ASSESSING AMERICA'S VACCINE SAFETY SYSTEMS PART 1

HEARING

BEFORE THE

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC

OF THE

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

FEBRUARY 15, 2024

Serial No. 118–89

Printed for the use of the Committee on Oversight and Accountability

Available on: *govinfo.gov, oversight.house.gov* or *docs.house.gov*

U.S. GOVERNMENT PUBLISHING OFFICE
54–866 PDF WASHINGTON : 2024

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

JAMES COMER, Kentucky, Chairman

JIM JORDAN, Ohio
MIKE TURNER, Ohio
PAUL GOSAR, Arizona
VIRGINIA FOXX, North Carolina
GLENN GROTHMAN, Wisconsin
MICHAEL CLOUD, Texas
GARY PALMER, Alabama
CLAY HIGGINS, Louisiana
PETE SESSIONS, Texas
ANDY BIGGS, Arizona
NANCY MACE, South Carolina
JAKE LATURNER, Kansas
PAT FALLON, Texas
BYRON DONALDS, Florida
SCOTT PERRY, Pennsylvania
WILLIAM TIMMONS, South Carolina
TIM BURCHETT, Tennessee
MARJORIE TAYLOR GREENE, Georgia
LISA MCCLAIN, Michigan
LAUREN BOEBERT, Colorado
RUSSELL FRY, South Carolina
ANNA PAULINA LUNA, Florida
NICK LANGWORTHY, New York
ERIC BURLISON, Missouri
MIKE WALTZ, Florida

JAMIE RASKIN, Maryland, *Ranking Minority Member*
ELEANOR HOLMES NORTON, District of Columbia
STEPHEN F. LYNCH, Massachusetts
GERALD E. CONNOLLY, Virginia
RAJA KRISHNAMOORTHI, Illinois
RO KHANNA, California
KWEISI MFUME, Maryland
ALEXANDRIA OCASIO-CORTEZ, New York
KATIE PORTER, California
CORI BUSH, Missouri
JIMMY GOMEZ, California
SHONTEL BROWN, Ohio
MELANIE STANSBURY, New Mexico
ROBERT GARCIA, California
MAXWELL FROST, Florida
SUMMER LEE, Pennsylvania
GREG CASAR, Texas
JASMINE CROCKETT, Texas
DAN GOLDMAN, New York
JARED MOSKOWITZ, Florida
RASHIDA TLAIB, Michigan

MARK MARIN, *Staff Director*
MITCHELL BENZINE, *Subcommittee Staff Director*
MARIE POLICASTRO, *Clerk*
CONTACT NUMBER: 202-225-5074
MILES LICHTMAN, *Minority Staff Director*

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC

BRAD WENSTRUP, Ohio, Chairman

NICOLE MALLIOTAKIS, New York
MARIANNETTE MILLER-MEEKS, Iowa
DEBBIE LESKO, Arizona
MICHAEL CLOUD, Texas
JOHN JOYCE, Pennsylvania
MARJORIE TAYLOR GREENE, Georgia
RONNY JACKSON, Texas
RICH MCCORMICK, Georgia

RAUL RUIZ, California, *Ranking Minority Member*
DEBBIE DINGELL, Michigan
KWEISI MFUME, Maryland
DEBORAH ROSS, North Carolina
ROBERT GARCIA, California
AMI BERA, California
JILL TOKUDA, Hawaii

C O N T E N T S

WITNESSES

INDEX OF DOCUMENTS

ASSESSING AMERICA'S VACCINE SAFETY SYSTEMS PART 1

Thursday, February 15, 2024

HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC
WASHINGTON, D.C.

The Subcommittee met, pursuant to notice, at 10:02 a.m., in room 2154, Rayburn House Office Building, Hon. Brad R. Wenstrup (Chairman of the Subcommittee) presiding.

Present: Representatives Wenstrup, Malliotakis, Miller-Meeks, Lesko, Cloud, Joyce, Greene, McCormick, Comer (ex officio), Ruiz, Dingell, Mfume, Ross, Garcia, Tokuda, and Raskin (ex officio).

Dr. WENSTRUP. The Subcommittee will come to order.

I want to welcome everyone here today.

Without objection, the Chair may declare a recess at any time.

Before I move on to opening statements, I want to go ahead and advise Members, although there are very few here, that may be an advice I give again, advise Members and remind them of all the rules of decorum.

The issues we are debating are important ones that Members feel deeply about. I understand that. While vigorous disagreement is part of the legislative process, Members are reminded that we must adhere to established standards of decorum and debate.

This is a reminder that it is a violation of House rules and the rules of this Committee to engage in personalities regarding other Members or to question the motives of a colleague. Remarks of that type are not permitted by the rules and are not in keeping with the best traditions of our Committee. This is a very serious matter.

The Chair will enforce these rules of decorum at all times, and I urge all Members to be mindful of their remarks today. If the Chair finds the Member to be in violation, the Member will be suspended from speaking for the remainder of the proceedings.

I now recognize myself for the purpose of making an opening statement.

Good morning. Vaccines are a crucial public health tool which save millions of lives. As a physician myself, I've administered many doses of vaccines, especially COVID–19 vaccines. In 2020, I even volunteered to participate in the Moderna vaccine trials.

Having this hearing is not an anti-vax hearing and I am not anti-vax. I shouldn't even have to say that, but, unfortunately, I do. I'm sure, as I sit here, there are people getting ready to use that very pejorative to discredit this hearing. Unfortunately, in an era of sound bites and newscycle whiplash, it seems there is little time for nuanced conversation about these topics. Today I hope we can have that nuanced conversation about process.

Sometimes we don't know any weaknesses in a system until it is truly tested. Now is the time to safeguard for the future and about how we can do better next time if there are things we recognize that could have been done better. It's now a time to look at the things we did well, as well. But we need to restore trust in public health and the process.

I'm very concerned with the hesitancy by so many today to vaccinate their children. That's a grave concern of mine. Testifying before us today are two senior officials who lead the government's post-marketing vaccine safety systems. These systems are absolutely critical to keeping the American people safe but also to earning and preserving their trust and the trust of the physicians that care for patients.

Our witnesses will discuss how these systems work, what they can do, what they can't do, and the challenges that they face. That's a fair process. The testimony is important to design better systems in the future, as needed.

One such system, the Vaccine Adverse Event Reporting System, or VAERS, as it is well-known, is perhaps the best known of these surveillance systems. VAERS has been a source of attention and controversy since the beginning of the COVID–19 rollout.

However, concerns about these data are usually met with dismissive replies. Unfortunately, they often point to the fact that VAERS is unable to prove causality, and it contains reports of people being hit by a car after vaccination. They say that VAERS is being misused by anti-vaccine advocates and that it is misinformation. These are all legitimate concerns of the American people especially.

This seems to ignore many legitimate questions that have been raised. For example, how does the government utilize this data? We want to know.

During her testimony before this Committee last June, Director Walensky assured us that the CDC had a responsibility to comb through every single report to VAERS, if you will. It's unclear if that has happened or if that's true.

People who have submitted reports to VAERS have told my staff that they were never contacted by CDC or FDA officials. A recent British Medical Journal investigation found this, too. It seems that both sides agree that there's something wrong here.

Further, while serious injuries caused by vaccines are rare, the government has assumed the responsibility to compensate for them. In doing so, vaccine manufacturers have been shielded from liability. Therefore, the government has an important duty, one that is essential in preserving trust in vaccines and how we message completely and honestly about them.

Appearing before us today is Commander George Reed Grimes, Dr. Grimes. Dr. Grimes is HRSA's Director of Injury Compensation

Programs and oversees the Countermeasures Injury Compensation Program, or CICP, as well as the Vaccine Injury Compensation Program, or VICP. Because COVID–19 vaccines were purchased and distributed by the Federal Government under the Public Readiness and Emergency Preparedness, PREP, Act, they are covered under CICP, whereas most other widely distributed vaccines are covered under VICP.

As of January 2024, CICP has compensated 11 claims out of the more than 12,000 that have been filed for COVID–19 vaccines. Because of its design, CICP payments are also significantly smaller than VICP, an average of about $3,700 compared with almost $500,000 in VICP. So, it appears that CICP may not be designed or equipped to handle a vaccine that was so widely distributed and mandated for many as COVID–19 vaccines were.

So, I have concerns that we wouldn't be able to expect people to line up and get vaccinated during the next pandemic if they feel that in some way they're going to be abandoned.

Again, this testimony is important for designing better systems for the future and establishing best practices. I hope this hearing will provide us with an opportunity to discuss what lessons were learned during the pandemic about our vaccine safety and surveillance systems. These lessons, I believe, are critical in preparing for future pandemics, which is the mission, one of the missions, of this Subcommittee.

And I look forward to a robust and on-topic discussion about these issues. And I want to thank everyone for being here, especially our witnesses for being here.

I would now like to recognize Ranking Member Ruiz for the purpose of making an opening statement.

Dr. RUIZ. Thank you, Mr. Chairman, and thank you to the witnesses for your participation in today's hearing.

Our Nation's vaccine safety systems play a critical role in protecting public health. Every day scientists, physicians, and public health officials work together as part of this system to monitor the safety and efficacy of vaccines to ensure the best possible products reach everyday Americans.

Their efforts have helped protect us from the threat of deadly diseases for decades, and their efforts during the COVID–19 pandemic helped contribute to one of the most successful vaccine rollouts in history, which, under President Biden's leadership, led the country out of the depths of the pandemic.

In total, these efforts saved 3.2 million lives, prevented 18.5 million hospitalizations, and saved the United States an estimated $1.15 trillion in medical costs.

As a physician who went out into underserved communities to administer vaccines during the height of the pandemic, I saw firsthand the difference these vaccines made in helping our communities overcome COVID–19.

So, at the end of the day, we were able to save so many lives, prevent so much illness, and reduce a mountain of medical costs on our system because these vaccines were shown repeatedly to be safe and effective due to extensive clinical data.

And, since then, our Nation's robust vaccine surveillance systems and countless other studies have only reaffirmed the safety of these

vaccines by monitoring for and evaluating serious adverse events, which remain rare.

This system has worked well. In fact, we saw it successfully identify safety signals and vaccines during the pandemic when it detected cases of thrombosis with thrombocytopenia syndrome, or TTS, associated with the Johnson & Johnson vaccine, resulting in the CDC and FDA releasing updated recommendations for vaccine products.

So, I do want to be clear that, while adverse events are rare, they are not impossible. That is why we must continue to invest in a strong, capable vaccine safety and surveillance system that is efficient in ensuring the best quality vaccines reach the American people. And it is why we must ensure that, when an adverse event does arise, people can receive the protection and compensation that they need.

There is good bipartisan work I know we can do on this front to strengthen the National Vaccine Injury Compensation Program and Countermeasures Injury Compensation Program to make them more efficient. And I hope that discuss—I hope that we discuss those reforms here today.

Today's hearing does have the potential to generate forward-looking policy solutions that improve people's lives. However, it only does so if we approach this topic with care, because if we don't, I worry that we are opening a Pandora's box that I fear we won't be able to close again.

Right now, we are already witnessing an alarming rise in overall vaccine hesitancy, which has been fueled by mis-and disinformation spread online during the last 4 years. And, as this mis-and disinformation has festered, immunization rates among Americans have fallen for COVID–19, polio, measles, mumps, and rubella. This should be alarming to us all. We've already seen outbreaks of measles pop up in under-vaccinated communities in the last year including in Philadelphia and Columbus. And we've already seen an additional 300,000 COVID–19 deaths in the U.S. that could have been prevented if not for a growing distrust in vaccines.

I worry that the politicization of medicine, the politicization of science and vaccines will ultimately hurt us all in the end and that the manufacturing of distrust in public health norms and institutions that we have held true for so long will make us less prepared to combat a future pandemic.

For example, Republicans are already 2.4 times more likely than Democrats or Independents to believe that COVID–19 vaccines are unsafe. Childhood vaccination rates are already at a historic low, and we are already in the process of undoing decades of progress in overcoming infectious diseases. And, unless we handle each opportunity to discuss this with immense care, we are hurtling toward an even more grim future.

So, I urge for a constructive, civil conversation among us all today that focuses on strengthening our current safety and compensation programs, enhancing confidence in our public health institutions, and building a brighter, healthier future for us all.

And I yield back.

Dr. WENSTRUP. Thank you, Dr. Ruiz.

Our witnesses today are Dr. Daniel Jernigan. Dr. Jernigan is the director of the National Center for Emerging and Zoonotic Infectious Diseases at the U.S. Centers for Disease Control and Prevention.

Dr. Peter Marks, Dr. Marks is the director of the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration.

Commander Dr. George Reed Grimes, Commander Grimes is the Director of Injury Compensation Programs at the U.S. Health Resources and Services Administration.

Pursuant to Committee on Oversight and Accountability rule, the witnesses will please stand and raise their right hands.

Do you solemnly swear or affirm that the testimony that you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

Thank you. You may be seated.

Let the record show that the witnesses all answered in the affirmative.

This Select Subcommittee certainly appreciates you all for being here today, and we truly look forward to your testimony.

Let me remind the witnesses that we have read your written statement, and they will appear in full in the hearing record. Please limit your oral statement to 5 minutes.

As a reminder, please press the button on the microphone in front of you so that it is on, and the Members can hear you. When you begin to speak, the light in front of you will turn green. After 4 minutes, the light will turn yellow. When the red light comes on, your 5 minutes has expired, and we would ask that you please wrap up.

I now recognize Dr. Marks to give an opening statement.

STATEMENT OF PETER MARKS M.D., PH.D.
DIRECTOR
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

Dr. MARKS. Chair Wenstrup, Chair Comer, Ranking Member Ruiz, Ranking Member Raskin, and Members of the Select Subcommittee, thank you for the opportunity to testify before you today to discuss the Food and Drug Administration's COVID–19 response and ongoing vaccine safety efforts.

Vaccines work. We know from clear and compelling evidence that vaccines save the lives of millions of children and adults every year by producing immune responses that prevent diseases, such as measles, influenza, and COVID–19.

Though they may not provide perfect protection, vaccines can often prevent the most serious consequences of disease including hospitalization and death.

The American public can be rest assured that vaccines that are authorized or approved are safe and effective. The vaccine development process and FDA's stringent regulatory and scientific evaluation process and continued safety surveillance ensure that the health benefits of available approved and authorized vaccines far outweigh any risks.

Regarding COVID–19 vaccines, FDA helped make these critical medical countermeasures available as quickly as possible without compromising our scientific and regulatory standards.

