and high-stakes pandemics and public health issues. But, starting in the spring of 2020, it has made his life tricky.

Trump insisted that he and Fauci worked fine together. But in the early days of the pandemic, the former president rarely hid his jealousy as Fauci became something of a public deity. Often Trump would proclaim that his judgments on Covid proved more prescient over time, like an early call to shut down travel from China. But Trump also routinely flouted the public safety guidelines that Fauci touted and their divergent approaches became an emblem for the then-president's much criticized pandemic response, writ large.

The publication of Fauci's emails only further animated Trump's animus.

"After seeing the emails, our Country is fortunate I didn't do what Dr. Fauci wanted me to do. For instance, I closed our Borders to China very early despite

his not wanting them closed. The Democrats and the Fake News Media even called me a 'xenophobe,'" Trump said in a statement Thursday. "In the end, we saw this was a life-saving decision, and likewise with closing our borders to Europe, specifically to certain heavily infected countries. I was later given

Trump's attack was not particularly pointed compared to the others that have come Fauci's way in recent days.

An analysis from GMF Digital at the German Marshall Fund provided to POLITICO showed that the online attacks on Fauci have grown more personal and egregious, with claims that he is "corrupt, a war criminal, deserves to go to prison, or is responsible for child abuse circulating on social media." GMF Digital found four "misleading" themes across social media including that Fauci lied about masks and other public health measures. The organization found that on Facebook, the top posts about Fauci emanated from Paul as well as a host of conservatives, including Ben Shapiro, Donald Trump Jr., Steven Crowder, Dan Bongino and Newsmax.

According to data from Bully Pulpit Interactive, Republicans or conservative interests over the last month have spent $300,000 on Facebook ads targeting Fauci.

Nearly seven years ago, during the heart of the Ebola crisis, the Obama administration's internal motto for handling challenging stretches was

“PTFOTV”: Put Tony Fauci on TV. No one had more credibility with the public or was a better spokesperson, said Ron Klain, who acted as Ebola czar under Obama and now serves as Biden’s chief of staff.

But in an ever-polarized nation, Fauci too has fallen victim to tribalism. His advocacy for mask wearing and social distancing — in the face of Trump’s opposition — was met by vocal detractors across the country, who launched anti-mask protests and demanded the economy reopen. His conservative predictions about the pace of vaccine development and the timeline for reopening the country led to criticism that his expertise had been dramatically overstated.

But the attacks on Fauci have increasingly veered into the conspiratorial, experts say. This week, Fox News’ Tucker Carlson questioned why one of the emails involving Fauci was redacted, then speculated that it could mean Fauci was under investigation.

“Republicans employed the same attempts to divide and distract the American people in 2020. We know that these strategies don’t work,” said Aneesa McMillan, deputy executive director of Priorities USA, a top Democratic super PAC. “The American people are looking for a concrete policy agenda that speaks to their priorities and improves their communities. The GOP has none of that — so they turn to fear-mongering and misinformation.”

At the heart of the current broadside against Fauci is reporting around — and the investigation into — the Wuhan lab leak theory, which holds that the virus leaked, accidentally or intentionally, from a virology lab in the city where it was first found. Republicans and right-wing media outlets have circulated such theories since the beginning of the pandemic even as scientists, including Fauci, insisted that problematic coronaviruses, from the SARS and MERS epidemics to Covid-19, were becoming increasingly common.

The pressure to probe Wuhan lab leak theories continued to mount, leading Trump's White House to demand in April 2020 that the National Institutes of Healthabruptly cancel a multimillion-dollar grant to EcoHealth Alliance, a nonprofit studying coronavirus origins that had worked with the Wuhan viral lab in the past. April emails between EcoHealth Alliance CEO Peter Daszak and Fauci, published as part of the recent FOIA, have become a new touchstone for conspiracy theorists, after Daszak thanked the NIAID director for dismissing lab leak theories early in the pandemic.

"I just wanted to say a personal thank you on behalf of our staff and collaborators, for publicly standing up and stating that the scientific evidence supports a natural origin for COVID-19 from a bat-to-human spillover, not a lab release from the Wuhan Institute of Virology," Daszak wrote to Fauci on April 18, 2020.

"Many thanks for your kind note," Fauci responded the next day, just over a week before POLITICO first reported that NIH canceled the EcoHealth grant. Daszak did not respond to a POLITICO request for comment.

Theories about a leak from the Wuhan virology lab became a consistent line of questioning for Republican lawmakers by last spring and soon turned into a mainstay of congressional hearings and increasingly contentious exchanges between Fauci and Paul, who sits on the Senate health committee. The longtime NIAID director and Kentucky doctor have exchanged barbs on television after Senate hearings where Paul accused Fauci of moving the goalposts on coronavirus science while the infectious disease scientist has told Paul that "with all due respect," he was "entirely and completely incorrect."

Paul was swift to accuse Fauci on Wednesday of knowledge of the Wuhan lab allegedly carrying out controversial "gain-of-function" studies, a field of research that alters viruses in a way that can make them more transmissible or help them hop to new hosts, such as humans.

A senior NIH official insisted to POLITICO that detractors such as Paul are taking Fauci's emails "out of context." But the prevailing posture, like that of the White House, was to downplay rather than engage.

FILED UNDER: TUCKER CARLSON, RAND PAUL, CONSPIRACY THEORIES, ANTHONY FAUCI,

the official said. "We're taking it seriously, of course, but it's not changing how

Republicans promote pandemic relief they voted against

By STEVE PEOPLES

May 6, 2021

NEW YORK (AP) — Rep. Nicole Malliotakis, R-N.Y., said it pained her to vote against the $1.9 trillion American Rescue Plan.

