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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, D.C.

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.

Present from Subcommittee on Oversight and

Investigations: Representatives Griffith, Duncan, Palmer, Lesko, Cammack, Rodgers (ex officio); Castor, DeGette, Schakowsky, Sarbanes, Tonko, Cardenas, Peters, Dingell, Barragan, Blunt Rochester, Craig, Trahan, and Pallone (ex officio).

Present from Subcommittee on Health: Representatives Guthrie, Burgess, Latta, Bilirakis, Johnson, Bucshon, Hudson, Carter, Dunn, Pence, Crenshaw, Joyce, Harshbarger, Miller-Meeks, Obernolte; Eshoo, Ruiz, Kuster, Kelly, and Schrier.

Staff Present: Sean Brebbia, Chief Counsel, Oversight & Investigations; Jolie Brochin, Clerk, Health; Lauren Eriksen, Clerk, O&I; 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 five minutes for an opening statement.

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 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, 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 of 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:]

**********COMMITTEE INSERT**********

*Mr. Griffith. All right. The chair recognizes the Oversight and Investigation Subcommittee ranking member, Ms. Castor, for five minutes for her opening statement.

*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 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 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 INSERT**********

*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 co-chairman of today's joint committee, Mr. Guthrie, for five minutes for his opening statement.

*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 two 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:]

326 **********COMMITTEE INSERT**********

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*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 five-minute opening statement.

*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, 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 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 under-funded 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, 18-and-a-half 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 INSERT**********

*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 five-minute opening statement.

*The Chair. 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 two 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 official 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 The Chair follows:]

**********COMMITTEE INSERT**********

*The Chair. Thank you.

*Mr. Griffith. I thank the gentlelady and now recognize the ranking member of the full committee, Mr. Pallone, for his five minutes.

*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 two 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 pre-dated 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 INSERT**********

*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 five 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.

TESTIMONY OF LAWRENCE A. TABAK, D.D.S., PHD., 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 THE HONORABLE ROBERT CALIFF, M.D., COMMISSIONER OF FOOD AND DRUGS, U.S. FOOD AND DRUG ADMINISTRATION

TESTIMONY OF LAWRENCE A. TABAK

*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 discuss 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 one 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 pan-coronavirus 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 understanding 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:]

**********COMMITTEE INSERT**********

*Mr. Griffith. I thank the gentleman. I now recognize Dr. Walensky for her five-minute opening statement.

TESTIMONY OF ROCHELLE P. WALENSKY

*Dr. Walensky. Chairs McMorris 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 three years ago, we were recording the first COVID-19 cases that sadly resulted in as many as 15,000 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 both down

nearly nine 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 three months after the bivalent vaccine was recommended, CDC scientists published data on vaccine effectiveness against symptomatic infection, and two weeks later followed up with data on how well these vaccines work to prevent severe disease and hospitalization.

Only one 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 subvariants. 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:]

**********COMMITTEE INSERT**********

*Mr. Griffith. I thank you and now recognize Dr. Califf for five minutes for his opening statement.

TESTIMONY OF ROBERT CALIFF

*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 a 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:]

**********COMMITTEE INSERT**********

*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 five 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 non-compliance 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 three 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 sub-award 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 five 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 under-served 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 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. Every single one of us has a role in misinformation 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.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Castor. 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 six months to get data use agreements 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, "Okay, 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 non-experts who are elected school board members voted down, and they met. And the kids were better off for what --the decisions that the non-experts 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. Yeah, 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 three 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. -- 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. Okay, 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 national-wide 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, 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, five 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 five 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 important

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. -- the mission --

*Dr. Tabak. -- 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. Okay. 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. -- 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. Yeah, I don't have much to add to that, except to say that there is incredible value in the independent expert opinion of non-governmental 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 five minutes of questions. Thank you.

*The Chair. 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 two-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.

*The Chair. 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.

*The Chair. 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.

*The Chair. Okay, okay.

*Dr. Walensky. So there are lots of studies now --

*The Chair. Dr. Walensky?

*Dr. Walensky. -- in Georgia --

*The Chair. 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.

*The Chair. 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.

*The Chair. So -- okay. So it is just going to continue. That is --

*Dr. Walensky. We will continue to recommend that, when there are high amounts of hospitalization, severe disease, and disease in the community --

*The Chair. 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 --

*The Chair. Yes.

*Dr. Walensky. -- yes, indeed, it is important that we recognize that our kids need to be in school.

*The Chair. Okay, yes.

*Dr. Walensky. We know that when masks don't -- when masking doesn't happen in high COVID-19 community levels, those do --

*The Chair. Okay, 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 Institute of Child Health and Human Development.

*The Chair. 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 five 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 --

*The Chair. In the office?

*Dr. Califf. -- nights and weekends.

*The Chair. 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 --

*The Chair. 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 five 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

1595 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 five minutes of questions.