During a once-in-a-lifetime pandemic that was a public health emergency, FDA scientists and employees worked around the clock cooperatively, intensively, and efficiently alongside researchers and manufacturers to minimize the time between the clinical development process, manufacturing scale-up, and the regulatory review process.

Hundreds of Americans were dying from COVID–19 daily at this time, and every day we could make vaccines available sooner counted. Every day counted, and we made them count.

Between December 2020 and May 2023, over 270 million people received more than 675 million doses of COVID–19 vaccines in the United States including over 650 million doses of mRNA vaccines. The COVID–19 vaccines have had a tremendous positive impact over the course of the pandemic globally, ultimately saving millions of lives since their introduction.

The vaccines continue to be among the most effective public health measures for preventing the serious consequences of COVID–19. A large part of what has made this public health success possible is the deployment of sophisticated safety monitoring. In fact, COVID vaccines are the most closely monitored vaccines that have ever been rolled out in U.S. history.

The safety of the approved and authorized COVID–19 vaccines has been monitored by FDA through both passive and active safety surveillance systems in collaboration with CDC and other governmental and nongovernmental partners.

FDA also participates in ongoing international pharmacovigilance efforts, and these are in addition to the safety surveillance efforts required of the vaccine manufacturers.

These surveillance tools work. In early 2021, just days after passive safety surveillance reporting through the Vaccine Adverse Event Reporting System detected that six out of more than 6 million patients who had received the Janssen COVID–19 vaccine had developed a rare blood-clotting disorder, CDC and FDA recommended pausing the use of that vaccine until the risk could be further evaluated.

Another example is the detection of myocarditis that occurred primarily in younger males from the use of COVID–19 vaccines, which led FDA to modify labeling and CDC to provide advice on the mRNA COVID vaccines to healthcare providers about how to reduce this risk.

Vaccines are one of the most highly effective public health measures, and they're responsible for saving millions of lives every year. The benefits of available approved and authorized vaccines in the United States when used appropriately continue to far outweigh any risks.

Staying up-to-date on vaccination has been and continues to be the best way to reduce the risk of death and serious illness or hospitalization from various infectious diseases including COVID–19.

Thank you for the opportunity to testify today. I look forward to answering your questions.

Dr. WENSTRUP. I now recognize Dr. Jernigan to give an opening statement.

STATEMENT OF DANIEL JERNIGAN, M.D., M.P.H.
DIRECTOR
NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. JERNIGAN. Thank you.

So, Chairman Wenstrup, Chair Comer, Ranking Member Ruiz, Ranking Member Raskin, and distinguished Members of the Subcommittee, it is an honor to appear before you today to discuss CDC's ongoing work to monitor the safety and effectiveness of vaccines.

I serve as the Director of the National Center for Emerging and Zoonotic Infectious Diseases at CDC, which includes CDC's Immunization Safety Office.

CDC works to protect against public health threats through prevention, detection, and response, and vaccines are a cornerstone of that work. They have played a leading role in irradicating smallpox, eliminating wild polio virus from the United States, and averting millions of illnesses and deaths from childhood-vaccine-preventable diseases.

During the COVID–19 public health emergency, over 676 million doses of COVID–19 vaccines were administered in the U.S., which are estimated to have prevented millions of hospitalizations and deaths. These public health successes have been made possible by a shared commitment to ensuring vaccines are safe.

As such, vaccine safety monitoring is a top priority for CDC, and we collaborate closely with FDA and other partners. We utilize multiple data systems in a complementary and layered approach to detect possible safety signals, investigate them rigorously, and act promptly when appropriate.

The Vaccine Adverse Event Reporting System, or VAERS, is a system where individuals, healthcare providers, and manufacturers can report adverse events following vaccination that may need to be investigated further. VAERS is not designed to determine if a vaccine caused a reported event. Rather it is an early warning system where we evaluate reports of serious adverse events and use complementary systems to further analyze potential safety concerns.

These other systems include the Vaccine Safety Datalink, which uses electronic health records for robust analysis, and the Clinical Immunization Safety Assessment Project, or CISA, which offers consultation to providers on patient-adverse events.

During the COVID–19 response, CDC also established V-safe, a smartphone app where individuals can report health impacts after vaccination. We also established a COVID–19 Vaccine Pregnancy Registry to monitor pregnancy and infant outcomes over time following vaccination.

CDC is committed to transparency and regularly shares information on vaccine safety with our Federal and state partners. And, in addition, there have been more than 30 public meetings of the Advisory Committee on Immunization Practices, or ACIP, featuring

research on COVID–19 vaccine safety and effectiveness. This approach to safety monitoring works. I'll share two examples with you and underscore Dr. Marks' comments.

The first is, during the first 6 weeks that the J&J vaccine was authorized for use, CDC identified six cases of a very rare but life-threatening blood clot through VAERS. When additional review identified a causal relationship between the J&J vaccine and the blood clot, CDC and FDA acted within days to quickly inform clinicians and the public, convened an emergency meeting of the Advisory Committee on Immunization Practices, and recommended a pause in administration of the J&J vaccine.

Further investigation led to preferential recommendation for mRNA COVID vaccines over J&J, and currently the J&J vaccine is not available in the United States.

The second example is myocarditis. In April 2021, CDC observed higher reports of myocarditis following mRNA COVID–19 vaccination, particularly in young men through the VAERS system. After confirming these events, using the Vaccine Safety Datalink, CDC quickly updated clinical considerations, while continuing to recommend COVID–19 vaccination. Further research has shown that the risk of myocarditis is substantially lower following vaccination than following infection.

As these examples show, vaccine safety monitoring by CDC and our partners is rigorous and transparent. The data continues to show that staying up to date on COVID–19 vaccines is an effective and safe way to prevent severe illness, hospitalizations, and death.

The development and administration of COVID–19 vaccines is a remarkable scientific achievement. After the most robust and comprehensive safety monitoring in our history, the science shows that we should all have confidence that COVID–19 vaccines are both safe and effective.

I appreciate the opportunity to discuss CDC's vaccine safety efforts and look forward to your questions.

Dr. WENSTRUP. Thank you.

I now recognize Commander Grimes to give an opening statement.

STATEMENT OF
COMMANDER GEORGE REED GRIMES, M.D., M.P.H.
DIRECTOR
DIVISION OF INJURY COMPENSATION PROGRAMS
HEALTH RESOURCES AND SERVICES ADMINISTRATION

Dr. GRIMES. Good morning, Chairman Wenstrup, Ranking Member Ruiz, and Members of the Subcommittee.

Thank you for the opportunity to speak with you today about the work of the Health Resources and Services Administration's Injury Compensation Programs.

I'm Commander Reed Grimes, Director of HRSA's division that overseas both the Countermeasures Injury Compensation Program, or CICP, and the National Vaccine Injury Compensation Program.

The Public Readiness and Emergency Preparedness Act of 2005, or the PREP Act, created the CICP to provide compensation for serious physical injuries or death directly caused by the administration or use of a covered countermeasure.

HRSA has received approximately 13,000 claims alleging a COVID–19 countermeasure injury filed with the CICP since the PREP Act declaration in 2020. Of these, roughly 9,600 alleged COVID–19 vaccines as the covered countermeasure. For context, the program received about 500 claims over its 10-year history prior to COVID–19.

While injuries are rare and the claims we've received for COVID–19 vaccines represent a small fraction, less than 0.001 percent of all COVID–19 vaccine administrations in this country, the caseload for the CICP is orders of magnitude higher than it was prior to 2020.

When I became Director in December 2021, I immediately focused on the need to increase the CICP's capacity to process claims. The PREP Act sets a high evidence standard for an individual to be compensated by the CICP. By law, we are required to establish that the covered countermeasure directly caused a covered injury, which must be determined based on compelling, reliable, valid, medical, and scientific evidence.

As a result, the CICP conducts medical reviews of each CICP claim to determine if it meets the statutory standard. This detailed review includes an iterative process of obtaining and reviewing comprehensive medical documentation from CICP requesters, as well as closely reviewing and monitoring the medical literature.

For compensable claims, the CICP must also collect detailed financial information, given that the program by statute can provide compensation only after other third-party payers.

At the time of the PREP Act declaration in 2020, the CICP had no direct appropriation and only four staff. We requested and Congress provided a direct appropriation for the first time in the history of the program in Fiscal Year 2022. With these funds, we've been able to increase hiring and now have over 35 full-time staff working to process claims.

We've also implemented other key process improvements to resolve claims at a faster rate. In 2023, we averaged more than 90 claims resolved each month, which is up from zero per month the year before I started in this role.

Additionally, we're improving information technology and other communication channels with requesters. While the program has made significant improvements, there's more to be done. The President's Fiscal Year 2024 budget requested $15 million to operate the CICP. With these funds, we want to continue to increase our capacity to analyze and resolve claims including through increased staffing and IT infrastructure improvements.

We are committed to working with Congress to meet the program's resource needs to increase the rate of CICP claim resolutions.

The CICP is also in the process of establishing an injury table for COVID–19 vaccine injuries that are presumed to be directly caused by a covered countermeasure. In order to establish this table, HHS must meet the high evidence standards set by Congress. The injury table is another tool that will allow us to streamline the claims review process and more expeditiously address requests.

Finally, I wanted to address the National Vaccine Injury Compensation Program, or VICP. The VICP was established under a different statute, the National Childhood Vaccine Injury Act of 1986. For a vaccine to be covered under the VICP, certain conditions must be met, including a recommendation from the CICP for routine—from the CDC for routine administration to children or individuals who are pregnant, and the vaccine must be subject to an excise tax. COVID–19 vaccines currently do not qualify for VICP coverage, which would require congressional action.

We at HRSA are diligently carrying out these programs as directed by Congress and thank you for the opportunity to be here today to discuss HRSA's work. And we look forward to continuing to work with Congress on these critically important programs.

Dr. WENSTRUP. Thank you all very much for your testimony.

I now recognize myself for questions, but I just want to say a couple of things before we start.

You know, I want everyone to understand, especially those serving on the government side, that public perception becomes reality. And, because of that, words matter. Words matter that are coming out, you know.

And, for those of us as Members of Congress or as physicians at home, we're face-to-face with people. We are sitting face-to-face with somebody. We're not just looking at data on a sheet and making decisions. It needs to be done, what you're doing, but there's a difference. And that's why I say words matter.

Let me give you an example. When you say, "safe and effective," that's relative in your mind. It's relative in your mind, but it's not to the person at home. They hear 100 percent safe and 100 percent effective. That's what they hear. This is why words matter.

Dr. Fauci, in his testimony even said you can never say that any treatment is 100 percent safe. Yet, in essence, that's what people heard and are still hearing today. We've got to change that because the doctor on the ground or the Member of Congress on the ground is one on one with somebody and explains that to them hopefully.

Yes, this vaccine saved hundreds of thousands of lives. I'll advocate for that anytime, and that's why I was for emergency use, because people were dying, and we knew from the trials that it could save lives and keep people out of the hospital. But we also knew that you could still get COVID. We never really heard that from the Federal level. We just heard it's safe and effective.

Now we have a society that thinks that the polio vaccine and the other vaccines aren't necessarily safe and effective the way they have been.

We never explained mRNA technology is different from the technology of the other vaccines that have been around forever. And you lump them together.

When people come to my office to tell me, "I had an adverse event of some type," I'm one on one with them. It's not just something on a piece of paper.

So, words matter. That's one of the things I want to stress across the board from this Subcommittee at the end of the day.

Early on, I will tell you that I even said to Secretary Azar, America needs to be hearing from the doctors treating COVID patients, not the politician who says, "If Trump makes this vaccine, I'm not

taking it." Is that helpful? We needed to be hearing from the doctors treating COVID patients, the doctors administering the vaccines, the doctors that were trying to save lives. That's who the public needed to hear—be hear about—hear from. We have to be careful with our words.

I'm grateful, Dr. Jernigan. Today you gave the caveat, didn't you? You said it kept you from being—in most cases it kept you from being hospitalized or dying, especially if you're amongst the most vulnerable. I appreciated that. That's the type of messaging we have to have going forward.

Let me tell you I'm grateful we live in a country that has these systems in place because they're there to protect the American people and to provide for better health in America. But there's ways we can do better, and that's what I want to talk about today.

So, I'm going to start by asking this question about vaccine safety surveillance as we get into that.

I want to ask each of you this question or at least Dr. Jernigan and Dr. Marks. Yes or no, is any pharmaceutical 100 percent safe?

Dr. MARKS. Thanks very much for that question, Chair Wenstrup.

No pharmaceutical is 100 percent safe. In fact, even the water we drink is not a hundred percent safe. If you drink too much of it on a hot day, you can die from complications of water poisoning.

Dr. WENSTRUP. Well said.

Dr. JERNIGAN. Yes, thanks for the question.

You know, as clinicians, we all recognize that no medical intervention is risk-free.

Dr. WENSTRUP. And I'll go to Dr. Grimes. You know, you—you've—there's a reason we have a compensation program.

Dr. GRIMES. Yes, sir. So, there's a reason we have a compensation program, and we're dedicated to diligently carrying that out.

I can't say it any better than my colleagues sitting next to me have.

Dr. WENSTRUP. Thank you.

So, it is important that we properly surveil for these inevitable injuries, unfortunately inevitable injuries, no matter how many or how few.

Would you agree with that, Dr. Marks?

Dr. MARKS. Chair Comer, I would agree fully with that, that if we want to maintain confidence in the vaccines and the other medical products that we authorize or approve, we must have very robust safety surveillance systems in place.

Dr. WENSTRUP. Dr. Jernigan

Dr. JERNIGAN. Yes, I agree that we really need those complementary layered and comprehensive and multiple vaccine safety monitoring systems.

Dr. WENSTRUP. Dr. Grimes?

Dr. GRIMES. Thank you. I couldn't agree more.

Dr. WENSTRUP. And I agree with that.

Do you feel that what we currently have is sufficient? And I don't mean that in an adversarial way. I mean, what are some of the things you think we could do better?

And, as I said at the beginning, sometimes it takes something like a pandemic to recognize where we can do better and so in

that—in the vein of surveillance system being sufficient, any ideas that you could add to that?

Dr. MARKS. Chair Wenstrup, thanks so much for that question.

I believe we had very good safety surveillance mechanisms in place that included overlapping systems, including passive and active systems, but I do believe we could do better.

I think there were challenges in getting data in real time that limit us in our ability to understand what was happening on the ground. And hopefully we can work better together with all of the individual states to have a more unified safety surveillance system, should this ever happen again or, for that matter, even on an ongoing basis for our medical products.

Dr. WENSTRUP. Thank you.

Dr. Jernigan.