But in the weeks that followed, the first-term Republican issued a news release celebrating more than $3.7 million from the package that went to community health centers in her district as one of her "achievements." She said she prided herself on "bringing federal funding to the district and back into the pockets of taxpayers."

Malliotakis is far from alone.

Every Republican in Congress voted against the sweeping pandemic relief bill that President Joe Biden signed into law three months ago. But since the early spring votes, Republicans from New York and Indiana to Texas and Washington state have promoted elements of the legislation they fought to defeat.

The Republicans' favorite provisions represent a tiny sliver of the massive law, which sent $1,400 checks to millions of Americans, extended unemployment benefits until September, increased the child tax credit, offered housing assistance for millions of low-income Americans and expanded health care coverage. Republicans tried to negotiate a smaller package, arguing that Biden's plan was too expensive and not focused enough on the nation's health and economic crises.

Democrats are promising to make the pandemic relief vote — and the Republican resistance to it — a central element in their political strategy moving into next year's midterm elections as they defend delicate House and Senate majorities. And there are early signs that Republicans may struggle to defend their opposition to the popular legislative package, which was designed to protect the nation's fragile economic recovery following the worst public health threat in a century.

GOP lawmakers have been especially bullish about promoting the rescue plan's Restaurant Revitalization Fund, which devoted $28.6 billion to the struggling industry. Applications for the program opened this week.

House Minority Leader Kevin McCarthy, R-Calif., topped a group of at least eight Republicans who have encouraged constituents to apply in recent days. The others included Sen. Roger Wicker, R-Miss., and Reps. Elise Stefanik, R-N.Y.; Greg Pence, R-Ind.; Jaime Herrera Beutler, R-Wash.; Beth Van Duyne, R-Texas; Troy Balderson, R-Ohio; and Anthony Gonzalez, R-Ohio.

"The Congresswoman is using her platform to inform her constituents of federal funds and resources available to them," Stefanik spokesperson Karoline Leavitt said. "She did not claim to support the bill in the tweet, and her constituents deserve to know about federal programs they can apply for regardless of how she votes."

Wicker's office noted that he voted against the full package, but led efforts to ensure the restaurant relief was included.

"Sen. Wicker co-authored the amendment that successfully added the Restaurant provision to the reconciliation bill. Why wouldn't he want to encourage participation?" Wicker spokesman Phillip Waller said.

The Independent Restaurant Coalition acknowledged the Republican's awkward position, but offered its thanks anyway.

"Senator Wicker did not vote for the package (we wish all members did!), but his work on the RESTAURANTS Act from the beginning made the relief fund possible," the industry group tweeted. "We are grateful for that work."

And White House spokesman Andrew Bates sarcastically expressed appreciation for the Republicans who have begun to tout elements of Biden's stimulus.

"The American people — majorities of Democrats, independents, and Republicans — have long been firmly unified behind the American Rescue Plan," Bates said. "So it's heartening to see Republicans in Congress reaching across the aisle to endorse it — even retroactively."

The politics of the Republican position are complicated.

The GOP ultimately benefited politically after uniting against the massive economic stimulus package signed into law by President Barack Obama in 2009. Republicans scored massive gains in the House and Senate the following year. While the GOP is optimistic it will retake the House majority in 2022, it's far from clear whether the stimulus vote will help it get there.

Polling suggests the Biden stimulus is overwhelmingly popular. Two in 3 voters have consistently supported the $1.9 trillion package in recent polling, while individual elements such as the $1,400 direct payments to individuals are even more popular.

And just three months after the bill was signed into law, the Republican opposition has only begun to be tested.

The Democratic National Committee has already launched "digital takeovers" of local news websites in Arizona, Georgia, Wisconsin, Nevada, New Hampshire, Florida, North Carolina and Pennsylvania to thank Democrats and highlight the Republican obstruction. The White House's political arm has also put up billboards in 20 states calling out Republicans and focused on the Republican opposition in training for Democratic officials.

"Between now and next year's midterm elections, we're going to make sure every voter remembers how Republicans tried to stand in the way of this economic boom and our return to normalcy," said DNC spokesman Ammar Moussa. "And you can count on Democrats to call Republicans out for their hypocrisy when they try to tout the same programs they voted against."

Beyond funding for restaurants, Republicans have also touted millions of dollars in health care grants allocated to their districts in the latest stimulus plan.

Rep. Madison Cawthorn, R-N.C., in late March pointed to millions of dollars in such grants on social media, saying he was "proud" to see the taxpayer dollars returning to his district. A spokesman did not respond to a request for comment.

Rep. Alex Mooney, R-W.Va., issued a news release at roughly the same time to promote more than $41 million spread across 12 health care centers in his district.

“I am glad that this funding has been secured,” he said, neglecting to mention how it was secured.

The four-term Republican congressman defended his decision to highlight the grants this week in a statement.

“Despite what anyone claims, all money that is appropriated by Congress is derived from the taxpayer, not President Biden,” Mooney said. “Taxpayers deserve to know how their money is being spent, especially as it affects their towns and communities.”

Malliotakis, who took office in January, promoted more than $3.7 million in health care grants from the Biden stimulus among her achievements in a self-issued “First 100 Days Report Card.”

“These grants were among the 9% of funds dedicated to COVID-19 relief that I was always in support of,” Malliotakis said in a statement. “Regardless of any particular vote, I’m going to help individuals, small businesses and nonprofit organizations get funding they are entitled to.”

https://apnews.com/article/personal-taxes-health-coronavirus-pandemic-business-government-and-politics-d0b1f48aa32baf6b47880faf15d5dea3

LEAVITT PARTNERS

COVID Patient Recovery Alliance

Overview of Recent Long-COVID Studies

This document provides an overview of relevant research studies the COVID Patient Alliance has identified as part of our daily intel scans. While this document is a high-level overview, we publish our monthly trackers to the website, linked here, which include more detailed information and additional studies that may be of interest. Further, the Appendix D of the National Research Action Plan lists ongoing studies various government agencies are undertaking and which topics they are researching.

