ASSESSING AMERICA'S VACCINE SAFETY SYSTEMS PART II

HEARING

BEFORE THE

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC

OF THE

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

U.S. HOUSE OF REPRESENTATIVES

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ASSESSING AMERICA'S VACCINE SAFETY SYSTEMS PART II

Thursday, March 21, 2024

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

The Select Subcommittee met, pursuant to notice, at 2:49 p.m., in room 2247, Rayburn House Office Building, Hon. Brad Wenstrup [Chairman of the Select Subcommittee] presiding.

Present: Representatives Wenstrup, Malliotakis, Miller-Meeks, Lesko, Joyce, Greene, Ruiz, Dingell, Mfume, Ross, and Tokuda.

Dr. WENSTRUP. The Select Subcommittee on the Coronavirus Pandemic will come to order. I want to welcome everyone.

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

Before I move on to opening statements, I want to go ahead and remind the Members of all the rules of decorum. The issues we are debating are important ones that Members feel deeply about. And while vigorous disagreement is part of the legislative process, Members are reminded that we must adhere to established standards of decorum in the debate. This is a reminder that it is a violation of House rules and rules of the 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 this committee. The Chair will enforce these rules of decorum at all times and urge all Members to be mindful of their remarks. If the Chair finds a 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, and now I guess I am talking to everyone, not just the Members who aren't here.

Anyway, I want to welcome everyone to part two of a hearing which we first held last month. During part one, I began by saying that vaccines are crucial tools for public health which save millions of lives, and I want to reiterate that today. However, the utility of vaccines is dependent on the American people's trust. Like any other medication, vaccines are only useful when people trust that they are safe, and patients elect to get vaccinated.

I have heard criticism that this committee is simply seeking to rehabilitate the image of Federal agencies despite their shortcomings during the pandemic, and I disagree with that characterization. Rather, my goal is to reform these agencies so they can earn the people's trust. You know, it is easy to kick and scream about the Federal Government's failures. It is quite another to actually fix the problems so that we may do better the next time. That is really the goal, but this can't be done without buy-in from all parties involved, including from Federal agencies.

During part one, we heard from three of the Federal Government's experts on vaccine safety, surveillance, and compensation. We learned that the government was unprepared for this massive wave of reports to its surveillance systems and claims to its compensation programs. You do not expect a pandemic every day. It is understandable. Today, we will hear from nongovernmental experts who utilize these systems from the other side, and it is important that the American people hear from the doctors who actually treat COVID patients. I've said that since the beginning of the pandemic. Unfortunately, during the pandemic, it seemed that the loudest voices were government, bureaucrats, and politicians, and I have found as a physician and as a Member of Congress that Americans want to be educated, not indoctrinated. It is key to the doctor-patient relationship.

So, one doctor who was bedside during the pandemic is Dr. Patrick Whelan. Dr. Whelan is a pediatric rheumatologist and an expert in molecular biology and immunology. Now, Dr. Whelan has co-authored a paper which studied COVID–19 vaccine trial data and found excess risk of certain serious adverse events. Dr. Whelan also submitted a VAERS report for a young child who experienced a cardiac event after a second COVID vaccination. Sadly, a week later that young man, that boy died. When Dr. Whelan tried to update the report, he discovered that the VAERS system is not set up to acknowledge updates such as this. VAERS still lists the outcome as cardiac arrest.

Dr. David Gortler is a pharmacist and pharmacologist who has experience as an investigational medicine scientist at Pfizer, as a professor at Yale School of Medicine, and as a medical officer and senior medical analyst at the FDA. Dr. Gortler has submitted written testimony today which indicates that the FDA systems and procedures for assessing and regulating COVID–19 vaccines are inadequate. Among other things, Dr. Gortler argues that the U.S. MedWatch surveillance system, which includes VAERS, should be used more aggressively to warn patients about adverse events.

We will also hear from an expert on vaccine injury compensation. As I stated at the last hearing, the government has assumed the responsibility to compensate for vaccine injuries, however rare they might be. Yet, it appears the government system may not be properly upholding this responsibility, especially during a time of a pandemic. Appearing before us today is Ms. Renée Gentry. Ms. Gentry is the director of the George Washington University Vaccine Injury Litigation Clinic and has practiced as a vaccine injury attorney for more than 20 years. Ms. Gentry will testify regarding Vaccine Injury Compensation Program and Countermeasures Vaccine Injury Compensation Program, which adjudicates claims for

COVID–19 vaccines. In her written testimony, Ms. Gentry has highlighted serious problems with these systems, which require modernization. Ms. Gentry also explains that the CICP gives the vaccine injured little more than a right to file and lose. We can't be fully prepared for a future pandemic until we properly address the shortcomings in our vaccine safety systems and any other shortcomings that we may recognize so that we can correct them.

I look forward to a robust and on topic discussion today, and 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. As we discussed during the first part of this hearing series, our Nation's vaccine safety systems play a critical role in protecting public health. For decades, these systems, which operate every day, thanks to the tireless work of our Nation's scientists, physicians, and public health officials, have helped ensure that the safest and highest quality vaccines and medical countermeasures reach the American people, protecting us from the threat of deadly diseases every day. And in the midst of a once-in-a-century public health crisis, these systems worked in tandem with the massive rollout of the safe and effective COVID–19 vaccines, a campaign that allowed us to put the darkest days of the pandemic behind us.

Working together, our Nation's public health officials, physicians, and healthcare workers partnered to get shots in arms, including through Federal initiatives and policies that increased availability and encouraged uptake. At every step of the way, they were united in putting patients first, and thanks to these efforts, we were able to safely reunite loved ones, turn the corner on the pandemic, and reopen schools, businesses, and workplaces. In total, 3.2 million lives were saved, 18.5 million hospitalizations prevented, and an estimated $1.15 trillion in medical costs avoided.