Dr. JERNIGAN. Yes, I think throughout the pandemic, we stood up really the most intensive vaccine safety monitoring in U.S. history. We really see the benefits of having a robust vaccine safety monitoring system, and sustaining that is going to be a critical feature for us moving forward.

Dr. WENSTRUP. Dr. Grimes.

Dr. GRIMES. And I would defer to my colleagues to my right. They're the experts in the field.

Dr. WENSTRUP. Fair enough.

One of the things, as I had the pleasure of meeting with you all individually ahead of time, what occurred to me in hearing some of the concerns, especially, you know, this pandemic came on quickly and you had workforce challenges, if you will, understandably, considering that in every component of what you do.

And one of the ideas I have is that I'm an Army Reservist. One of the ideas I have is we have a Reserve Component in each one of your categories of interest where we can call up experts in the field that can handle the increased load during a pandemic. To me, that would really aid our national security and our national health security.

And so, it's just a thought, but I'd love to get your opinions on it because I know you face many challenges by the overload of what took place.

Dr. Marks.

Dr. MARKS. Chair Comer—sorry—Chair Wenstrup. Sorry. Chair Wenstrup, thank you so much for that question.

I really appreciate the opportunity to reflect on this issue. When the pandemic happened, we at FDA were dealing with our usual files that we have. There are many vaccines that are important for everyday life, measles vaccine, et cetera, that we have to review. So, we didn't have a cadre of people to just move over, and so we had to pull people to work on the COVID–19 vaccines. And many of them had to learn how to deal with Emergency Use Authorization.

I couldn't agree with you more that if we had a cadre of people ready to move over, very familiar with Emergency Use Authorization, and able to quickly move to reviewing vaccines in a pandemic settings, that would greatly help us in the future.

Dr. WENSTRUP. Thank you.

Dr. Jernigan.

Dr. JERNIGAN. Yes, thank you.

I think you pointed out the workforce. And, certainly in public health, both at the state, territorial, tribal level at CDC, we have an aging workforce. We need more public health people working in the field.

We at CDC really are having to act as a response agency and really not structured that way. So, having some additional ways to quickly mobilize folks to stand up systems quickly, to implement innovations very rapidly, that really requires a robust workforce that we really need going forward.

Dr. GRIMES. Thank you for the question.

I think we in the CICP at the beginning of the pandemic had four staff, as I mentioned in my opening comments. And we needed to scale up to do the volume of the work, and that is one of the things that we look to for the future are those opportunities and strategies to optimize scalability and flexibility to perform the essential functions of our critical programs.

Dr. WENSTRUP. Yes, I appreciate that. As somebody who's endured mass casualty events, you know, to be able to be prepared for that or at least have the call-up ability to do that, I think that's something that I hope that we can look into as a Congress to consider that type of reserve workforce that's ready to go on day one.

As of February 2024, VAERS reports for COVID–19 vaccines total significantly higher than all other vaccines combined since 1990, as reported. This is a surprising figure.

Dr. Marks, was the government prepared for such an avalanche of reports to VAERS? And it kind of goes with what we just mentioned. So——

Dr. MARKS. Chair Wenstrup, thank you so much for that question.

And I apologize about your name before. It shows when you're nervous, things can happen.

But your—the point is extremely well taken. We try to be prepared for that, but the avalanche of reports was tremendous. And it, again, required retasking people on the fly to, I think, for—and I'll let my CDC colleagues speak to this. We had to usually staff up and had many meetings, working to increase our ability to go through these reports, because, as you already mentioned, the—what the public sees on the public VAERS page is just a small fraction of the information that we ultimately collect and sift through that is very important to determining whether an adverse event is truly related to the vaccine.

Now one of the criticisms that we often receive is that we don't make that additional information available, and I would say to you that it's a challenge because what we've learned is it's very challenging to make available essentially protected health information, because if you have a ZIP Code that someone was pregnant, you know, if you have a ZIP Code of someone in Akron, Ohio, that they were pregnant and they had COVID, you could potentially reidentify them.

So, this is one of the challenges we face in making available information, but I think we'd like to work to make the most information available as possible.

Dr. WENSTRUP. Do you have any concept on that, Dr. Marks? As far as this number, you know, childhood vaccines, they are spaced out. This was a vaccine that was being administered to a—would it be a larger swath of the population? Was the number higher but maybe the same per capita, if you will? Does that make sense, the question?

Dr. MARKS. Yes, so I can't think—you know, our seasonal influenzae campaigns often administer about 150 million doses over the course of a number of months. Here we had, you know, millions of doses rolled out really on top of each other at a tremendously rapid rate.

And, in addition, we encouraged people. Part of the Emergency Use Authorization process, we were encouraging safety reporting because we felt we needed to know about any potential adverse events so we could try to investigate and find out if there was something we were missing.

Dr. WENSTRUP. Did you have anything to add to that, Dr. Jernigan?

Dr. JERNIGAN. No, I think that covered—covered a lot.

Dr. WENSTRUP. I now recognize Dr. Ruiz for 5 minutes—for questioning.

Dr. RUIZ. Today's hearing comes at a pivotal time in the ongoing efforts to fortify declining vaccine confidence, one of the greatest public health challenges of our time. And I agree with the Chairman; words matter. And what we say here today will have significance ramifications on whether millions of Americans will continue to place their trust in safe and effective vaccines including the COVID–19 vaccine.

Before I get to my question, I'd like to enter into the record a letter the Select Subcommittee received from more than 50 medical and public health organizations and experts ahead of today's hearing.

There you go.

Dr. WENSTRUP. Without objection.

Dr. RUIZ. This letter, which was led by Vaccinate Your Family and signed by a broad coalition that includes the American Academy of Pediatrics, the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, the American Public Health Association, the American Heart Association, Doctors for America, and many more warns us of the potential damage that could be done if today's hearing fails to handle the subject of vaccine safety carefully and without bias.

And, just this morning, a group of six leading medical societies representing more than 560,000 physicians issued a joint statement with a similar warning, calling on the Select Subcommittee to, quote, "Acknowledge the overwhelming evidence-based science and recognize how COVID–19 vaccines protect and save millions of lives."

I'd also like to enter this statement into the record.

Dr. WENSTRUP. Without objection.

Dr. RUIZ. Now as a physician and as Ranking Member of this Select Subcommittee, I want to ensure that today's conversation remains rooted in the facts. And the facts are that, while delivering effective COVID–19 vaccines to the American people at a historic

pace, our Federal public health officials went to painstaking lengths to evaluate their safety, and they are continuing to do so.

Dr. Marks, your division of the FDA is responsible for evaluating clinical trial data to authorize and approve products including the COVID–19 vaccine. Could you please explain for us the rigorous standards the FDA has followed in its authorization and approval processes for the COVID–19 vaccines?

Dr. MARKS. Thanks so much for that question, Ranking Member Ruiz.

The COVID–19 vaccines, the—before we even started to receive data, we put forth guidance, first in April and then subsequently in October 2020, which described our expectations for the safety and the efficacy of these vaccines. That's the standard that we would use before we could issue an Emergency Use Authorization.

We then for—the initial Emergency Use Authorization required manufacturing data that was equal to what we would have or nearly equal to what we would have required for a biologics license application, and we required effectiveness data that was near or equal to what we would have required for a biologics license application.

We couldn't speed up time. So, we, in order to get the vaccines to people in need, when thousands of people were dying, we actually allowed the safety to be authorized with just 2 months of median followup rather than the normal 6 to 12, but we were confident that that would capture adverse events. So, we had good safety data.

And then, when we went to finally do the biologics license application, we go through very large datasets. For instance, the Pfizer vaccine had 43,000 people involved in clinical trials, about 21—22,000 of whom had received the vaccine initially, and then thousands more received it after 6 months.

So, we went through a tremendous amount of data, looked at the adverse events, and looked at the effectiveness data. So that, plus looking carefully at the manufacturing.

Dr. RUIZ. And what has the clinical trial data shown regarding the safety of the COVID–19 vaccines?

Dr. MARKS. The safety of the COVID–19 vaccines includes that there are some initial discomfort potentially in the arm, fatigue that could occur. And there are rarely more serious side effects. We identified myocarditis and rare allergic reactions and, thankfully, by putting mitigation strategies in place, both of those have been decreased in occurrence.

Dr. RUIZ. Dr. Jernigan, your division at CDC is responsible for operating surveillance systems that detect adverse health effects, mild or serious. Could you please explain the multitiered system that CDC has in place to monitor for safety concerns regarding vaccines that have been brought to market?

Dr. JERNIGAN. Sure. Thanks for the question.

And, you know, like I said, we've been putting through the most intensive vaccine safety monitoring in U.S. history, and that at CDC includes five different systems.

The first of those is the Vaccine Adverse Event Reporting System that we talked about, which is essentially an open door to get those reports in.

The second is the Vaccine Safety Datalink, which is a very large electronic health records, about 13.5 medical records in it, where we look for trends.

We have a pregnancy monitoring system. We have a Smartphone-enabled app called V-safe. And we have a Clinician Immunization Safety Assessment Program where we have medical experts that can provide input into the safety monitoring.

That system has been tremendous in us being able to follow what's going on with vaccine issues.

What we've found so far, at least with the Vaccine Safety Datalink, is that there are lower rates of death in those that are vaccinated compared to the unvaccinated, and there are lower rates of cardiac complications compared to those that have been unvaccinated.

What we're looking for in that VAERS system and these other systems is for signals of things that might be a problem that we need to followup on.

I think this process works. We were able to find, like we mentioned in our opening statements, there were six cases of a blood clot problem, a very rare problem that we identified very early. We were able to communicate that to clinicians, communicate that, and follow a science-based process that we have at CDC where the science is evaluated. The data is analyzed. It's provided to the Advisory Committee for Immunization Practices. And we know that the Committee advises and provides it to the director to decide.

So that process, that science-based process is what we've been following, utilizing the data.

Dr. RUIZ. So, let's talk about the VAERS for a second. So that is a system where individuals can report their system—symptoms that they believe may be associated with the vaccine.

How do you then determine if it, in fact, is associated with the vaccine or it's not associated with the vaccine?

Dr. JERNIGAN. Yes, so VAERS is a—it's essentially front door where anybody——

Dr. RUIZ. It's a screening mechanism.

Dr. JERNIGAN. Correct. They can put in anything they think may be associated with that vaccine. That means that we have a lot of reports that may not exactly be associated with the vaccine, but there's a process for reviewing those.

Every serious adverse event in VAERS is followed up, medical records are collected, and autopsy records are collected to identify that.

We don't use VAERS to determine if an adverse event is caused by the vaccine. We don't use it to look at trends about whether the vaccine's more commonly causing a problem versus what's in the general population. We use different datasets to do that.

Dr. RUIZ. So, one can't subscribe the data from VAERS to being the actual rate of death or serious illness because that—that is an initial screening, and then the investigation that occurs afterwards will determine whether it was, in fact, related to the vaccine or not.

Dr. JERNIGAN. Correct.

Dr. RUIZ. So, then there are cases, for example, where death was reported that you found that it wasn't due to the vaccine, correct?

Dr. JERNIGAN. Correct. So, for instance, a hospice patient who is one of the more vulnerable people that we do want to get vaccinated, they may have a standing order for "do not resuscitate." And so that patient may die 2 days after getting the vaccine, but it really may not be associated with the vaccine.

There are reports of vehicle injury in folks that have been vaccinated. There are even reports of family members who died for—caring for a vaccinated patient, but the death was not in the vaccinated patient—who had not been vaccinated.

So, there are a number of those reports. But what we want is to be able to say: What's the impact of those vaccines? And we look to other datasets to really give us that information.

Dr. RUIZ. Thank you.

And as I mentioned in my opening statement, this rigorous surveillance system has demonstrated its effectiveness for the COVID–19 vaccines, detecting exceedingly rare cases of thrombosis with thrombocytopenia syndrome, or TTS, among patients who receive the J&J vaccine, for example.

Dr. Jernigan, could you explain how the detection of these cases reflects the effectiveness of CDC's vaccine safety surveillance system?

Dr. JERNIGAN. Yes, I think these indicate that the process works. You mentioned the TTS associated with the J&J vaccine. The systems have been able to pick up myocarditis and show that risk of getting myocarditis is much lower among those vaccinated than among those that were unvaccinated.

It's even a system that we've been able to pick up signals that turn out not to be signals.

Dr. RUIZ. Uh-huh.

Dr. JERNIGAN. So, something called ischemic stroke can occur, and we picked up a signal, but when we continued to follow it, it went away.

So, we get signals that sometimes are there, sometimes aren't. But it allows us to see things early so that we can act quickly and change recommendations when needed.

Dr. RUIZ. Thank you.

And, Dr. Marks, my understanding is that, following the detection of these cases, FDA limited the use of the J&J vaccine. Could you explain FDA reached this decision?

Dr. MARKS. Ranking Member Ruiz, thank you for that question.

So, we evaluated the data that came in regarding the vaccine itself, the J&J vaccine. There were also another—there was another vaccine that was like that vaccine that was being used outside of the United States, which had a similar issue. We looked at the totality of those data.

And then we changed the fact sheets for providers and for patients, making a recommendation that this not be kind of the first-line vaccine to be used but that it be used in those where a single-dose vaccine, which that particular vaccine was—was desirable rather than a two-dose regimen.

Dr. RUIZ. And so, in this instance, our surveillance systems worked as designed, detecting rare but serious adverse events and informing a policy decision to best protect patients and consumers. Is that correct?

Dr. MARKS. That's correct.

Dr. RUIZ. And what would you say to Americans who may believe that action taken to address rare adverse events with the J&J vaccine draw into question the safety of the broader universe of COVID–19 vaccines?

Dr. MARKS. I would say that this—the—I think what we see here in vaccine safety surveillance that may be confusing for the public sometimes is that, as an amateur radio operator, I sometimes listen to very weak signals, and sometimes that means you turn up the gain.

We have the gain of our vaccine safety surveillance system turned up very high. That's the ability to detect signals. That means sometimes we hear things that turn out not to be true, as Dr. Jernigan just noted.

I think we have the gain turned up high, and we've appropriately found signals, and we continue to look for signals. We sometimes find them.

And, as I speak, we're in the process of evaluating whether there are signals that have been detected are real or whether they turn out to be just a statistical anomaly.

Dr. RUIZ. So, I'm not an amateur radio guy. I'm a doctor. And it kind of sounds like what you're talking about is specificity and with—or sensitivity. And so, you know, it sounds like we want to detect as much as we can and then rule out the false positives, correct?

Dr. MARKS. So, in doctor's language—sorry——

Dr. RUIZ. Yes.