Prevalence

Date	Article	Publication	Author	Key Takeaways
5/24/2022	Post–COVID Conditions Among Adult COVID-19 Survivors Aged 18–64 and ≥65 Years — United States, March 2020–November 2021	CDC	CDC	**Case-patients=353,164;** Control patients=1,640,776. Patients were followed for 30–365 days after the index encounter until the first occurrence of an incident condition or until October 31, 2021, whichever occurred first. One in five adult COVID survivors under the age of 65 in the United States has experienced at least one health condition that could be considered long-COVID; one in four for patients 65 and older. In both age groups, COVID patients had twice the risk of uninfected people of developing respiratory symptoms and lung problems, including pulmonary embolism. Post-COVID patients aged 65 or older were at greater risk than the younger group of developing kidney failure, neurological conditions and most mental health conditions. The most common post-COVID conditions, regardless of age, were respiratory problems and musculoskeletal pain. The risk of post-COVID patients aged 65 and older developing the 26 health conditions the study evaluated was between 20 percent and 120 percent greater than people who didn't get COVID. Those aged 18 to 64 had a 10 percent to 110 percent greater risk than uninfected people of developing 22 of the health conditions. Between 30 days and 365 days after their COVID diagnosis, 38 percent of the patients experienced one or more new health problems, compared to 16 percent of the non-COVID patients. The younger age group, 18-to-64, was somewhat less likely to have those problems — 35 percent developed long-COVID issues, compared with 15 percent of uninfected people. In the 65-and-older group, 45 percent had new health conditions, compared with 19 percent of uninfected people. Concluded that nearly 21 percent of the younger group and nearly 27 percent of the older group developed health problems that could be attributed to long-COVID.

Prevalence				
Date	Article	Publication	Author	Key Takeaways
6/15/2022	Post-acute COVID-19 syndrome and its prolonged effects: An updated systematic review - PMC (nih.gov)	Annals of Medicine and Surgery	Almas, T. et al	This updated systematic review of **21 studies and 54,730 patients** is the largest cohort of patients with post-acute effects of COVID-19 evaluated to date. The systematic review aimed at estimating the prevalence of post-acute COVID-19 symptoms in view of published literature that studied prolonged clinical manifestations after recovery from acute COVID-19 infection. Twenty-one articles qualified for the final analysis. The most common persistent clinical manifestations were fatigue (54.11%), dyspnea (24.38%), alopecia (23.21%), hyperhidrosis (23.6%), insomnia (25.98%), anxiety (17.29%), and arthralgia (16.35%). In addition to these symptoms, new-onset hypertension, diabetes, neuropsychiatric disorders, and bladder incontinence were also reported.
7/6/2022	Long Covid estimates are startlingly high. Here's how to understand them	STAT	Elizabeth Cooney	"Whatever long-COVID's toll turns out to be, it will be too many people. However you gather or analyze the data, the proportion of people whose troublesome, sometimes disabling symptoms linger after their acute COVID-19 infections clear is sizable and worrying. It's the cruelty of large numbers: Even if the actual prevalence of long-COVID is much smaller than recent estimates, a small percentage of a large number is a large number.""1 in 5 may be an underestimate." "Even if it's in single digits at the end of the day, once a formal case definition and a true prevalence study can be accomplished, it's still a lot of people. But it's very hard to pinpoint a solid number." "Priya Duggal, and epidemiologist at John Hopkins School of Public Health, said that even with caveats, she finds the data pretty consistent for a range of **20% to 30% of people** experiencing long-COVID symptoms "It's still a substantial number of people. To me, that's the take-home point," she said. "The second point is that it's real." Long-COVID has the potential to widen existing gaps in health, Linda Sprague Martinez of the Boston University School of Social Work said, "We don't want to wait. Getting ahead of it will be really important for us."
3/2/2022	Science & Tech Spotlight: Long COVID	GAO	N/A	Studies in the U.S. estimate that 10 to 30 percent of COVID-19 survivors develop long COVID. If so, **7.7 million to 23 million** people in the U.S. may have developed long COVID as of February 2022. In January 2022, the Brookings Institution conducted a meta-analysis to suggest that long COVID may be responsible for over 1 million workers being out of the labor force at any given time. Long-COVID is a post-viral syndrome, and post-viral syndromes are well documented for a range of infections. One study found that more than 27 percent of SARS survivors had chronic fatigue syndrome 4 years after their initial infection. One study of nearly 4,000 long COVID patients found that 45 percent reduced their work hours. Another study used the electronic health records of more than 200,000 COVID-19 survivors and found that within 6 months following initial infection, one-third experienced neurological or psychological symptoms such as anxiety, depression, post-traumatic stress disorder, and psychosis. The report highlights the four "key theories of causation" that have emerged (micro clots, autoimmunity, persistent virus, reactivation of latent Epstein bar), as well as organ damage as a potential cause of long-COVID.