*Mr. Burgess. Thank you, Mr. Chairman. I appreciate

your aggression.

Dr. Walensky, just a quick follow-up 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. Okay.

*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 policy-makers have been through hell.

There is a piece making the rounds currently, a Newsweek op ed piece written by a doctor -- or medical student, more correctly, Kevin Bass. And he observes, "It is 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 is okay to be wrong, and admit where one was wrong and what

one has learned. That is a central part of the way science worked.''

So it is with that backdrop -- and I appreciate so much Dr.-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 okay just to have the humility that we didn't anticipate that there would be that two-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. -- but there is an --

*Mr. Burgess. Will you get it for us?

*Dr. Tabak. -- a disbarment office.

*Mr. Burgess. Will you get that? Because I am --

*Dr. Tabak. Of course.

*Mr. Burgess. -- 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 health care 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. Okay, 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.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Burgess. Clearly, there is a lot of pent-up demand because of the three 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 4 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 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. Okay.

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

And also the information --

*Dr. Walensky. Workforce authorities would be incredibly helpful: overtime and danger pay. When we send somebody to Mubende, Uganda in an Ebola outbreak we want to be able to give them danger pay. Those things would help.

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 to happen.

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 five 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 answered 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 health care 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 health care workforce back because of everything that has happened with COVID?

*Dr. Walensky. Yeah, 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 , 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 a 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 sustainable funding in those areas. People often want to go back to the communities in which they were raised, but there isn’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 sub-variants: 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 and academics. It is now the case that more 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 five 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 three 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 are at Yale, who have done some of these estimates that you previously heard about in terms of 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

1992 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. Yeah, 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 make sure that we get vaccine into those pharmacies.

One of the challenges also was the multi-dose. 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 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 Healthcare Safety 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.

Okay, 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. Okay. 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 three 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 across agencies the Government can create policies. 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. Cardenas.

*Mr. Cardenas. 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 under-served 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 under-represented 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 under-served 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. Cardenas. 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. Yeah, 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 due to a digital divide, a literacy divide, or because of 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. 46 million rural Americans who have half the vaccination rates in their pediatric populations. So we really need to reach people where they are.

But, the misinformation 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 regarding misinformation and disinformation. And I would urge, again, all of us have a role in addressing misinformation and disinformation. Thank you.

*Mr. Cardenas. 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

2256 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 one billion for "vaccine confidence’’ activities. Would you say the one 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. -- 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. Okay, 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. -- specifically for COVID-19.

*Mr. Johnson. Okay. 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. Okay, 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?

2322 *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. -- 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 deployed 2,500 people into our response who had full-time previous jobs.

*Mr. Johnson. Okay. 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 five 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 one million people in one 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 health care 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 health care, 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 health care 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 affect the most vulnerable. That is how they work, 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. We wanted 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 multi-generational 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 -- eight 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 two weeks ago will be reporting to 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 three 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 re-establish 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. Yeah, 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. Okay, 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. Okay, 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. Yeah, 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. Okay.

*Dr. Walensky. I do appreciate you 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. Okay, fair enough. And I saw -- it is basically --

*Dr. Walensky. -- 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-Barre 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 increase 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.

[The information follows:]

**********COMMITTEE INSERT**********

*Dr. Califf. There is a -- it gets into details, because --

*Mrs. Dingell. I want details.

*Dr. Califf. -- 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 microbiologies 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 five 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 two years.

We still got existing vaccine and mask mandates that are -- and we have experienced diverting funds away from frontline health care 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 health care 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. Okay, I will accept that, and I appreciate that answer. That is what this was intended for --

*Dr. Tabak. And we --

*Mr. Carter. -- 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. -- to convene a government-wide 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. Okay. Then it goes on to say that -- in the 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 [sic] 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 [sic] research conducted in the Netherlands, and that was an influenza.

*Mr. Carter. Okay, 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. Okay. 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 three 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 three 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. Yeah, 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 into 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 health care 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 Community Health Information Network has saved over 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 three 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 and where our vaccines are reaching the disease.

And importantly, 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 health care 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, which includes immunization data -- to this day I can't tell you what percentage of hospitalized COVID-19 patients are immunized 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 five 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 sub-grants 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. Oft times 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 the 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, at 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, D.C. -- 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, 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 okay.

*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 certain 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 follow-up, 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 follow-up 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 five 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. Yeah, 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.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Burgess. 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 five 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 two 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.

Often times, those data are not fully completed. And so that gives us a limited view, as well. But if, through our data modernization 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 health care providers that don't really know what to do.

And Dr. Tabak, what guidance do you have for health care 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 RECOVER 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 asked for permission to enter into the record.

*Mr. Griffith. Without objection.

[The information follows:]

**********COMMITTEE INSERT**********

*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 three years have now passed since this onset of this pandemic, and I think there is 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 ACTIV 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. -- we are working towards that goal.