Dr. MARKS. This is the idea here is indeed to have a very sensitive system to pick up any signal, and then we then go back and try to make sure it's truly related to the vaccine. Thank you.

Dr. RUIZ. So, I hope my colleagues will heed the warnings we received ahead of today's hearings and keep our discussions rooted in objective information. Public confidence in vaccines, which have saved millions of lives and continue to be the most significant public health intervention of our time, is not something that should be undermined for partisan gain.

So, I thank you, and I yield back.

Dr. WENSTRUP. I now recognize the Chairman of the full Committee, Mr. Comer, from Kentucky for 5 minutes of questions.

Mr. COMER. Thank you, Mr. Chairman.

I want to talk about the vaccine approval process and some safety signals that were downplayed.

Dr. Marks, Pfizer submitted their full approval application on May 18th, 2021, correct?

Dr. MARKS. That's correct.

Mr. COMER. And January 18, 2022, was the original required action due date, correct?

Dr. MARKS. That's correct.

Mr. COMER. And you worked with Dr. Philip Krause and Dr. Marion Gruber on this, correct?

Dr. MARKS. That's correct.

Mr. COMER. Thank you.

When Pfizer submitted the application, Dr. Krause and Dr. Gruber oversaw the approval process. According to documents and

testimony, they believed they could and should approve the vaccine faster than 8 months. They proposed the end of October 2021. You, Dr. Marks, requested September 15, 2021. They hesitated, but obliged. You, Dr. Marks, then said you wanted it approved even faster than September 15, but they declined.

According to them, after they declined, you and former FDA Commissioner Janet Woodcock relieved them from their roles in the approval process. They said that they felt, quote, "substantial pressure," unquote, from you to approve this vaccine faster than they thought was defensible.

My question is, did anyone instruct you to speed up the approval timeline faster than September 15, 2021?

Dr. MARKS. Chair Comer, thank you for that question. I think it deserves an explanation.

But what was going on during that summer that changed the situation was, in the week ending July 10th of 2021, there were 1,645 deaths; in the week ending August 14th, there were 9,406 deaths.

There were an increasing number of deaths from COVID–19, and there was clear knowledge that having an approved vaccine would help Americans feel more comfortable getting vaccinated. So, we felt speeding up the vaccine approval process——

Mr. COMER. So let me interrupt. Did anyone instruct you, or is this just a decision you made on your own?

Dr. MARKS. This was a decision that I had made on my own.

Mr. COMER. So why were you pressuring the doctors and then removing them from the approval process when they disagreed?

Dr. MARKS. The approval process was one that was—needed to move as rapidly as possible. One of the physicians——

Mr. COMER. OK. Let me—let me—we may go back to that.

Do you recall any conversations regarding the need to approve the vaccines in order for it to then be mandated?

Dr. MARKS. There was an acknowledgment that an approval could allow vaccine mandates to occur, but they were not conversations over that, that it were——

Mr. COMER. So, Dr. Gruber wrote that you and Dr. Woodcock expressed your opinion that absent a license states cannot require mandatory vaccination. Do you recall this conversation?

Dr. MARKS. I don't know what you're referring to, but I—there is probably—it's just a statement of fact that that once you have a licensed vaccine, a mandate could be placed.

Mr. COMER. Do you recall why Dr. Gruber and Dr. Krause expressed concern about accelerating the approval of the vaccine?

Dr. MARKS. They were concerned about the workload.

Mr. COMER. OK.

Dr. Gruber wrote that taking a thorough approach was important because of increasing evidence of association of this vaccine and development of myocarditis, especially in young men.

Do you recall seeing safety signals regarding myocarditis in young men during this time?

Dr. MARKS. There were—yes, there were safety signals known, and they were placed on the label.

But, Chair Comer——

Mr. COMER. Let me finish. Did you ever have any conversations regarding the vaccine approval with the Department of Defense?

Dr. MARKS. I can't recall any conversation directly with the Department of Defense.

Mr. COMER. Did anyone else at FDA have conversations regarding the vaccine approval with Department of Defense?

Dr. MARKS. I can't speak to the conversation of others I'm just not aware of.

Mr. COMER. Did you express your desire to approve the vaccine by August 20th?

Dr. MARKS. I did.

Mr. COMER. And it was ultimately approved on August 23d, correct?

Dr. MARKS. Correct.

Mr. COMER. And just for the record, the military mandate was issued on the 24th, and that is interesting timing.

Thank you, Mr. Chairman, and I yield back the balance of my time.

Mr. WENSTRUP. I now recognize Mrs. Dingell from Michigan for 5 minutes of questions.

Mrs. DINGELL. Thank you, Mr. Chairman.

I am concerned that America's confidence in—in the safety and efficacy of vaccines is of critical importance to our Nation's public health. For hundreds of years, dating back to 1796 and cow pox, vaccines have saved lives and reduced the threat of deadly diseases, from polio to measles to COVID–19.

However, we are now witnessing a startling decline in immunization levels across the board. And I'm deeply concerned about what this means for our Nation's ability to respond to public health threats in the future. We're having measles breakouts. We've got one in Washington, DC, from exposure at the airport.

So, I want to focus on what we can and should do to promote vaccine confidence with constructive reforms that enhance community engagement and strengthen the vaccine systems.

One way I think we can go about this is approaching people with compassion, but making sure that their questions are answered honestly, with trustworthy, accurate information that breaks through some of the noise, by the way, that's a lot of false information online.

During the height of the pandemic, Democrats passed the American Rescue Plan, which not only helped get vaccines out to the American people but also invested in community-based outreach programs to help increase vaccine uptake. These programs focused on meeting people where they were, to equip them with transparent, reliable information about vaccine safety and development.

Dr. Jernigan, I'd like to get your thoughts—short, because I have some other questions. How does the CDC work to proceed people with timely, accurate information regarding vaccine safety and efficacy?

Dr. JERNIGAN. Thanks. Yes, at CDC, we are committed to transparency, and we regularly share that information on vaccine safety with our Federal partners, state partners, through our different communication mechanisms that we have—through the web, through other media, et cetera.

Mrs. DINGELL. So, I think it's important that people know about the known side effects of the vaccine or rare adverse events that may occur after vaccination.

The Subcommittee is probably tired of hearing me talk about getting Guillain-Barré after a swine flu shot—which, by the way, I was mandated to get and assured that it was safe and effective, and it was obviously neither.

And I was scared to death to get this COVID vaccine. I sought out accurate information from physicians at U of M and any doctor I knew walking down the street—some of them may not have been qualified—to reassure me about the safety of the COVID–19 vaccine. And I finally did get it, and prepared to die. But, unfortunately, I'm still here giving everybody a hard time—well, fortunately. I shouldn't say it that way.

But, ultimately, I supported the Biden administration's commonsense policies to increase vaccine uptake because I believed we had systems in place. The systems that we're discussing today were working to ensure that adverse events could be detected and meaningfully addressed.

Dr. Jernigan, can you please speak to the ways in which the CDC provides transparent information regarding rare adverse events that may occur from various vaccines, including COVID–19 vaccines?

Dr. JERNIGAN. Thanks.

So, as we mentioned, there are a number of different surveillance systems that we monitor. Once we see any signal there, we communicate that to the general public, to the healthcare providers. We provide that information to the Advisory Committee, and then recommendations can be changed.

So, we are committed to transparency. We provided information on risk-benefit analysis at 30 different ACIP, Advisory Committee, meetings over the last 3 years. So, we get that information out so people can understand.

Mrs. DINGELL. So do you think doctors are getting it.

And what steps do you think Congress should take to support and strengthen these efforts? For example, what role does comprehensive funding from Congress play in CDC's ability to operate these surveillance programs?

Dr. JERNIGAN. Certainly, we want to work very closely with healthcare providers. It's really that connection between the healthcare provider and the patient that is where the decisions and the understanding comes from many times. We want to get that information out.

We have safety systems right now that were at one level before the pandemic, are at a very high level now in terms of the activities that we're doing. And we are not needing to go back to where we were before. We need to sustain those systems that are broad now, help us with new vaccines that come out, get the most information about safety.

Mrs. DINGELL. So, in the rare instances when something does go awry and an adverse event occurs, people need to know there is protection and compensation available to them should they need it.

Commander Grimes, how do our Nation's vaccine compensation programs work to adjudicate valid claims or compensate individuals as quickly as possible?

Dr. GRIMES. Thank you, ma'am, for that question.

So, the Countermeasures Injury Compensation Program, or the CICP—we're required by statute to make a determination based on the compelling, reliable, valid, medical, and scientific evidence that a serious physical injury or death was directly caused by the countermeasure.

We have at least three advanced practice providers that review each claim. And a claim is reviewed for legal sufficiency to ensure that it meets with the statutes set by Congress.

Mrs. DINGELL. Thank you, Mr. Chairman. I'm out of time. But I hope we all will work together to make sure people do keep confidence in—vaccines prevent death, ultimately.

Dr. WENSTRUP. I now recognize Ms. Malliotakis from New York for 5 minutes of questions.

Ms. MALLIOTAKIS. Good morning, and thank you, Mr. Chairman, for holding this important hearing on vaccine safety and injury compensation.

I would like to extend my gratitude to all the witnesses for taking the time to share their expertise with us today.

In March 2020, our world experienced a profound and undeniable shift, and the rapid spread of COVID–19 brought both fear and uncertainty. Then, in an extraordinary triumph of science innovation, a vaccine was developed in record time. This groundbreaking moment held the promise of protection and a return to normalcy.

However, subsequent actions, from overstating vaccine efficacy to the implementation of sweeping mandates and the suppression of open scientific debate, eroded public trust, and these decisions left lingering questions about vaccine safety, sparking both valid concerns and unfounded fears.

We have systems expressly designed to monitor for vaccine-related harms and provide recourse for injuries. Unfortunately, the actions surrounding the COVID–19 vaccine have highlighted areas where these systems may have fallen short. And we can start rebuilding trust for safe and effective vaccines in the future. After all, we do know that vaccines really are oftentimes lifesavers.

But I do want to point specifically to the concerns about post-vaccination heart issues, particularly myocarditis in young people. In fact, myocarditis is one of the injuries that have been compensated for.

And I'd like to know from both—either Dr. Jernigan or Dr. Marks, what specific monitoring—or, I guess, safety monitoring or research projects are currently underway by the CDC or the FDA to delve deeper into this issue?

Dr. MARKS. So, I'm happy to start. Thank you for that question.

We have had multiple go-rounds in our adverse event reporting systems that use active surveillance—one of them is called the BEST System—to look among large data bases—claims data bases and electronic healthcare records—to look at the incidence of myocarditis in vaccinated individuals versus nonvaccinated individuals.

And some of that work has now been published. I think it leads us to understand that, after the first COVID–19 vaccine, where—

the primary series, given two doses 3 to 4 weeks apart—there was a risk in the younger age range of males that was about 1 in 10- to 1 in 20,000—1 in 10,000 to 1 in 20,000 individuals got myocarditis. Now, with the spacing out of the vaccines, that risk is almost undetectable.

And there was a recent study published in JAMA Pediatrics, in 3-million-plus individuals, ages 5 to 17 years, who had received 5.9 million vaccine doses, which really only—again, it confirmed what we had seen: There was a signal for myocarditis or pericarditis only after the primary vaccination series with the Pfizer mRNA vaccine in those 12 to 17 years of age, and that now that signal is not being seen more recently.

So, I think we've learned something about how to deploy the vaccines. And I think that's why CDC—I can turn it over to Dr. Jernigan—has changed their recommendations for how they be used.

Ms. MALLIOTAKIS. Yes, if you'd quickly add to that.

Dr. JERNIGAN. No, just to say that we do have systems—the VAERS system, the Vaccine Safety Datalink that is also monitoring, other systems that are continuing to monitor for myocarditis.

Ms. MALLIOTAKIS. OK.

As more time passes, is the FDA actively conducting safety surveillance on those who received the early COVID–19 vaccines? Like, are there specific health markers that you are studying that may signal trends requiring further inquiry?

Dr. MARKS. Thanks very much for that question. In fact, every time we go through and do the safety surveillance, we start back, and it goes back to 2020. In some cases where we're looking for certain things, we might use a different window. But, indeed, we have to look from the beginning of the period of surveillance.

I can turn it over to Dr. Jernigan because he can speak for CDC in that regard.

Dr. JERNIGAN. So, with regard to myocarditis, we certainly have been monitoring the issue with various different data systems. I think the most recent data really demonstrates that there's about eight times less likely to get myocarditis if you're vaccinated compared to those that are unvaccinated.

Ms. MALLIOTAKIS. Yes. Not just myocarditis; everything.

Dr. JERNIGAN. Repeat the question then.

Ms. MALLIOTAKIS. As more time passes, is the FDA actively conducting extended safety surveillance on those who received the early COVID–19 vaccines?

Dr. JERNIGAN. Yes, most of the reports that we get of adverse events are in the few weeks following the vaccination. In terms of monitoring these over time, we do have vaccine effectiveness systems that are in place at CDC.

Ms. MALLIOTAKIS. OK.

I've run out of time, but thank you very much.

Dr. WENSTRUP. I now recognize Ms. Ross from North Carolina for 5 minutes of questions.

Ms. ROSS. Thank you very much, Mr. Chairman.

And thank you so much to our witnesses for being here today.

I just want to correct the record on some misrepresentations that we've heard here but we've also heard in the public regarding the COVID–19 vaccine and vaccine safety systems more broadly.

In listening to today's hearing, one might be led to believe that reports submitted to the Vaccine Adverse Event Reporting System, or VAERS, are the most meaningful measure of adverse health events and should be the sole basis for evaluating whether the COVID–19 vaccines are safe.

However, my understanding is that VAERS is just one surveillance program within a multilayered vaccine safety system that CDC operates, and that submissions to VAERS—which are unverified, can be submitted by anyone, regardless of how likely a vaccine is to have created an adverse event—can act as early warnings to be prompt deeper investigations through these other surveillance programs.

Is that correct, Dr. Jernigan?

Dr. JERNIGAN. Yes. Yes, so VAERS is a system for getting information in and quickly identifying trends, but it is not the data set that we use to determine causality or the impact of the vaccine.

Ms. ROSS. And can you explain in more detail how VAERS prompts this deeper investigation through other safety surveillance programs at the CDC?

Dr. JERNIGAN. Yes. I think, over the last several years, there have been 676—over 676 million doses of vaccine that have been administered, and we've had a significantly, exceedingly rare number of adverse events reported. There's an even lower number of serious adverse events. Each of those serious adverse events does have a follow-up. They ask for medical records and for autopsy records.