Prevalence				
Date	Article	Publication	Author	Key Takeaways
4/7/2022	Factors Associated with Post-Acute Sequelae of SARS-CoV-2 (PASC) After Diagnosis of Symptomatic COVID-19 in the Inpatient and Outpatient Setting in a Diverse Cohort	Journal of General Internal Medicine	You, S.M. et al	**N= 1,038 adults** with laboratory-confirmed symptomatic COVID-19 infection. 29.8% developed PASC. The most common persistent symptom was fatigue (31.4%) followed by shortness of breath (15.4%) in hospitalized patients and anosmia (15.9%) in outpatients. Hospitalization for COVID-19 (odds ratio, 1.49), having diabetes (OR, 1.39), and higher BMI (OR, 1.02) were independently associated with PASC. Medicaid compared to commercial insurance (OR, 0.49) and having had an organ transplant (OR 0.44) were inversely associated with PASC. Age, race/ethnicity, Social Vulnerability Index, and baseline functional status were not associated with developing PASC.

Demographics of Individuals with Long-COVID				
Date	Article	Publication	Author	Key Takeaways
9/16/2022	COVID-19 linked to increased Alzheimer's risk	Neurology Reviews	Burton, K.	A recent study of over **6 million people** aged 65 years or older found a 50%-80% risk for Alzheimer's in the year after COVID-19 infection. The overall risk for new diagnosis of AD in the COVID-19 cohort was close to double that of those who did not have COVID-19. Study researchers also found that the risk was especially high for women older than 85 years. **Women's chances of an Alzheimer's diagnosis following COVID was 82% higher, compared with 50% higher for men.**
3/1/2022	Findings From Mayo Clinic's Post-COVID Clinic: PASC Phenotypes Vary by Sex and Degree of IL-6 Elevation	Mayo Clinic Proceedings	Michael Peluso and Steven Deeks	**N=108**; the first patients in the Mayo Clinic's post–COVID-19 care clinic (PCOCC), evaluated at a median 149 days after acute infection. 84% of participants were not hospitalized during acute infection. **Women made up the majority of those seeking care at the PCOCC, which is similar to other studies that have reported a female predominance of long-COVID especially those that included non-hospitalized individuals.** Fatigue-, orthostasis-, and chest pain–predominant phenotypes were more common among women; dyspnea (shortness of breath) more common among men. The authors characterized fatigue-, myalgia-, and orthostasis-predominant phenotypes as central sensitization (CS) phenotypes and compared them with the dyspnea/chest pain phenotype (cardiopulmonary phenotype). Possible explanations for more women presenting for care for long-COVID include differences in risk factors for SARS-CoV-2 infection or PASC; differences in severity, organ involvement, or immune response of acute illness; differences in PASC phenotypes (more women with multisystem symptoms and no evident organ dysfunction); differences in the trajectory of post-COVID inflammation or symptoms; and differences in care-seeking behavior. Female predominance is well established in autoimmunity and other postinfectious conditions that may be related to CS, such as myalgic encephalomyelitis/chronic

Demographics of Individuals with Long-COVID				
Date	Article	Publication	Author	Key Takeaways
				fatigue syndrome, fibromyalgia, and postural orthostatic tachycardia syndrome. The inflammatory cytokine interleukin 6 (IL-6) is elevated among most of those with long-COVID, with higher levels in women and those with the CS phenotype compared with the cardiopulmonary phenotype. The consistent association of systemic inflammation and specifically elevated IL-6 with PASC across multiple studies raises the possibility of IL-6 inhibition as a potential PASC treatment.
7/22/22	Long COVID in the Long Run—23-Month Follow-up Study of Persistent Symptoms	Open Forum Infectious Diseases	Helmsdal, G. et al	**N=170.** Symptoms of long-COVID were found in 38% of participants followed for a median of 22.6 months. The most prevalent symptoms were fatigue, affected taste and smell, and difficulties remembering and concentrating. **Predictors for long COVID were older age and number of symptoms in the acute phase.**
3/29/2022	Long Covid May Become a Crisis for Black Americans, Experts Say	The New York Times	Lola Fadulu	"But health experts warn that crucial data is missing: Black Americans have not been sufficiently included in long-COVID trials, treatment programs and registries, according to the authors of a new report released on Tuesday." "We expect there are going to be greater barriers to access the resources and services available for long-COVID," said one of the authors, Dr. Marcella Nunez-Smith, who is the director of Yale University's health equity office and a former chair of President Biden's health equity task force. "So much of even getting a long-COVID diagnosis is tied to having had a positive test right at the beginning," said Dr. Nunez-Smith, adding that early on in the pandemic, many Black Americans "weren't able to secure a test and in some cases, were denied testing. She emphasized the importance of investing adequate resources into studying long-COVID. "Like everything else, without intentionality, we're not going to get to equity there," she said.