*Mr. Dunn. You know, Singapore studied SARS-CoV-1 and T cell immunity, literally, six, seven 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 the questions that they would like answered.

We do have programs like Vaccinate with Confidence and Let's Rise promoting vaccine confidence among racial and ethnic minorities by working with community partners and healthcare providers. 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. Tabak.

*Ms. Kelly. Tabak. 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 five 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 sub-grant?

*Dr. Tabak. The experiment in The Netherlands, I believe, was a sub-award, 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. Okay. And how, then, did the NIH know about the experiment, if it was a sub-grant?

*Dr. Tabak. It was approved under the then-DURC/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 sub-grantee, 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?

*As you know, that sub- award 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

Dr. Tabak. It is possible.

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 two years?

*Dr. Tabak. The most important point to appreciate here is that the viruses that were under study in that sub-project 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 viruses 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 multi-layered 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. Okay. 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 ACTIV 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 follow-up 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, three 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. -- 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. Yeah, so through PREVENT we were able to receive OTA, other transaction authority, but we were unable to receive the data authorities that we need and the workforce authorities that we need.

From a workforce standpoint, CDC is a response-based agency, we are but at the size, scale, and scope has changed. If we are going to be able to

3723 be -- to respond to the size, scale, and scope

required over these last three years, we need to have the authorities that other response-based agencies do: workforce hiring authorities, danger pay, over-time, as well as our data authorities.

It took us six 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. Okay. 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 employee, how many do you have, do you know?

*Dr. Califf. We have 18,000 employees in total.

*Mrs. Harshbarger. Eighteen thousand employees, but there is ten 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.

[The information follows:]

**********COMMITTEE INSERT**********

*Mrs. Harshbarger. 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 one 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 follow-up 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.

[The information follows:]

**********COMMITTEE INSERT**********

*Mrs. Harshbarger. 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 okay --

*Mrs. Harshbarger. Yes.

*Mr. Griffith. We will get that in writing later. I now recognize --

*Mrs. Harshbarger. Thank you.

*Mr. Griffith. -- Representative Tonko of New York for his five 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 two 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 follows:]

**********COMMITTEE INSERT**********

*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.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Tonko. Thank you.

*Mr. Griffith. I thank the gentleman. The gentleman yields back. I now recognize the gentlelady, Dr. Miller-Meeks from Iowa, for her five 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 non-recognition 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 one 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 six-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 one 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. -- 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 three 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 health care 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 necessarily as robust, . 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. Okay, 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. Tabak or Tabak?

*Dr. Tabak. It is Tabak.

*Mrs. Cammack. Tabak?

*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 okay.

*Mrs. Cammack. Okay, 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. Okay. 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 de-platform 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 de-platform these multiple accounts.'' These de-platforming 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. Okay. 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. Barragan.

*Ms. Barragan. 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 non-infectious 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 non-infectious diseases?

*Dr. Walensky. Yeah, thank you so much for that. I think it is critically important to recognize our role in our infectious diseases, for sure, and in non-infectious diseases, as well -- so as you know, heart disease, mental health, opioids, diabetes, cancer, in the prevention and outreach for all of those non-infectious diseases.

What I think is lost in the conversation and is 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 disease experts 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 non-fatal overdoses related to injection drug use. The co-incidence 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. Barragan. 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. Barragan. 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 five 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 mask and the vaccine. Up until 2022 CD [sic] guidance was used as a premise to keep children as young as two years old in masks on public transportation and in the schools.

One of the things that really struck me was the video of

a two-year-old and his family being kicked off a plane because the two-year-old wouldn't wear a mask. I have three kids. I remember them being two. 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. Okay. 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. Yeah, I --

*Mr. Palmer. -- 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 pre-symptomatic transmission, rather than post-asymptomatic transmission alone.

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 is 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 whether it works.

It is also the case that our masking guidance was very much related to 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. -- 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 school kids.

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 follow-up 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. Yeah, 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 health care,

and had seen that we were able to safely bring health care 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. -- 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. -- in the last seconds that I have got here is --

*Mr. Griffith. Your time is up, Mr. --

*Mr. Palmer. -- you took input from the unions --

*Mr. Griffith. Mr. Palmer, your time is up.

*Mr. Palmer. -- 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 health care 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 two 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 two 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 five 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 individuals, 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 child care 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 brand new 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 reason, I think, that we need to recognize is that ACIP recommending and CDC put forwarding the COVID-19 vaccine on the pediatric schedule 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. Okay. 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 PUL042. 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. -- and not inhibiting it.

*Dr. Califf. -- 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. -- 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 follow-up 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 follows:]

**********COMMITTEE INSERT**********

*Mr. Griffith. All right. That being said, pursuant to committee rules, I remind members -- that would be you and me, Cathy.

*The Chair. Okay.

*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.]