We utilize it in different systems, like our Clinician Immunization Safety Assessment Program that can then evaluate some of the findings. We also have other data sets that can really tell us if there's an increased signal across the general population that we need to be worried about.

Ms. ROSS. Thank you for that.

And then, for the reasons you just explained it, it seems that the VAERS data, on its own, does not provide a strong basis for evaluating causality and that doing so does require this multilayered approach. Is that correct?

Dr. JERNIGAN. Correct.

Ms. ROSS. And how far are you into that multilayered approach for the COVID vaccines?

Dr. JERNIGAN. Well, in terms of using all those different systems, we have used—they're on an ongoing basis. And we've presented at each of the advisory committees on what we're finding in all of those systems regularly.

Ms. ROSS. OK.

And so, just to be abundantly clear, using the VAERS data exclusively to make claims about COVID vaccines causing adverse health effects would be flawed?

Dr. JERNIGAN. VAERS is not intended to determine if a vaccine is causing an adverse event.

Ms. ROSS. OK. Thank you very, very much.

Dr. Marks, my colleagues have attempted to distort an email that you sent in July 2021 regarding the authorization of the Pfizer booster. They've claimed that this is evidence of political interference that undermined patient safety in favor of expediting the timeline for this product.

Dr. Marks, I'd like to give you an opportunity to correct the record on the misrepresentations of this email that have been made, and just give you—I have a minute and 15 seconds. It's all yours.

Dr. MARKS. Thank you so much for the opportunity, Congresswoman Ross.

At the time that these boosters were authorized, just before, we had an increasing number of deaths, starting to run into the thousands per day, in the United States, and there was great urgency to think about what we could do to try to reduce that number of deaths. It had become clear that immunity was waning and that potentially giving a booster could restore immunity and decrease the number of deaths.

And so, we moved with all due haste, not because of any kind of external pressure, but because of internal pressure. We felt compelled to try to save American lives, because thousands of people were dying. And as somebody who was one of the architects of Operation Warp Speed, I had a pretty good idea about how to find efficiencies to move forward.

It was critical to move as fast as we could. And, by the way, the data that has now been published showed that introduction of that first booster was probably responsible for saving hundreds of thousands of lives as we entered the Delta and Omicron waves.

Thank you.

Ms. ROSS. Thank you so much for that explanation.

And, Mr. Chairman, I yield back.

Dr. WENSTRUP. I now recognize Mrs. Lesko from Arizona for 5 minutes of questions.

Mrs. LESKO. Thank you, Mr. Chairman.

Thank you all for being here.

Dr. Marks, we spoke over the phone back on August 10th of 2021, and I was asking about VAERS, because I had lots of constituents reaching out to me, saying there was tons of adverse effects, there was thousands of deaths, et cetera, and they were very concerned. And I asked how many were confirmed. And, at that time, you said four; there were four cases that you confirmed deaths of that were caused by the vaccine.

And I suggested at the time that the CDC and the FDA do a better job of telling the public not just how many cases were reported but how many were actually confirmed. And if I heard you right, just recently you said, well, we don't want to give out too much information because of privacy rights.

But certainly, we could put out how many were confirmed deaths, couldn't we?

Dr. MARKS. Congresswoman, thank you so much for that question. I fully agree with you that we probably have not done a good enough job of communicating, sometimes——

Mrs. LESKO. Well——

Dr. MARKS [continuing]. The actual numbers of deaths versus what's in VAERS. In fact, we just nearly fell prey to it here at this hearing.

There are only handfuls—and I'll ask Dr. Jernigan to comment on this as well—handfuls——

Mrs. LESKO. Well——

Dr. MARKS [continuing]. That we can actually associate with——

Mrs. LESKO [continuing]. Can I ask why you haven't done it?

I mean, this was August 2021. It's very logical to me that, if you're saying people—the public shouldn't count on VAERS because anybody can report to that—which they can—why wouldn't you as actively report to the public, "Well, we confirmed this really low number of cases that actually were caused by vaccines"?

I mean, it's been years now. Why haven't you done it?

Dr. MARKS. We did present that in various settings, including at, I believe, at the Advisory Committee of Immunization Practices. It was mentioned at our Vaccine Advisory Committee. It perhaps did not go as broadly as——

Mrs. LESKO. Is there an easy place for the public to find this? I remember you gave us some kind of link back in 2021, but it was really difficult to get to, if I remember right.

And so why not spend the time, like, making—if the goal is to give confidence to people in getting vaccines, why in the world would you just not say, "OK, what we have done is we've investigated these deaths, we've done this, we've done that, and we only found, you know, a handful"? I mean, it doesn't make any sense to me.

But I want to continue. I'm sorry. I have only a short period of time.

One of my former constituents—and I think I talked to you about this, Dr. Marks—from Surprise, Arizona, Steve Wenger, worked for a company that forced him, mandated him, to receive the COVID vaccine in May 2021. He got the J&J vaccine.

Within a month of receiving the vaccine, he was in the hospital, paralyzed from his neck down. He spent over 3 months in the hospital and was eventually diagnosed with Guillain-Barré syndrome. And, actually, the doctor has said right on his medical stuff that it was most likely caused from the vaccine.

Steve continues to struggle with his injuries today, all because he was forced to take an experimental vaccine at the urging of the health agencies.

Mr. Wenger's injury was also reported to VAERS. And he filed a claim with CICP about 2 years ago, he said, and has not heard back at all; he said, not even a form letter.

So, I want you to know that, Commander, so that—maybe my office can give you his name so you can at least respond that you got the claim from 2 years ago.

Also, there was a New York man who suffered from HLH after his COVID vaccine. His initial report was classified as "life-threatening." His second report, filed after his death, was classified as "hospitalized." The family called to request a correction to the second report to be a fatality and was instructed to file another report and was then sent a form condolence letter from the CDC. And the

fatality was in May 2021; the form letter was received in December 2022.

The family was subsequently sent an automated message at the end of 2023 to update their VAERS report on his condition. "He is dead," they said.

The family has been very distressed by the lack of proper investigation done and classification that he's actually died.

And so, all I'm saying—I've run out of time—is that, as you have said, you've increased the number, Commander, from 4 personnel to, I think you said, 35. Obviously, more work needs to be done if people haven't been—you know, the person died, and it still says they're hospitalized. I mean, this is a huge problem.

And, with that, I yield back.

Dr. WENSTRUP. I now recognize the Ranking Member of the full Committee, Mr. Raskin from Maryland, for 5 minutes of questions.

Mr. RASKIN. Thank you, Mr. Chairman.

Dr. Marks, you said a moment ago that the vaccine booster alone saved hundreds of thousands of lives. How many lives have been saved by the COVID–19 vaccine generally?

Dr. MARKS. It's estimated about—in the United States, about 3.2 million lives. And it's estimated that, globally, COVID–19 vaccines have saved over 14 million lives, conservatively.

Mr. RASKIN. And we've lost more than a million people to COVID–19?

Dr. MARKS. That's correct, about 1.1 million. I kept a daily record of the number of people dying, which got up to about 3,300, about a World Trade Center disaster, a day.

Mr. RASKIN. Deborah Birx, who was former President Trump's White House Coronavirus Response Coordinator, stated that a sequence of missteps and mistakes made by the prior administration's pandemic response cost hundreds of thousands of American lives.

So, I take it, one of the points you have to make is that the public health response of the Federal Government makes a huge difference in terms of health outcomes for the American people?

Dr. MARKS. I would agree with that.

Mr. RASKIN. Whether it's measles or tuberculosis or COVID–19, would you agree that vaccines save lives in the aggregate?

Dr. MARKS. I think that, by definition, for us to approve or authorize a vaccine, there has to be overwhelming evidence that many more lives are saved than might be taken by a vaccine. In other words, the safety profile, by definition, has to be excellent.

Mr. RASKIN. Gotcha.

So, Dr. Jernigan, it seems as if one of the things that's created political or social conflict around this is the inevitable fact that, even when vaccines save a huge number of lives, millions of lives, as Dr. Marks just testified, if in a small number of cases there are adverse results, the people who suffer them, and their families, are understandably very upset about that.

Would you agree that that's a general conflict or dynamic that exists with all vaccines?

Dr. JERNIGAN. Correct. I think, you know, we recognize that no medical intervention is risk-free. So that goes with medical interventions.

Mr. RASKIN. And I can imagine if I had a family member who suffered an adverse reaction to any vaccine—measles, TB, COVID–19—I would say, I just wish they hadn't gotten it in the first place. And, of course, if anyone had been able to predict it, they would've been told not to get it.

On the other hand, if we just said to everybody, "There's a tiny number of people who suffer an adverse result; therefore nobody should get it," we know a lot more people are going to suffer and die because of it.

Is that a basic problem that you wrestle with in your field, Dr. Jernigan?

Dr. JERNIGAN. Correct. I think anytime we're talking about public health measures, we have to think about the risks and the benefits. And the way that we communicate that is very important so that people will take those interventions.

Mr. RASKIN. Have you detected anything at the CDC, through your surveillance systems, that has caused you to doubt the safety or the appropriateness of the CDC's original and continuing recommendation that people get vaccinated against COVID–19?

Dr. JERNIGAN. So, you know, I dedicated my life to public health, and I do care deeply about protecting Americans and using the best available science, and I want to stress that the COVID vaccine is safe, and it is effective.

We have safety monitoring systems in place that have detected certain signals; we've acted on those quickly.

Mr. RASKIN. Would you agree that the COVID–19 vaccine and its roll-out in the Biden administration has been one of the great achievements of modern science and public health?

Dr. JERNIGAN. I think over the last 4 years we've had a once-in-a-lifetime event that required an incredible response from all of us, and so would agree that the use of vaccines has been a remarkable achievement for us all.

Mr. RASKIN. There's a paper that someone sent to me called "Excess Death Rates for Republicans and Democrats During the COVID–19 Pandemic" from the National Bureau of Economic Research, which makes the point that there were substantially—or, there have been substantially higher death rates for registered Republicans when compared to registered Democrats, and this has been connected to vaccine hesitancy or fears.

And I'd like to submit this for the record.

But I just wonder if you would opine on this for a second. Have we ever seen a case like in the past, where there's actually partisan differences in people's willingness to get a vaccine, their skepticism, and then death rates arising from such differences?

Dr. JERNIGAN. I think you point out the importance of us getting to—so that folks can be vaccinated.

Mr. RASKIN. Thank you very much.

And I'll submit this for the record, Mr. Chairman, if I could.

Dr. WENSTRUP. I now recognize Ms. Greene from Georgia for 5 minutes of questions.

And, without objection, submitted to the record.

Ms. GREENE. Thank you, Mr. Chairman.

I'm not a doctor, but I have a Ph.D. in recognizing bullshit when I hear it.

I'd like to point out to everyone that we knew early on—as a matter of fact, everyone knew early on—that the people that were at risk of hospitalization and dying of COVID were those that were obese, had diabetes, were over the age of 65. We also knew that children were at no risk, practically zero risk, of being hospitalized or deaths from COVID–19. We knew that young people—healthy young people were not at risk.

However, Dr. Marks, you rushed through this process of authorizing these vaccines, even though you knew the side effects, you knew about myocarditis, and you knew about the studies.

So, let's be very real about the situation that we have.

[Chart.]

Ms. GREENE. Here we have—let's talk about the reports on VAERS. Some people in here are trying to belittle these reports, but these reports come from people—people that died, people that got injured.

And in December, in the middle of December—I think it was the 10th or the 11th—the first vaccine was approved, it was authorized, under emergency use. Boom, 10,596 reports in less than a month. 2021, 706,767 reports on VAERS for vaccine injuries and deaths. 2022, it was 206,676. 2023—and it went going down because the mandates stopped.

Now, let's talk a little bit more about the vaccines. Here we have reports: deaths, 18,372; permanent disability, 17,842; hospitalizations, 86,452; emergency room or office visits, 315,048; serious adverse events, 113,449. This is from the congressional Research Service about VAERS. All kinds of injuries—miscarriages, heart attacks, myocarditis, permanent disability, neurological problems. And it goes on and on and on.

These are the reports from people being forced to take vaccines. Shouldn't have happened.

Mr. Grimes, I've just told you the numbers of reports. However, under CICP, there are only 10,640 of these COVID–19 claims that are currently pending or are in review. And as of January 1st, 2024, CICP only compensated 11 of the 40—oh, wait. Let's make that number clear to everyone. Only 11 people have been compensated. Only 11 people have been compensated out of the 40 COVID–19 claims that determined were eligible. Only 40 were determined eligible. That is amazing.

And the average award was only about $3,700. On the other hand, the average VICP payout over the last 35 years is approximately $490,000. If you die or get injured from a COVID–19 vaccine, your average payout's $3,700.

I'd like to recognize someone in the room today who's here, Brianne Dressen.

She's met with you, Dr. Marks. She's met privately with you about her vaccine injuries.

She participated in a clinical trial, she was injured, and then she was dropped from the trial for the COVID–19 vaccines. Her medical expenses are $433,000 a year.

She filed with CICP. Mr. Grimes, she's gotten no response.

She's right here.

Could you raise your hand, Ms. Dressen, please? Thank you.

Perhaps you could meet with her after this meeting.

Dr. Marks, you admitted to her that vaccine injuries are real—that they're real—although you rushed through the authorization, and now you've authorized that children should receive these vaccines, and even babies as young as 6 months old. That is shameful. That's shame-—I'm not asking you a question. I'm going to continue speaking. Thank you. This is my time.

The National Institute of Health also saw Ms. Dressen for her neurological complications that have been quite severe. They studied her, and then they dropped the study and asked her to be quiet about it.

These are the real stories of the vaccine-injured. They were totally, completely wiped off of social media. There's been thousands of peer-reviewed medical studies, thousands of them, studying vaccine injuries. They are real. People are dying. People are having heart attacks, strokes, blood clots. And many other countries are dropping the COVID–19 vaccine and saying we shouldn't give them to children.

It's time to be honest about the vaccine-injured. And we need to stop allowing these COVID–19 vaccines to be given out——

Dr. WENSTRUP. The gentlelady's——

Ms. GREENE [continuing]. To children.

Dr. WENSTRUP. The gentlelady's time has expired.

I now recognize Mr. Garcia from California for 5 minutes of questions.

Mr. GARCIA. Thanks, Mr. Chairman.

I am sorry you all had to go through that. That was a lot of conspiracy theories and wild accusations, which we know have been debunked by medical science. And we should be clear that vaccines work and save lives, and they have millions of lives in this country.

Now, it's really unfortunate that we're actually here having this hearing trying to poke holes and cause more vaccine hesitancy amongst the public. But we know that we're here because Committee Members on this Committee have demanded that we have this hearing, and we continue to cave and give those Members everything that they want.