Risk Factors/Co-Morbidities				
Date	Article	Publication	Author	Key Takeaways
9/19/2022	Association of COVID-19 With Major Arterial and Venous Thrombotic Diseases: A Population-Wide Cohort Study of 48 Million Adults in England and Wales	Circulation	Knight, R. et al	A recent UK-based study analyzed the risk of blood clots after COVID-19 infection, using data from **48 million people** registered in the National Health System. Study researchers found that, among the **1.4 million** diagnoses of COVID-19, about **10,500 patients** developed blood clot-related issues. And they also found that the risk of deep vein thrombosis was almost double in people who had COVID compared to those who had not. Further, the study researchers found that the risk of blood clots stays higher than normal for about a year after COVID-19 infection.
9/15/2022	Two-Year Health Outcomes in Hospitalized COVID-19 Survivors in China | Chronic Obstructive Pulmonary Disease	JAMA	Yang, X. et al	In this longitudinal cohort study that included **1864 patients**, the most common symptoms at 2 years after SARS-CoV-2 infection were fatigue, chest tightness, anxiety, dyspnea, and myalgia, and most symptoms resolved from 1-year to 2-year follow-up, although the incidence of dyspnea showed no significant change. Patients with severe disease during hospitalization, especially those who required intensive care unit admission, had higher risks of persistent symptoms and higher chronic obstructive pulmonary disease assessment test scores.
9/7/2022	Associations of Depression, Anxiety, Worry, Perceived Stress, and Loneliness Prior to Infection With Risk of Post–COVID-19 Conditions	JAMA Psychiatry	Wang, S. et al	This prospective cohort study used data from 3 large ongoing, predominantly female cohorts: Nurses' Health Study II, Nurses' Health Study 3, and the Growing Up Today Study. **N=54,960 total participants;** N=3193 of whom did not report infection at baseline and reported a positive SARS-CoV-2 test result during follow up (1 to 47 weeks after baseline). Among participants who did not report SARS-CoV-2 infection at baseline (April 2020) and reported a positive SARS-CoV-2 test result over 1 year of follow-up, depression, anxiety, perceived stress, loneliness, and worry about COVID-19 were prospectively associated with a 1.3- to 1.5-fold increased risk of self-reported post–COVID-19 conditions, as well as increased risk of daily life impairment related to post–COVID-19 conditions. Participants with 2 or more types of distress prior to infection were at nearly 50% increased risk for post–COVID-19 conditions. All types of distress were associated with increased risk of daily life impairment (783 cases) among individuals with post–COVID-19 conditions (RR range, 1.15-1.51).
8/5/2022	Post–COVID-19 Symptoms and Conditions Among Children and Adolescents — United States, March 1, 2020–January 31, 2022	CDC	CDC	**N=781,419 patients** aged 0–17 years with COVID-19; N=2,344,257 patients aged 0–17 years without COVID-19. Compared with patients aged 0–17 years without previous COVID-19, those with previous COVID-19 had higher rates of acute pulmonary embolism (adjusted hazard ratio = 2.01), myocarditis and cardiomyopathy (1.99), venous thromboembolic event (1.87), acute and unspecified renal failure (1.32), and type 1 diabetes (1.23).Patients with COVID-19 were also more likely than were those without to develop smell and taste disturbances (aHR = 1.17), circulatory signs and symptoms (1.07), malaise and fatigue (1.05), and musculoskeletal pain (1.02).
6/28/2022	Long COVID burden and risk factors in 10 UK longitudinal studies and electronic health records | Nature Communications	Nature Communications	Thompson, E.J., et al	Key risk factors associated with increased risk in long COVID included: (1) Age — with 1.2% of 20-year-olds experiencing impacts on daily life, and 4.8% of 60-year-olds. Debilitating symptoms are roughly four times as common in 60-year-olds than 20-year-olds; (2) Being female; (3) Having poor pre-pandemic mental health and poor general health; (4) Having asthma; and (5) Those with overweight or obesity problems.

Risk Factors/Co-Morbidities				
Date	Article	Publication	Author	Key Takeaways
6/4/2022	Individuals with Diabetes are Up to Four Times More Likely to Develop Long COVID-19	AP News		One systematic review of peer-reviewed observational research studies found that 43% of studies identified diabetes as a potent risk factor for PASC. However, this conclusion is limited by the heterogeneity of studies with regard to PASC definitions (e.g., ongoing symptoms of fatigue, cough, dyspnea etc.), populations at risk (hospitalized vs. non-hospitalized populations), and follow-up times (ranging from four weeks to seven months). Quote from study co-lead author: "As time goes on, we are seeing the negative impacts that long COVID has on the daily lives of patients. Though more research is needed, we now know that patients with diabetes are at a disproportionate risk of long COVID and that these patients should be closely monitored…Careful monitoring of glucose levels in at-risk individuals may help to mitigate excess risk and reduce the burden of lingering symptoms that inhibit their overall wellbeing."
3/25/2022	Understanding Long Covid	New York Times	Johnathan Wolfe	Discusses prevalence, theories of causation, risk factors, protective effect of vaccines. Causation: "There are different theories, but one of the leading theories has to do with the body's inflammatory reaction."; "Another theory is that the body's immune response didn't shut down after the acute threat from the virus was defeated." Risk factors: latent Epstein-Barr, high viral load at initial infection, autoantibodies, and certain comorbidities like diabetes. "A couple of studies have suggested that if you've been vaccinated and are then infected with COVID, it might make you less likely to have lingering symptoms, but at least one study suggested that vaccination didn't make any difference. If you consider that vaccines, generally put you at lower risk for acute outcomes like hospitalization, then it makes sense that there might be some positive effect on reducing long-term symptoms. But having a mild COVID infection definitely doesn't prevent long-COVID— many people with long-COVID did not get very sick initially or might even have had an asymptomatic COVID infection." "There has been some skepticism about long Covid, including from primary physicians, and a lot of throwing up of hands. People may find that they go to their primary physician, and they get a scan, and nothing shows up. A lot of times there isn't anything physically that an X-ray or blood test can show…It may be better to try to seek help from a long-COVID clinic at that point where at least you will get recognition that what you're going through is a real thing and needs attention."
1/28/2022	Leave no one behind: inclusion of alpha-1 antitrypsin deficiency patients in COVID-19 vaccine trials	European Journal of Human Genetics	Yang, C., Zhao, H., and Tebbutt, S	Emerging evidence suggests that α-1 antitrypsin (A1AT) plays a critical role in preventing SARS-CoV-2 infection and may be a promising therapeutic option for patients with COVID-19. A1AT deficiency (AATD) is an inherited disease characterized by dysfunctional or insufficient levels of A1ATAs and is associated with a risk of developing COPD and asthma, which evidence suggests are associated with an increased risk of developing long-COVID. It can therefore be hypothesized that AATD individuals are at greater risk of long COVID. Patients with AATD may derive limited benefit from the current COVID-19 vaccines, but this population has not been included in the COVID-19 vaccine clinical trials and studies have yet to characterize the safety, immunogenicity, and efficacy of COVID-19 vaccines for AATD patients.