Now, we also know that we have a Member of this Committee that just actually made some comments, who's been on social media demanding that we hold this exact same hearing.

[Chart.]

Mr. GARCIA. This is the same person that we know that has, on countless posts, has spread misinformation, encouraged parents to refuse routine vaccinations for their children—which you just heard, by the way—and even compared our pandemic response efforts to the Holocaust.

I want to just actually read something which is in the public record—I'm not saying anything that's not in the public record—that a Member of this Committee actually said, this same person that is actually attacking vaccines, said that "vaccinated employees get a vaccination logo, just like the Nazis forced Jewish people to wear a gold star."

I want to read that again: "Vaccinated employees get a vaccination logo, just like the Nazis forced Jewish people to wear a gold star."

That is the level of insanity and attacks that we are having here as we actually debate the lives saved around vaccinations.

Now, this same Member has also held shadow public hearings promoting ideas that COVID is a bioweapon to target people of specific races and the vaccines, and I quote, cause "turbo-cancers."

I want to read you this quote. And it's, again, in the public record, at a hearing. "Have the COVID vaccines resulted in an increase in cancers? And are turbo-cancers real?"

Now, Mr. Chairman, this is, I mean, in my opinion, just insanity. We know that's not the case.

Dr. Marks, can you clarify once again for the American people, do the COVID vaccines cause turbo-cancers?

Dr. MARKS. I'm a hematologist and oncologist that's board-certified. I don't know what a turbo-cancer is. It was a term that was used first in a paper in mouse experiments, describing an inflammatory response.

There are—we have not detected any increase in cancers with the COVID–19 vaccines.

Mr. GARCIA. Thank you. And I—and thank you for correcting the record——

Dr. MARKS. But may I—may I just add something here.

I do need to apologize to the thousand or so parents of children who are under 4 years of age who have died of COVID–19 who were unvaccinated. Because there were deaths and are continuing to be deaths in children, and that is the reason why they need to get vaccinated.

Thank you.

Mr. GARCIA. And I agree with you 100 percent. And the fact that we are now having parents that are choosing to vaccinate their kids less than before, because of all of the attacks on vaccinations, is shameful. And it's shameful that Members of Congress continue to put down vaccinations as an opportunity to get our communities healthier.

And, Dr. Marks, I want to thank you for the work that you did. My mom passed away to COVID–19. My stepfather passed away due to COVID–19. Both would've taken that vaccination in an instant if it was available to them.

And so, anytime that folks, especially folks on this, you know, Subcommittee on the pandemic, attack vaccines, it's personally insulting to all the families that have actually lost loved ones. We've saved millions of lives because of the vaccine. It's unfortunate we keep causing this harm.

I just want to say, last, that—Dr. Marks, do you agree that additional lives would've been saved—additional—the lives that—the folks that were not vaccinated that we lost—over a million, obviously, in this country—wouldn't a vast majority of those lives have been saved had we had the vaccine and had they been vaccinated?

Dr. MARKS. Multiple studies show that 80 to 85 percent of the deaths that occurred were in unvaccinated individuals. So, if we would've been able to reach a higher vaccination rate, it's likely that we would've had fewer deaths. And countries where they reached higher vaccination rates had fewer deaths per capita.

Mr. GARCIA. Thank you.

And I encourage this Committee and all Members of Congress to encourage vaccinations across this country to save more American lives.

With that, I yield back.

Dr. WENSTRUP. I now recognize Mr. Mfume from Maryland for 5 minutes of questions.

Mr. MFUME. Thank you, Chair Wenstrup and Ranking Member Ruiz.

I want to join in with the previous comments of Members of the Committee and welcome all of you again for being here with us today.

Mr. Chair, I would also, on a point of personal privilege, remind Members of this Committee, even though I am not the Chair, that there should be some sense of decorum, and vulgarity should be discouraged.

So, if I ever say that I'm a Ph.D. in BS, it means "Bulgarian sunshine." You will not hear me talk about, explicitly, the thing that I won't mention here today. There are people watching across this Nation who want and, quite frankly, really expect that the Congress, if no other place, will conduct itself in a way that does not insult any of them personally because of vulgarities and in a way that we should, in fact, conduct business.

Mr. Chair, the American ethic has always been one of independence and self-sufficiency. As a society, we see our health decisions as deeply personal and deeply private. In some instances, that proclivity toward individualism can lead to a hesitancy surrounding certain health innovations such as vaccines.

In the case of the COVID–19 pandemic, fearmongers amplified vaccine hesitancy. And it was done, as we all know, without, necessarily, substance or facts, but through fear, by way of news networks, late-night talk shows, and syndicated radio shows.

Those talking heads unfortunately took advantage of certain communities' negative experiences with the American public health system by playing on fear and mistrust and by amplifying over and over again a vaccine hesitancy across the Nation.

Now, when you do that, you really play with fire—in this case, the fire that the gentleman from California mentioned also about how we lose loved ones, how people die, and how that rate of death accelerated over and over again.

I really want to thank God that Jonas Salk, the great virologist, in 1955, did not run into that nonsense when he developed the vaccine for polio. Parents were clamoring because they wanted their children to be able to walk and have a good life. There was a sense of sense and sensibility that went along with that.

So, when it's done right, it's done right. So many children and others were vaccinated for polio successfully. And were there some bad stories along the way? I'm sure there was, just as we've heard, when you're dealing with science, there is not of a 100-percent certainty in everything.

Mr. Chairman, my colleagues on both sides of the aisle know that COVID vaccines, even under accelerated development timelines, have proven over and over again to be safe.

I would ask unanimous consent, Mr. Chair, that I submit into the record this article from Vox, the general interest news site, entitled, "Will America continue to turn away from vaccines?"

Dr. WENSTRUP. Without objection.

Mr. MFUME. Thank you, sir.

Dr. Jernigan, can you explain for the Committee again, if you don't mind—I mean, there are some people watching this around the Nation who have tuned in late and perhaps missed some of the earlier discussion.

Can you explain for the Committee again, if you might, the multilayered process of vaccine safety monitoring that the CDC implemented for COVID–19?

Dr. JERNIGAN. Thanks. And, you know, I've worked in public health since 1994, responded to multiple infectious disease emergencies, and this is the most robust vaccine safety monitoring system that we have ever had.

There are five different systems. We use all of those to determine the impact of those vaccines and the association with safety. All of those systems are used by CDC.

Mr. MFUME. And can you also corroborate that this seems to be, at least, by all standards, an incredibly thorough process that meets all the merits of scientific approach and scientific roll-out for such? Why are these systems so crucial in maintaining and strengthening vaccine confidence in the United States.

Dr. JERNIGAN. Yes. I think, you know, we want to make the best recommendations with the best available science. And so, for that, at CDC, we use a science-based process to get to those recommendations.

And so, making sure that science is first, and making sure that we have the data and making the right recommendations with the best available science.

Mr. MFUME. Thank you.

I want to thank all of you again for being here with us.

And, Mr. Chairman, I yield back.

Dr. WENSTRUP. I now recognize Dr. Miller-Meeks from Iowa for 5 minutes of questions.

Dr. MILLER-MEEKS. Thank you, Mr. Chairman.

And I want to thank the witnesses for testifying before the Select Committee today.

I want to also say that I am a former director of the State Department of Health in Iowa, Public Health, and was vaccinated, and gave vaccines in all 24 counties of my district; however, have never been for a vaccine mandate for COVID–19, both when I was distributing vaccines as well as today.

Dr. Marks, COVID–19 remains somewhat of a public health challenge, especially given declining vaccination rates and growing vaccine hesitancy and fatigue. And let me say, as a public health director and as a state senator, vaccine hesitancy and fatigue is not new, this has been an issue, but it has been greatly enhanced through COVID–19 vaccine mandates.

To optimize the effectiveness of COVID–19 vaccines, I understand that the FDA has recommended periodic updates to vaccine composition. As we have seen with influenza, a clear framework for

strain selection supports the timely availability of a diverse supply of COVID–19 vaccine platforms.

I believe that multiple FDA-approved vaccine options can play a role in preserving consumer choice of products and ensuring equity of access, both of which can contribute to increased consumer acceptance and uptake of vaccines without forcing Americans to receive a specific option.

Can you please speak to how the agency is taking steps to ensure vaccine manufacturers have the essential time needed to adapt their products accordingly and scale up production for vaccines for new virus variants?

Dr. MARKS. Congresswoman Miller-Meeks, thanks very much for that question.

I would certainly agree with you that at FDA we take seriously the need to have choice among vaccines, because that will allow a greater vaccination rate, because we understand that some people may not feel comfortable with certain types of vaccines; they may want a more traditional vaccine rather than a newer vaccine.

That's why we've been continuing to work with manufacturers to try to make sure that, when we roll out the next update, we will have a diversity of choice, at least more than one type, of vaccine that will be available. So, you will see, as we move into the spring, we will, as you've noted, go through a strain selection process.

We're already having dialog with manufacturers to help them get prepared—because there's a lot of pre-work that they can do at risk to prepare for this—so that we can hopefully have the choice that you're talking about.

Dr. MILLER-MEEKS. Thank you.

Dr. Grimes, as you know, COVID–19 vaccines are covered countermeasures under the Countermeasure Injury Compensation Program, CICP, which is overseen by HRSA, instead of the National Vaccine Injury Compensation Program, VICP.

With FDA being responsible for authorizing and approving the COVID vaccines and HRSA being responsible for adjudicating CICP claims for the COVID shots, I'm concerned that there's too much government involvement and overlap with COVID–19 vaccine claim adjudication.

Furthermore, the CICP was not designed for a pandemic as large as the COVID–19 pandemic was, adding to the argument that VICP is the appropriate location to house the COVID–19 vaccine injuries, in addition to the RSV and dengue vaccines, which are already available.

While I recognize that adding vaccines to VICP is through a 75-cent excise tax on pharmaceutical manufacturers, which would require congressional action, it nonetheless warrants attention by this Select Subcommittee.

When a new vaccine is approved and marketed, what steps are required to ensure access to compensation under the VICP program? And what happens if a new vaccine is not added to the list of taxed vaccines?

Dr. GRIMES. Thank you for that question.

So, as you note, we have two programs that are administered through HRSA—the Countermeasures Injury Compensation Pro-

gram and the National Vaccine Injury Compensation Program—that are both in my division.

With the National Vaccine Injury Compensation Program, it's a tripartite system, though, where we work with Department of Justice and with the U.S. Court of Federal Claims to do separate duties to adjudicate the claims.

For a vaccine to be covered under the CICP, three criteria must be met. One is the routine recommendation by the CDC for routine administration in children or individuals who are pregnant. The second is the excise tax imposed by Congress, as you note. And the third is a notice of coverage that the Secretary of HHS would add.

For a dengue or RSV or COVID–19 vaccine to be added to the program, all of those would need to be met.

Dr. MILLER-MEEKS. So, Dr. Grimes, what's the rate of denial for compensation for claims for COVID–19 vaccines in CICP?

Dr. GRIMES. So, thank you. I don't have the rate, but we have adjudicated 2,214 claims.

Dr. MILLER-MEEKS. I think it's about 98 percent.

And if I can just quickly followup, I understand that there's a current backlog of claims in CICP by about more than 10,000. Why is there a backlog of claims for the COVID–19 vaccines?

Dr. GRIMES. Thank you for that question.

So, at the beginning of the COVID–19 pandemic, we had not had a direct appropriation with the CICP. We also had only four staff. When we received our first direct appropriation in Fiscal Year 2022, we were able to ramp up quickly, and now we have over 35 staff who are assisting to adjudicate claims.

Dr. MILLER-MEEKS. Thank you.

My time's expired, but I'd like to submit some additional questions to be answered after the hearing.

Dr. WENSTRUP. So, ordered.

Dr. MILLER-MEEKS. Thank you very much.

Dr. WENSTRUP. I now recognize Ms. Tokuda from Hawaii for 5 minutes of questions.

Ms. TOKUDA. Thank you, Mr. Chair.

I am deeply concerned about some of the dangerous rhetoric we've heard throughout today's hearing, which appears purposely aimed at undermining confidence in vaccines.

I agree with you, Mr. Chair: Words matter. So do facts.

Ahead of today's hearing, the Select Subcommittee received a letter from the Association of State and Territorial Health Officials, an organization representing public health officials from red states and blue states alike. This letter underscores the importance of, quote, "informing the public truthfully about the safety and effectiveness of vaccines," end quote, and urging the Select Subcommittee to, quote, "engage this topic responsibly and with the utmost integrity," end quote.

Mr. Chair, I'd like to enter this letter into the record.

Dr. WENSTRUP. Without objection.

Ms. TOKUDA. Thank you, Mr. Chair.

I am concerned that, with today's hearing, my Republican colleagues have failed to handle this subject with the care our public health officials have asked for, recklessly amplifying the spread of misinformation about the COVID–19 vaccine.

And while my colleagues on the other side of the aisle may claim that today's hearing is only about the COVID–19 vaccine, they cannot and must not ignore the fact that the COVID misinformation—intentional spread of disinformation of the COVID–19 vaccine has resulted in across-the-board decreases in immunization levels over the last few years. In fact, the world is experiencing the largest global decline in decades in the number of children receiving basic immunizations.

A recent survey conducted by the Annenberg Public Policy Center at the University of Pennsylvania found that the number of Americans who viewed vaccines as less than effective has increased since April 2021. According to the survey, roughly one in three Americans think it's likely safer to get COVID–19 than to get the vaccine; one in six Americans believe that vaccines cause autism; and Americans are now less likely to consider getting the measles, mumps, rubella vaccines than they were in April 2021.

As a mother of two boys, I am deeply concerned about what this means for our children, especially when we are seeing outbreaks of previously controlled diseases like polio and measles pop up not just in other countries but right here in the United States.

Since measles was declared eliminated in the U.S. in 2000, we have seen consistent outbreaks, mostly especially in under vaccinated communities. These have included outbreaks of 8 cases in Philadelphia in December 2023 most recently and an outbreak of 85 cases among unvaccinated children in central Ohio in 2022.

The savings of vaccination to medical economic costs and to human lives cannot be ignored. CDC estimates that immunizations for children born between 1994 and 2021 will prevent over 1 million deaths, 29 million hospitalizations, and save nearly $2.2 trillion in societal costs. And already we know that COVID–19 vaccines have saved more than 3.2 million lives, as has been referenced in this hearing.

Let's be clear: No parent—no parent at all—wants to do their children harm. But many parents are, sadly, getting and trustingly acting upon false information like what we have heard in this hearing room today.

So, I'd like to discuss today how we can make sure that parents get the best and most accurate information they need so that we can promote confidence in long-trusted lifesaving vaccines and prevent outbreaks of deadly diseases.

Dr. Marks, can you please explain how the FDA evaluates vaccines to ensure that they are safe and effective for age groups that they are intended to be used for?

Dr. MARKS. Thanks, Congresswoman, for that question.

So, every vaccine that we authorize or approve, we require to have manufacturing information to show that it's high quality, and that we have to have information on its effectiveness and safety in the specific age population that it's being prescribed in, or we have to be able to understand that it's going to function similarly in that age group that we're authorizing or approving it for.

So, it is a process that we take very seriously at the agency. And there is a very dedicated group of people that spend their time poring over data to make sure that, in the thousands of records that are submitted to us, thousands of pages—for instance, over a

million pages for one of the biologics license applications for one of the mRNA vaccines—that we get that authorization or approval right.

Ms. TOKUDA. Thank you.

Mr. Marks, if parents have questions about vaccines for their children, what steps do you recommend that they take to get their questions answered? And I'm not talking about the internet.

Dr. MARKS. No. I think Chair Wenstrup and I talked about this the other day.

The primary thing that I think we need are conversations between parents and their providers. And that provider doesn't have to be a physician; it could be even a nurse practitioner or someone in a doctor's office that's a physician assistant.

But having that conversation, that individual conversation, where people can ask questions and have them answered—at least—I've spent a lot of time during the COVID pandemic doing that, and it makes a huge difference. So, I believe in the primacy of the provider-patient relationship.

Thank you.

Ms. TOKUDA. Thank you.

I am out of time, but I would reiterate that, today, while we have seen Republican lawmakers across the country attempt to sow distrust in lifesaving vaccines, I hope that this Committee can correct course and focus on work that matters—keeping our people alive, keeping them safe. And that means preventing outbreaks of deadly diseases, expanding access to critical vaccines, and safeguarding the health and safety of Americans——

Dr. WENSTRUP. The gentlelady's time has expired.

Ms. TOKUDA [continuing]. Across our country.

Thank you very much.

Dr. WENSTRUP. The gentlelady's time has expired.

I now recognize Mr. Cloud from Texas for 5 minutes of questions.

Mr. CLOUD. Thank you, Chairman, and thank you all for being here.

We often hear from agencies that they could fix everything if only they had more funding, more authority, more data. The COVID–19 pandemic showed us that we had a different problem, and that is a perverse incentive structure that governs our approach to public health.

Early on in the pandemic, the Federal Government provided billions of dollars to pharmaceutical companies for development. Much of that work was aided by the work of taxpayer-funded scientists at NIH.

Then we purchased the vaccines back from the pharmaceutical companies.

Next, the FDA and the CDC, which were responsible for evaluating the safety and effectiveness of the vaccines, cleared them for emergency use.

Then, not content with recommending the vaccines and providing information for the American people to make their own decisions, the Federal Government attempted to force everyone to get the vaccine, blatantly disregarding scientific evidence and constitutional considerations.

At the same time, the government provided the vaccine manufacturers with special liability protections, ensuring they can't be sued for any adverse effects.

And, instead, a government bureaucrat gets to decide whether or not someone was injured and offer them a minuscule amount of money as compensation if they manage to make through an arbitrary process, which is very intensive.

So, right now, we have the same agency funding the research, approving and mandating, and then finally adjudicating the COVID vaccines. It concentrates too many of the critical government functions in the same unaccountable hands.

Now one of the big issues on top of this is the fact that so much of the misinformation that came out during COVID was actually fostered by the Federal Government in the sense that we actually had the Federal Government colluding with system social media companies to discourage scientific opinion that went against what was the stated mandate at the time.

And so, to help clear the record, I'd like to ask y'all a couple of things.

And, Dr. Marks, you stated that vaccines work at the outset. I don't think this Committee is designed to question that. But there is a—an attempt in this conversation to kind of throw the COVID–19 a very new, different scientific approach to vaccines, with a new data set that's still developing and all those kinds of things, with very well-established vaccines like polio or chicken pox or meningitis or these types of things, when, I think, Americans rightfully so, after watching the government over the last couple of years, could have some concerns about COVID–19 and the information that's been presented.

So, I wanted to ask you each a couple of questions. It's a simple yes or no.

Does the COVID–19 vaccine prevent the disease from getting it—from you receiving the disease?

Dr. MARKS. You can't have a yes-or-no answer to that question because it will reduce your risk of serious outcomes, such as death or——

Mr. CLOUD. Right. I'm not—I'm not debating whether or not it helps people—it mitigates some of the—but what the——

Dr. MARKS. I care if I'm alive or dead. So, I think they do a very good job of preventing death and hospitalization.

Mr. CLOUD. I——

Dr. MARKS. They may not prevent—they may not prevent——

Mr. CLOUD. I agree.

Dr. MARKS [continuing]. Infection.

Mr. CASTOR. The mantra at the time was to stop the spread, and so we were understood that we either did not receive it or could not transmit it when it was released.

Could you speak to that, Dr. Jernigan? Can you receive it, or can you transmit it after receiving the COVID–19 vaccines?

Dr. JERNIGAN. Yes, I think, having worked at CDC for 30 years and seeing the benefits of vaccine, you know, we have to make the best recommendation.

Mr. CLOUD. Can you transmit it, or can you receive it after receiving the COVID–19 vaccine?

Dr. JERNIGAN. I think we need to make the best recommendations that we have.

Mr. CLOUD. That's a yes-or-no question. It's very simple.

Commander Grimes, can you receive?

Dr. GRIMES. I think we make the best recommendations for the public——

Mr. CLOUD. Can you still——

Dr. GRIMES [continuing]. As we possibly can.

Mr. CLOUD [continuing]. Get COVID after getting the COVID–19 vaccine?

Dr. JERNIGAN. Yes.

Dr. MARKS. Yes.

Mr. CLOUD. Yes. OK.

Dr. MARKS. That's correct.

Mr. CLOUD. Does it prevent you from transmitting it?

Dr. MARKS. Although it may—there's—there's data that shows that, earlier in the pandemic, there was some reduction in transmission, the data on that are very challenging to—to pin down, but it does not absolutely prevent transmission.

Mr. CLOUD. It does not prevent transmission. Thank you very much.

I would ask you, Dr. Jernigan, why does the CDC website then list it as a vaccine-preventable disease? And why does it call it a recommended immunization?

Dr. JERNIGAN. Well, vaccine-preventable diseases are referring to things that benefit from getting the vaccine. What we know from COVID is it does prevent you from getting severe disease, hospitalizations, and deaths.

Mr. CLOUD. I agree. No one's questioning that. No one's questioning that, but it's listed among these other—the issue right now and why we're seeing a bunch of vaccine hesitancy is because the information coming from the Federal Government has been murky at best on this subject and so people don't know what to trust.

And so, my question to you is, why do you list this, along with very other proven that have a long set of scientific data, as a—as a vaccine that prevents disease?

Dr. JERNIGAN. All vaccines have variable different levels of effectiveness, and so this is a vaccine-preventable disease just like all the others are.

Mr. CLOUD. OK. Y'all have done a great job of filibustering my time.

I have to yield back.

Dr. WENSTRUP. I now recognize Dr. Joyce from Pennsylvania for 5 minutes of questions.

Dr. JOYCE. Thank you, Dr. Wenstrup, for convening this hearing for our panel for appearing today.

This is an incredibly important discussion topic and as our continued work on this Committee to get to the bottom of both the origins of COVID–19 and also the government response.

Understanding how Federal agencies tracked the rollout of the COVID–19 vaccines and documented instances of injury or adverse effects is critically important for any future responses.

As a doctor, having accurate and up-to-date information before treating patients during a public health emergency is of utmost importance.

While Federal health agencies have several systems for vaccine safety surveillance, the most well-known during the pandemic became the Vaccine Adverse Event Reporting System, or VAERS. The government also has two systems for adjudicating and compensating vaccine-related injuries, the Countermeasures Injury Compensation Program, which is CICP, and the Vaccine Injury Compensation Program, which is VICP.

Two of the key differences between the CICP, which covered the COVID–19 vaccines, and the VICP, which covers most other vaccines, are who adjudicates the claims and who covers the damages.

In CICP, in CICP, claims are adjudicated by HRSA whereas, in VICP, claims are adjudicated by the Court of Federal Appeals. And, in terms who pays for the CICP, it is appropriated funds whereas, in VICP, the money comes from an excise tax that is levied on manufacturers on each vaccine dose.

Before the COVID–19 pandemic, CICP was a very small program due to its limited scope. However, claims have exploded now that widely distributed and even mandated COVID–19 countermeasures are covered under the program.

As of January 1 of this year, the total number of CICP claims ever filed was 13,406, and COVID–19 claims account for 12,854, nearly 96 percent of the total. Because of CICP's design and their limited resources, adjudication of claims is a lengthy and a burdensome process. It is also reported that 10,640 of these COVID–19 claims are currently pending or under review.

Commander Grimes, how is the CICP structured to ensure accessibility and fairness to petitioners? And how does this compare to VICP or even the traditional litigation system?

Dr. GRIMES. Thank you for that question.

So, in the CICP, we administer the program by statute. An individual that we call a requester files a request for benefits and then must submit medical records to the CICP to show that there is compelling, reliable, valid medical and scientific evidence to support that it was directly caused by the use or administration of a covered countermeasure.

A covered countermeasure could be COVID–19 vaccine. It could be a smallpox vaccine.

Dr. JOYCE. Let's stay focused on the COVID–19 vaccine, because that's what our obligation is in this Select Subcommittee.

Do you feel it is more appropriate to have petitioners, your word, for COVID–19 claims to be paid by the vaccine manufacturer or by the American taxpayer?

Dr. GRIMES. So, the petitioners are for the National Vaccine Injury Compensation Program, and those are through the routine administration with an excise tax levied on it whereas the requesters through the CICP are paid for compensation of claims through appropriated funds and through administration of the program—is also paid from those appropriated funds.

Dr. JOYCE. As a physician, I am also worried that, in some cases, health practitioners do not know where and how to report adverse effects, which is critical to ensuring that all vaccine events are ac-

counted for. I also have concerns of how these events and potential risks are reported to healthcare providers.

For each of you, could you take turns and describe what your respective agency ensures against any adverse effects that are reported and how those reports are managed and how those information is conveyed to the frontline individuals who are dealing with this?

Dr. Marks.

Dr. MARKS. So, thank you for the question.

So, we—each vaccine label actually, whether it was the authorized vaccines or the approved vaccines, has information on where to report adverse events, into the Adverse Event Reporting System.

When we get those, we could combine with CDC, sort through those events, and we take them seriously and investigate them to sort out whether there are any signals there.

Dr. JOYCE. Dr. Jernigan.

Dr. JERNIGAN. Yes. So, we provide information through the vaccine information sheets that are provided to everybody that gets vaccinated, so they understand the potential risks.

We also communicate to the public and then take information that comes in through VAERS, put that together, put that and communicate that with the advisory committee. And then recommendation can be changed, if needed.

Dr. JOYCE. Commander Grimes, do you see any faults in this system?

Dr. GRIMES. I'm here to testify on behalf of the Director of the Division of Injury Compensation Programs and not to such of the—CDC and FDA systems.

Dr. WENSTRUP. The gentleman's time has expired.

I now recognize Dr. McCormick from Georgia for 5 minutes of questions.

Dr. MCCORMICK. Thank you, Mr. Chair.

I'll cut straight to the point because I know we're on a timeline, and I'm the last. So, congratulations on that.

I want to point out that it was President Trump's Operation Warp Speed that had unprecedented delivery of a vaccination in record time.

I think it's ironic that this scientific achievement will forever be tainted by the government's handling of COVID–19 and the mistrust that was created from this vaccine policy and the Federal programs that surround it.

To void myself of partisanship in this case, I'd like to highlight that it is the Democrats that have touted this program that President Trump not only came up with but received the vaccination himself and admits openly to getting the booster, as well. So, there are some ironies in this argument all the way around.

So, the question is, why has America become so distrustful of vaccinations, as my colleagues have pointed out. Why is it that they no longer want to get a vaccination that may have potential benefit? I would make the—a couple of points on this.

First of all, when you insert yourself between a doctor and a patient and some doctors contradict you and you sensor them, even when you're not a doctor treating patients, people are going to say,

why does the government have authority to do that, to sensor my doctor?

And then, second, when you start requiring people to do something instead of encouraging, the natural resistance of a freedom-loving people that were founded on those principles will be to resist what you're requiring.

So, it shouldn't be any surprise to us, when the people say, "I'm not going to do what you're telling me I have to do, when my doctor may agree with me and not you. You're the government." Why do I—assert ourselves in inappropriate ways?

And really, when we talk about the evolution of science, when you have immunity and you're still requiring a vaccination that could cause a hyperimmune response, which we're all scientists and we can admit to, there's risks versus benefits on every decision; when the government says we're going to make a carte blanche requirement without taking science into account, it's no wonder people are mistrustful of our recommendations. This is the problem we have right now.

So, let's talk about the vaccination liability and compensation program. It came to my attention last February when I heard from constituents that COVID–19 vaccine injuries, claims that were sent to CICP were constantly lost, ignored, or denied, or caught up in the bureaucracy with little or no transparency.

Now, March 3 of last year, several of my colleagues and I wrote a letter to HRSA about our serious concerns regarding the Countermeasures Injury Compensation Program, the CICP, and its failure to respond to our constituents in a reasonable timeframe.

Now, first of all, I appreciate Commander Grimes. I will say, unlike a lot of the government agencies that are high up, you responded. You actually came by my office, and I do appreciate that. I think you care.

And you also point out that you had a very small, when you started out, you had, what, four people working for you, which was based on the pre-pandemic response force on injury that can cause and you're trying to respond to 13,000 people with four employees. Since then, you've been plussed up to 35 people, I believe.

Am I accurate in saying it was 13,000 claims approximately?

Dr. GRIMES. We have approximately 13,000 COVID–19 countermeasure claims, about 9,600 of which allege vaccine.

Dr. MCCORMICK. OK. And of those, which ones have—how many have been closed?

Dr. GRIMES. 2,200, about.

Dr. MCCORMICK. Yes, OK. And then the number is 35 employees now that are handling those claims, right?

Dr. GRIMES. Yes, so since we——

Dr. MCCORMICK. That's OK. I got to be quick because we're on a timeline here.

Dr. GRIMES. Understood.

Dr. MCCORMICK. How many claims are you processing per month now?

Dr. GRIMES. So, in the year 2023, we processed 90 claims for a month over that year, and that velocity increased throughout the year.