Risk Factors/Co-Morbidities

Date	Article	Publication	Author	Key Takeaways
1/25/2022	Immunoglobulin signature predicts risk of post-acute COVID-19 syndrome | Nature Communications	Nature Communications	Cervia, C. et al	The group of patients who developed long-COVID had the following characteristics: Higher percentage of severe COVID-19 cases (odds ratio 3.87; p=0.001), more often required hospitalization (odds ratio 2,55; p=0.014), More COVID-19-related symptoms during initial infection (odds ratio 1.81; p=0.001), decreased levels of two immunoglobulins, IgM and IgG3, at the time of infection and at 6-month follow up, asthmatic, and higher age (odds ratio 1.67; p=0.008). "94% of individuals with a history of asthma bronchiale developed PACS (long-COVID) and 71% developed post-COVID-19 syndrome, defined as prolonged symptoms for more than 12 weeks after symptom onset. 59% of individuals without a history of asthma bronchiale developing PACS and 42% developing post-COVID-19 syndrome" These findings were translated into a model, termed PACS score, which, when applied to our cohort comprising 134 followed-up and extensively characterized COVID-19 patients, the PACS score performed better than a symptom-based score, was independent of timepoint of testing and sex, and only required broadly available Ig measurements rather than specialized tests, such as SARS-CoV-2-specific immunoassays."
1/24/2022	Multiple Early Factors Anticipate Post-Acute COVID-19 Sequelae	Cell	Yu, S. et al	A deep multi-omic, longitudinal investigation of 309 COVID-19 patients from initial diagnosis to convalescence (2-3 months later), integrated with clinical data and patient-reported symptoms found four long-COVID-anticipating risk factors at the time of initial COVID-19 diagnosis: type 2 diabetes, SARS-CoV-2 RNAemia, reactivation of the Epstein-Barr virus (which infects most people, typically at a young age, and becomes dormant), and the presence of specific autoantibodies. The researchers state, "We find that immunological associations between PASC factors diminish over time, leading to distinct convalescent immune states. Detectability of most PASC factors at COVID-19 diagnosis emphasizes the importance of early disease measurements for understanding emergent chronic conditions and suggests PASC treatment strategies."

COVID-19 Variants and Long-COVID

Date	Article	Publication	Author	Key Takeaways
9/26/2022	Post COVID-19 condition after Wildtype, Delta, and Omicron variant SARS-CoV-2 infection and vaccination: pooled analysis of two population-based cohorts	medRxiv	Ballouz, T. et al	**N=1,350** SARS-CoV-2-infected individuals from two representative population-based cohorts in Switzerland, diagnosed between Aug 5, 2020, and Feb 25, 2022. Study researchers found strong evidence that vaccinated individuals infected with Omicron had a reduced risk of developing long-COVID, compared to non-vaccinated Wildtype-infected individuals (odds ratio 0.42). The risk among non-vaccinated individuals was similar after infection with Delta or Omicron compared to Wildtype SARS-CoV-2. No difference in prevalence with respect to the number of received vaccine doses or timing of last vaccination. The prevalence of long-COVID-related symptoms among vaccinated,

COVID-19 Variants and Long-COVID				
Date	Article	Publication	Author	Key Takeaways
				Omicron-infected individuals was lower across severity levels. In cluster analyses, researchers identified four clusters of diverse systemic, neurocognitive, cardiorespiratory, and musculoskeletal symptoms, with similar patterns across variants.
8/17/2022	Neurological and psychiatric risk trajectories after SARS-CoV-2 infection: an analysis of 2-year retrospective cohort studies including 1 284 437 patients	Lancet	Taquet, M. et al	Study researchers looked at **1.25 million people** in the UK who had been diagnosed with COVID over the last two years and found an increased risk of neurological conditions for up to two years after infection, including dementia, psychosis, and brain fog. The study researchers also found increased risk of anxiety and depression, but these subside about two months after infection. **According to the research, the newer variants of the virus (Delta and Omicron) are more likely to trigger serious mental health disorders than the Alpha strain.**
6/17/2022	Risk of long COVID associated with delta versus omicron variants of SARS-CoV-2 - The Lancet	Lancet	Antonelli, M., et al	In this UK-based case-control observational study, study researchers compared the relative odds of long-COVID during the omicron period vs. the delta period. Study researchers identified over **56,000 omicron cases** (i.e., receiving a positive test between Dec 20, 2021 and March 9, 2022) and nearly **42,000 delta cases** (i.e., receiving a positive test between June 1, 2021 and Nov 27, 2021). Study researchers found that the odds of long-COVID were 24-50% lower during the omicron wave compared to the delta wave.
3/24/2022	Different SARS-CoV-2 variants may give rise to different long COVID symptoms, study suggests	European Society of Clinical Microbiology and Infectious Diseases		Researchers did a retrospective observational study of **428 patients** treated at the Careggi University Hospital's post-COVID outpatient service between June 2020 and June 2021, when the original form of SARS-CoV-2 and the Alpha variant were circulating in the population. Patients had been hospitalized with COVID-19 and discharged 4-12 weeks before attending a clinical visit at the outpatient service and completing a questionnaire on persistent symptoms; median time between discharge and study participation = 53 days. 76% of patients reported at least one persistent symptom. The most common reported symptoms were shortness of breath (37%) and chronic fatigue (36%), sleep problems (16%), vision problems (13%), and brain fog (13%). Analyses suggest that people with more severe forms, who required immunosuppressant drugs such as tocilizumab, were six times as likely to report long-COVID symptoms, while those who received high flow oxygen support were 40% more likely to experience ongoing problems. Women were almost twice as likely to report symptoms of long-COVID.