Dr. MCCORMICK. Of those 2,200 claims, how many have been shown to have some merit for injury?

Dr. GRIMES. Currently there are about 40 that have been found to have an injury that was directly caused by a covered countermeasure.

Dr. MCCORMICK. OK. So, a pretty small percentage, correct?

Dr. GRIMES. Yes, sir.

Dr. MCCORMICK. OK. So, just to do the math, that means that each employee's handling about 2.7 cases per month and showing 40 out of 2,200 cases that have been processed so far. Of the 13,000, that means we probably have about 10,800 cases in backlog.

I know you've asked for more employees so you can process faster, but at 2.7 per employee, it would take us about 10 years to process the remaining claims.

And the application process to get this denial processed through some sort of appeals process has an even smaller approval rating. It's a judge, jury, executioner.

I just don't think it's right. I think we need to streamline this process. You need as a leader, in my opinion—we talked about this any office—make sure you know what paperwork is required, how it's processed, and we need to spread the process about tenfold in order to do our job for the American people.

And, with that, I'm out of time, and I yield.

Mr. CLOUD. Mr. Chairman, I'd ask unanimous consent to submit this for the record. It's an article from The New York Times that said COVID—entitled "COVID Shots for People. Much of the world has decided that most young children don't need to receive COVID booster shots. The U.S. is an outlier."

Dr. WENSTRUP. Without objection.

Mr. CLOUD. Thank you.

Dr. WENSTRUP. I now would like to recognize Ranking Member Ruiz for a closing statement.

Dr. RUIZ. Yes, this just, again, you know, medicine is very nuanced. Our human body is so remarkably beautifully made, and our physiology is a complete wonder still. You know, taking a snapshot of a time and using it to go back and define the entire experience of COVID in children is, again, misleading.

Now with rates that are low, with information that we have on children, children that are at high-risk, immunocompromised should get the vaccine. And, in certain areas where the rate is low and the risk of getting infected in an otherwise healthy child, then one would reconsider whether that child would need a booster or in this—in this situation.

So, you know, throwing these kind of facts out there without the context and understanding is wrong, and it's very misleading.

In fact, you know, we've talked about how VAERS here is a screening, not the definitive tool, to use the rate of side effects or serious side effects from getting the vaccine. These are individuals who get the vaccine. And whatever they feel afterwards for a certain time period, they report it, which we want them to do that. We want them to do that. It is a way to screen for this, and we want to have high sensitivity to reduce the false negative. But

then, with this kind of screening test, you have a high false positive.

And that's why we need to reevaluate, do more in-depth investigation on an individual basis to determine whether, in fact, it was caused by the vaccine.

So, we already laid out the reasons scientifically why VAERS is not the, of the five systems, the five multilayered system, VAERS is not the system to use as the definitive rate of infections. But to use it, because it has the false positive, is intentionally falsely misinterpreting the data that is causing vaccine hesitancy.

And people know but they intentionally still speak to it as if it's the definitive data, and that's the part that gets me. That's disinformation. That's not misinformation. That is intentionally giving false information for their own personal and partisan political gain. That's a clear example of what we've been talking about of politicizing science. OK?

So, let's just go back and summarize that, in total, COVID–19 vaccines saved 3.2 million lives, prevented 18.5 million hospitalizations, and saved the United States an estimated $1.15 trillion in medical costs.

So, when we say that the vaccine doesn't prevent getting sick or it doesn't stop the spread of disease, let's go back and talk about the nuanced aspects of the use of vaccines, which is supposed to boost your immune system. And, if you have a high enough immune response to the virus, then, yes, for those individuals, it does prevent them from getting sick.

Am I right, Dr. Jernigan?

Dr. JERNIGAN.

[Nonverbal response.]

Dr. RUIZ. Am I right, Dr. Marks?

Dr. MARKS. Correct.

Dr. RUIZ. Correct.

So, by lowering the risk of getting infected, yes, it does prevent getting vaccines for those individuals. OK? But it's not an absolute.

But, when we talk about absolutes, again, we are intentionally giving disinformation to the American public that they don't work. OK?

Now, if you lower the risk of getting the illness and getting sick or if you increase your immune response enough to prevent symptomatic infection, then wouldn't you say that that reduces the risk of spreading it to other people?

Dr. Jernigan.

Dr. JERNIGAN. I think the more you can lower the viral load, the more likely you are to be able to——

Dr. RUIZ. The "viral load" is a medical term that's important to understand.

So, when you—the vaccines increase your immune response, combats the virus, lowers the viral load. If you have a small viral load, you decrease the risk of spreading the disease.

Is that correct, Dr. Marks? Do I have that physiology or pathophysiology ready—right?

Dr. MARKS. That will be correct.

Dr. RUIZ. That will be correct.

So, would it be correct to say that, indeed, vaccines reduce the spread and, for some individuals, prevent the spread of the virus to other people? Correct?

Dr. MARKS. I think we can say that that's a general statement. I wouldn't want to make it as an absolute statement.

Dr. RUIZ. Correct. That's my point.

Dr. MARKS. But in the spirit of today's hearing——

Dr. RUIZ. That's my point——

Dr. MARKS [continuing]. More information.

Dr. RUIZ [continuing]. Is by—is by intentionally using absolute statements like that without the nuances and you know, and people should know better They're disinforming the community.

And what I said was not absolute. What I said was it reduces the risk of spread. And, for some people, it reduces the spread. So, it does, and it can reduce the spread with that nuance.

And it is because of the safety and efficacy of these vaccines that we are ultimately able to overcome the pandemic. It's because of the vaccines that we're able to change the vaccine guidelines over time or our social distancing practice or wearing a mask, correct?

And, yes, there is work to be done to promote vaccine confidence in the United States and strengthen existing compensation programs. Yes, we can agree on that. It requires funding, capacity, human resources. We can fix the systems to help make it better.

But there's no doubt that the multitiered, multisystem vaccine safety apparatus surveillance systems is the best in the world. And we should talk about that instead of focusing on these false positives or false narratives so that we can build confidence in the American people.

So, misusing our platforms as Members of Congress to spread false or disinformation about vaccines does a disservice to the American people. It manufacturers distrust. Conspiratorial accusations manufacturer distrust. Fearmongering manufacturers distrust.

And, with increased distrust, you increase vaccine hesitancy. With less people taking the vaccine, more people get infected. The pandemic spreads, and more people die.

So how does this help us prevent or better prepare for the next pandemic? It doesn't. It makes it worse and puts people's lives at risk and harms, actually harms, the American people. So, this is the opposite of helping to prepare and mitigate the harms of the next pandemic.

So, I hope that we can find a path forward in the serious work that needs to be done to save lives in the event of a future pandemic and keep people safe in the here and now from current threats.

And, as I said when we started today's hearing, we are already in the process of undoing decades of progress in overcoming infectious diseases. So, we must handle each opportunity to discuss this matter with immense care before we reach a point from which we cannot return.

So, I hope going forward everyone can drop the outrageous false rhetoric that we've heard by some today and instead identify a constructive path forward that protects the people's health.

I yield back.

Dr. WENSTRUP. Thank you.

This hearing should not have been political, and most of it was not, I would say, today fortunately. But the fact that it is simply is further evidence this conversation is completely necessary to take place.

You know, I can say that I have invested in all sides of the issues around the pandemic, starting in 2020 being on the Intelligence Committee and also researching what other countries were doing. How are we going to try and treat people? How are we going to try and save lives, right? Learned a lot.

As Representatives, we're the conduit to asking their questions. It's not easy for them to just call you and get an answer, although I thank you for taking my call early on, Dr. Marks, during the pandemic.

Perception is reality. I mentioned that at the beginning. And that's what we have to—that's what we have to face. And words matter because when you say "reduce," it's different than saying "prevent." And that happened too often, not necessarily from your voice, but it happened, and that's what America heard.

I think it became clear today about the VAERS system. It's not the be-all to end-all. It's the initial recycling can, if you will, and then you decide what actually goes further. But we didn't say that, but it's the only one America saw. It's the only thing that was out there for the public. So, what do we expect? And I think that that matters.

You know, we see things on some of these natural items in the drug store. It will say on there "not approved by the FDA as legitimate treatment." But it's OK to take, but it isn't necessarily going to meet all its claims necessarily. We put that out there. That's an honesty. That's an honest approach to what—what America is out there.

You know, look, I think there's never been a question that vaccines save lives by anyone. I'm from Cincinnati. Do you know how much pride in Cincinnati we take because it's the home of Albert Sabin and the polio vaccine? You know, it's huge. That's in our DNA in Cincinnati. We grow up knowing that. We take pride in it.

But we can't leave behind those that have been injured simply because they don't necessarily fit a narrative regarding the vaccine safety. We got to take all that into consideration.

We heard today patients and parents should have a conversation with their personal healthcare provider to assess the vaccine, whether it's appropriate for their particular position, condition, whatever. You know, Dr. Marks, I heard you today very caringly, I feel, say you have regret about those under 5 years old that may have died from COVID.

But I talked to pediatricians. And some say, yes, I think they should be vaccinated if they've got A, B, C, D, or E.

And I think that's important. One size doesn't fit all in medicine. It never has and never will. That goes back to talking to your doctor, and that goes back to revealing all the data about those that may have died. You know, these are children that maybe would have died if they got the common cold. I don't know. But those are things you have to take into consideration.

I've learned a lot about COVID–19. I think if we want to assess somebody's vulnerability, maybe we should check their furin levels, and I won't go into the science of that, that maybe you all understand, because that's what it takes to cleave the furin cleavage site, which makes it more infectious to humans. That's another story.

But, you know, this Committee, I think we did a good job today if we really look at the facts that we revealed and discussed openly about where our pitfalls are. And I'm not just blaming the government because it's politicians, too. It's politicians that drove a lot of distrust in what was coming out of public health.

Look, I just go back to the beginning. President Trump says we need to restrict travel. Dr. Fauci told us that he recommended that we restrict travel. What happened to President Trump when he said that? He's a racist.

And people started—politicians say, "Oh, no, there's nothing to worry about here. That's a racist comment. Come to Chinatown." You know, let's create a super spreader.

That's a problem. That's a problem on our side, and that's why I say we need to hear from the doctors treating COVID patients more than anyone else.

You know, again, lives have been saved. Well, we can't ignore the maladies. We can't ignore certain things, you know.

You know, I mentioned before, Dr. Marks, you're advocating Operation Warp Speed. We were with you all the way. But you have a politician saying that, in essence, Dr. Marks, if it's your vaccine, she's not taking it. That doesn't help us. That creates vaccine hesitancy.

When a politician stands up and says, "If you take this, you're not going to the ICU and you're not going to die," yet some were going to the ICU, and some were dying, that's a fact. And it may have been a lot of other reasons for it.

China comes out, says, "We've got this under control." The WHO parrots it. Dr. Lane goes to China. They got it all under control. That's the advice given to politicians.

So, of course, there's distrust. But there, that came from China themselves. They didn't have it under control. Yet that's what they were telling everybody. That leads to distrust. So, we must trust but verify, especially when we're taking advice from an adversary.

Look, the risks have to be put out. No drug can run a commercial—regardless of what you think of commercials on drugs—they can't run it without listing all the risks. Doctors have to sit—or it's malpractice if they don't go over the risks. We weren't doing that, and we issued a mandate, said you got to get it, or you'll lose your job. They go to the drug store, and get it and get their card. Did they have a sit-down?

I'm glad to hear you all agree today, at least I think you do, that it requires—the best practice is to have a conversation with your doctor about your personal health. And the better data the doctor has, the better we can treat patients. That's what we're after, saving lives, treating patients better.

I mentioned before about, you know, there's a difference between saying—effectiveness data is different than just saying it's effective. There's data that might say it's not a hundred percent effective, right? And we know that. But this is what the public hears.

And so, they get confused because they know, "Well, I know some people had an adverse reaction. Why are we saying it's safe? It's not a hundred percent safe."

So, you may have done work completely 100 percent right, but if it's not messaged clearly or accurately down the line, that's a problem.

I often ask, where's our Surgeon General to be talking about this? You know, when I grew up, it was C. Everett Coop, and people trusted it.

The reason I said we need to hear from doctors treating COVID patients, I'm reminded of General Schwarzkopf during the Gulf War. Every night America tuned in to see what the general had to say about the war, not what a politician had to say about the war. I think that makes a huge difference.

We recognize today gratefully that what you're telling the American people, when we recognized myocarditis is a problem, we did something about it. That's important. That builds public trust. But if it's perceived that we're just ignoring it and mandating this anyway, it's a problem.

I question why we quit talking about convalescent plasma as a form of treatment. Especially when we knew that the vaccine we had did not prevent you from getting COVID—you just got less sick—why were we not focusing more on treatments like that that were very effective? At least in Cincinnati, I saw that.

Why did we ignore natural immunity? I was told I needed a booster to go to Germany. I had been vaccinated, both doses of Pfizer. I got COVID several months later, and the only reason I knew is because I couldn't smell garlic salt. That's the only way I knew.

And, when I got my antibodies checked—I wanted to do T cells, as well. When I got my antibodies checked, when I'm being told I need a booster, the strong number was 40; my number was 821, and I've got the lab report to show it.

Now you have a conversation with your doctor about that. Why did we put this aside?

And that's what America understood. Why are we not talking about the benefits of natural immunity? Why are we not saying, if you have natural immunity, you are less likely to get another round of COVID? Why were we not looking at that kind of data to see?

Those are things we should have done. Actually, I wanted to do that through the military, and Secretary Austin never responded. Matter of fact, it was 22 physicians that signed that letter to the Secretary of Defense, and he never responded. He never answered our question even after several attempts.

So, we have some things that, you know—we've got people here that want to make a difference, especially going forward. But we can't ignore these hiccups. We can't ignore these questions that the American people have.

If I only sat here in Washington, I can't have this discussion with you the way I'm having it. But it's you go home, and you're the conduit to the government. And you know what? If we aren't honest, if we can't be trusted, we don't get elected. But they see people in Washington never leave amongst the unelected. Just understand

that. That's why it's important we have this conversation. That's why it's important that we do better going forward.

And I thank you all for your time today. I appreciate the work that you do. We want to be helpful to make it even better in the future. So, I thank you all again for being here, for your important, insightful testimony.

With that, and without objection, all Members will have five legislative days with which to submit materials and to submit additional written questions for witnesses, which will be forwarded to the witnesses for their response.

If there's no further business, without objection, the Select Subcommittee stands adjourned.

And thank you all for attending.

[Whereupon, at 12:37 p.m., the Committee was adjourned.]