Vaccination and Long-COVID				
Date	Article	Publication	Author	Key Takeaways
9/8/2022	You Can Still Get Long COVID If You're Vaccinated and Boosted (msn.com)	TIME	Jamie Ducharme	Studies have come to very different estimates about the degree of protection vaccines offer against long-COVID; this is because of differences in how they were designed, how long they tracked people, and how they defined Long COVID, says Dr. Ziyad Al-Aly, chief of research and development at the Veterans Affairs St. Louis Health Care System, But regardless of the exact numbers, "the common thread is vaccines do offer some protection, but it's never complete," he says. "It's partial." That makes sense because the shots weren't designed with chronic symptoms in mind, but rather to reduce the severity of acute disease, which offers some secondary benefits for long-COVID prevention.
7/1/2022	Association Between BNT162b2 Vaccination and Long COVID After Infections Not Requiring Hospitalization in Health Care Workers	JAMA	Azzolini, E. et al	**N=2260**; 739 COVID positive (89 asymptomatic); Study conducted from March 2020 to April 2022 with workers from 9 Italian health care facilities. 229 (31%) participants who tested positive for COVID had long-COVID. The prevalence of long COVID varied across the pandemic waves, from 48.1% in wave 1 to 35.9% in wave 2 to 16.5% in wave 3. (Wave 1: wild-type; Wave 2: Alpha: Wave 3: Delta and Omicron). The number of vaccine doses was associated with lower long COVID prevalence: 41.8% in unvaccinated patients, 30.0% with 1 dose, 17.4% with 2 doses, and 16.0% with 3 doses. Older age, higher body mass index, allergies, and obstructive lung disease were associated with long-COVID.
5/25/22	Long COVID risk falls only slightly after vaccination, huge study shows	Nature	Reardon, S.	A study of over **13 million** people found that COVID-19 vaccination lowers the risk of long-COVID by about 15 percent. The study used US Department of Veterans Affairs national healthcare databases to build a cohort of 33,940 individuals with breakthrough infections (BTI) and several controls of people without evidence of SARS-CoV-2 infection, including contemporary (n=4,983,491), historical (n=5,785,273) and vaccinated (n=2,566,369) controls. Compared to people with SARS-CoV-2 infection who were not previously vaccinated (n=113,474), people with BTI exhibited lower risks of death (HR=0.66) and incident post-acute sequelae (HR=0.85). Altogether, the findings suggest that vaccination before infection confers only partial protection in the post-acute phase of the disease; hence, reliance on it as a sole mitigation strategy may not optimally reduce long-term health consequences of SARS-CoV-2 infection.
5/18/2022	Trajectory of long covid symptoms after covid-19 vaccination: community based cohort study	BMJ	Ayoubkhani, D; et al	**N=28,356** aged 18-69 years who received at least one dose of an adenovirus vector or mRNA COVID-19 vaccine after testing positive for SARS-CoV-2 infection. A first vaccine dose was associated with an initial 12.8% decrease (in the odds of long-COVID. A second dose was associated with an initial 8.8% decrease in the odds of long-COVID, with a subsequent decrease by 0.8% per week. Heterogeneity was not found in associations between vaccination and long-COVID by sociodemographic characteristics, health status, hospital admission with acute COVID-19, vaccine type (adenovirus vector or mRNA), or duration from SARS-CoV-2 infection to vaccination. Conclusion: " The likelihood of long-COVID symptoms was observed to decrease after COVID-19 vaccination and evidence suggested sustained improvement after a second dose, at least over the median follow-up of 67 days. Vaccination may contribute to a reduction in the population health burden of long covid, although longer follow-up is needed."

Vaccination and Long-COVID				
Date	Article	Publication	Author	Key Takeaways
4/26/2022	Do Vaccines Protect Against Long Covid? - The New York Times (nytimes.com)	New York Times	Pam Belluck	What does the research show so far? The jury is out; there's studies showing substantial protection, some showing a slight benefit, and one showing none. Why is the research conflicting? Differences in the studies themselves: Different definitions for long-COVID; Differences in how symptoms were measured or how long patients were tracked; Studies relying on patient surveys may yield very different results than those based on electronic medical records; and Homogenous populations (VA study = mostly older, white males). Most of the data follows patients infected early in the pandemic. Some new studies include people infected with delta; omicron is too new for any studies to be done on that variant yet in regard to long-COVID. Vaccines are very effective at preventing people from getting seriously ill from infection by all the variants known so far. And many studies have found that Covid patients sick enough to be hospitalized were more likely to have lasting health issues. So, by keeping people out of the hospital, vaccines should reduce the chances of that type of long-term post-Covid case." Akiko Iwasaki, an immunologist at Yale, has said that vaccines may be able to provide lasting relief in people whose symptoms are caused by vestiges of the virus if the antibodies generated by the vaccines eliminate those remnants. But in people whose symptoms may be caused by a post-viral response resembling an autoimmune disease, she said, vaccines may help only temporarily, and problems like fatigue could re-emerge. Can getting vaccinated help if you already have long Covid? Research is once again mixed – some saw improvement in their symptoms after being vaccinated, some saw no change, some worsened.

SARS-CoV-2 and NIAID-supported Bat Coronavirus Research

An Analysis: Evolutionary Distance of SARS-CoV-2 and Bat Coronaviruses Studied Under the NIH-supported Research Grant to EcoHealth Alliance

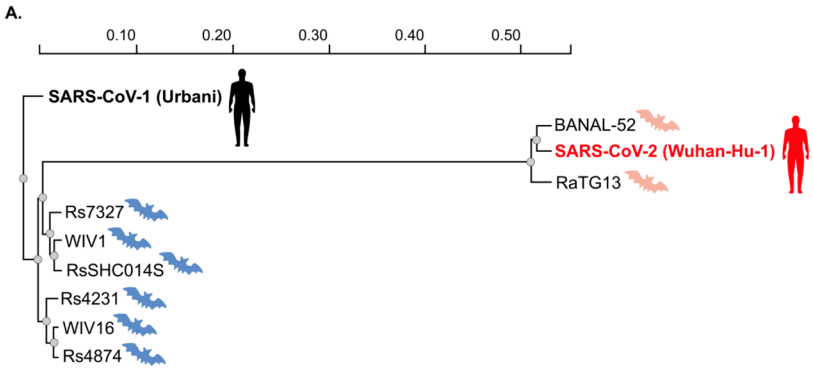
The research that NIH approved under the grant to EcoHealth Alliance with a subaward to the Wuhan Institute of Virology in Wuhan, China sought to understand how animal coronaviruses, especially bat coronaviruses, evolve naturally in the environment and have the potential to become transmissible to the human population. This research included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other occupations with high exposure to wildlife for evidence of bat coronavirus infection and analyzing data to predict which newly discovered viruses pose the greatest threat to human health.

Coronaviruses use a protein called spike to bind to a protein on the surface of a host cell to facilitate infection. Some coronaviruses, including SARS-CoV-1 (the cause of the SARS outbreak in 2003) and SARS-CoV-2 (the cause of the COVID-19 pandemic), use the angiotensin converting enzyme-2 (ACE2) protein to help enter and infect host cells. In order to study animal coronaviruses circulating in nature, the investigators replaced the spike protein from a well-characterized bat coronavirus, WIV1-CoV, with the spike protein of animal coronaviruses recently discovered in bats in China. Using techniques common in virology, experiments involved a single round of infection in several cell lines, and in some cases, in mice that were genetically modified to express the human version of ACE2. All other aspects of the mice, including the immune system, remained unchanged. The ACE2 transgenic mice were used to determine if spike proteins from bat coronaviruses discovered in China were capable of binding human ACE2, and therefore, whether the bat coronaviruses themselves, which were already present in the environment, could potentially infect humans and cause disease. WIV1-CoV is not known to cause infection in humans but has been shown in the laboratory to infect both human cells and ACE2 transgenic mice (ref), making it an ideal tool to use for these studies. Several of the bat coronaviruses used in these experiments were also found to be capable of replicating in ACE2 transgenic mice, indicating that the spike protein from the naturally occurring bat coronaviruses from which they were made could bind ACE2 in vivo.

Questions have been raised about whether this NIH-funded research had a role in the emergence of SARS-CoV-2. In this regard, the chimeric viruses that were studied (i.e., the WIV-1 virus with the various spike proteins obtained from bat viruses found in nature) were so far distant from an evolutionary standpoint from SARS-CoV-2 (Figure 1) that they could not have possibly been the source of SARS-CoV-2 or the COVID-19 pandemic. The body of the scientific data from this award including the bat coronavirus

sequences published in the scientific literature and public databases makes this conclusion readily apparent to anyone with experience in and knowledge of virus phylogeny and evolutionary biology.

Figure 1. Relationship of bat coronaviruses to SARS-CoV-1 and SARS-CoV-2.



A) A phylogenetic tree based on nucleotide sequences of indicated coronavirus spike proteins demonstrating the evolutionary distance of SARS-CoV-2 with the bat coronaviruses experimentally studied under the NIH grant to EcoHealth Alliance (blue bat icons). Bat coronaviruses most closely related to SARS-CoV-2, none of which were studied in the EcoHealth grant, are denoted with orange bat icons. The scale bar represents the number of nucleotide substitutions per site.
Credit: NIAID

B) Comparison of the nucleotide sequence identity of indicated coronaviruses to SARS-CoV-2. The left panel shows the percent identity of indicated coronavirus spike nucleotide sequences to SARS-CoV-2. The right panel shows the percent nucleotide identity of the indicated full coronavirus genomes to SARS-CoV-2.
Despite the similarity of RaTG13 and BANAL-52 bat coronaviruses (orange bars) to SARS-CoV-2 (red bars), experts agree that even these viruses are far too divergent to have been the progenitor of SARS-CoV-2, further highlighting that the bat coronaviruses studied under the EcoHealth Alliance grant (blue bars) could not have been the source of SARS-CoV-2 and the COVID-19 pandemic. Several other similarly divergent viruses that failed to replicate in cells are not shown (ref).
Credit: NIAID

The above figure shows the sequence relationships between SARS-CoV-1, SARS-CoV-2 and the naturally occurring bat coronaviruses used in experiments under the NIH grant to EcoHealth Alliance and reported in the scientific literature (ref) or annual progress reports. From this analysis, it is evident that the viruses studied under the

EcoHealth Alliance grant are very far distant from SARS-CoV-2. Included for comparison is RaTG13, one of the closest bat coronavirus relatives to SARS-CoV-2 collected by the Wuhan Institute of Virology (ref) and BANAL-52, one of several bat coronaviruses recently identified from bats living in caves in Laos (ref). Although RaTG13 and BANAL-52 are 96-97% identical to SARS-CoV-2 at the nucleotide level (>900 nucleotide differences across the entire genome), the difference actually represents decades of evolutionary divergence from SARS-CoV-2. Experts in evolutionary biology and virology have made it clear that even the closest known relatives of SARS-CoV-2, which were not studied under the EcoHealth Alliance grant, are evolutionarily too distant from SARS-CoV-2 to have been the progenitor of the COVID-19 pandemic (ref, ref). Field studies continue the search for more proximate progenitors.

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