And along the way, our vaccine safety systems functioned as they should by collecting a wide breadth of data that has overwhelmingly reaffirmed the safety and efficacy of COVID–19 vaccines while detecting safety signals for rare adverse events. For example, during the pandemic, this system detected cases of thrombosis with thrombocytopenia syndrome, or TTS, linked to the Johnson & Johnson vaccine. When the safety signals were identified, the CDC and FDA took swift actions to update recommendations for vaccine products. During last month's hearing, we discussed this example as a case study of why it is so important that we continue to invest in our vaccine surveillance systems. And we discussed the importance of ensuring that there are adequate compensation systems in place so that people who experience rare, yet serious adverse events can receive timely compensation and access the care that they need. So, by pursuing these two policies—robust vaccine surveillance funding and necessary reforms to our Nation's compensation programs—we can better prepare our Nation for future public health crises and boost vaccine confidence in the process. And in doing so we will keep COVID–19 at bay and improve our defenses against a vast array of viruses that threaten our public health daily.

So, this work could not be more important than at this current moment. You see, we are at a tipping point when it comes to vaccine confidence. 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. Americans are also now less likely to consider getting the measles, mumps, and rubella vaccines than they were 3 years ago. This is extremely troubling as we continue to see outbreaks of measles due to waning vaccination levels that threaten children's health across the country. In fact, the United States may lose our measles elimination status that we have held for the last 24 years. We must correct course before it is too late.

Approaching each opportunity to discuss this topic with care, collaborating with community-based organizations on vaccine outreach, and strengthening access to care are all critical components of this work. Just as critically important is continuing to work with physicians and healthcare leaders to enhance trust in public health. As a physician, I understand that stronger collaboration between providers, patients, and policymakers is the key to solving the challenges in public health that we face. So, I hope that today's discussion fosters that collaboration and that we come away from this discussion better prepared for the future. I yield back.

Dr. WENSTRUP. Thank you very much. I am going to introduce our witnesses now. Some of the accolades I may have already mentioned, but we will go through them. I think it is important.

Dr. Patrick Whelan. Dr. Whelan is an Associate Professor of Pediatrics at UCLA, Adjunct Professor in Molecular Microbiology and Immunology at USC, and Lecturer in Pediatrics at Harvard Medical School.

Dr. David Gortler. Dr. Gortler is a pharmacist and pharmacologist who has worked at Pfizer, Yale Medical School, and the FDA. Dr. Gortler is currently a Senior Research Fellow for Public Health Policy and Regulation at the Heritage Foundation.

Ms. GENTRY. Ms. Gentry is the Director of the Vaccine Injury Litigation Clinic at the George Washington University.

Dr. Yvonne "Bonnie" Maldonado. Dr. Maldonado is the Chief of the Division of Infectious Diseases, Department of Pediatrics at Stanford School of Medicine.

Pursuant to Committee on Oversight and Accountability Rule 9(g), 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?

[A chorus of ayes.]

Dr. WENSTRUP. Thank you. Let the record show that the witnesses all answered in the affirmative. The Select Subcommittee certainly appreciates you all being here today for this event, and we look forward to your testimony.

Let me remind the witnesses that we have read your written statements. They will appear in the full record on the hearing, but please limit your oral statements to 5 minutes at this time. And as a reminder, press the button in front of you on the microphone so that it is on, and members can hear you. And when you begin to speak, the light in front of you will turn green. After 4 minutes,

the light will turn yellow, and when the red light comes on, your 5 minutes has expired, and we ask that you wrap things up.

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

STATEMENT OF PATRICK WHELAN, M.D., PH.D.
ASSOCIATE CLINICAL PROFESSOR, PEDIATRICS
UCLA DIVISION OF RHEUMATOLOGY

Dr. WHELAN. My thanks to Dr. Wenstrup and Dr. Ruiz and all the members of the subcommittee for inviting me today to contribute to your deliberations on our vaccine safety systems. Allow me to make clear that I am speaking in my own capacity as a physician and researcher and not on behalf of any of the institutions with which I have been affiliated. I completed a Ph.D. in microbiology and immunology and had the privilege as a young man to care for Dr. Jonas Salk when he was a patient toward the end of his life. My day job is as a rheumatologist in Los Angeles, and as Dr. Wenstrup mentioned, I have been lecturing for the past 13 years in virology at the University of Southern California. And I have also had the privilege of being affiliated for nearly 30 years with Harvard Medical School in Boston, and I still teach a Harvard extension course, an undergraduate course in the spring.

During the pandemic, I cared for innumerable pediatric and adult COVID patients, and I hold the CDC and the FDA in the highest regard. In November 2020, I chaired a study group for the American College of Rheumatology that was focused on COVID vasculitis, and it was attended virtually by nearly a thousand rheumatologists. I appreciated that day that the mRNA vaccines then under development were novel in a way that was not widely appreciated. They encode the very protein that itself is causing the respiratory failure in those who were most severely affected by the disease. This is in contrast to the other vaccines that we depend on, which are either attenuated live virus vaccines like measles, mumps, rubella; non-pathogenic component vaccines like the Hepatitis B virus; or inactivated toxins like tetanus toxin.

In December 2020, on the eve of the first advisory committee hearing to consider approval of the Pfizer vaccine, I wrote a letter to the FDA pointing out a new study that found enduring myocarditis in two-thirds of healthy young people who had been infected with COVID. I urged the committee then to specifically assess the effects of vaccination on the heart and suggested that although everyone wanted to quickly bring the pandemic to an end, it would be worse if we failed to anticipate long-lasting side effects of these new vaccines. I never heard back from anyone at the FDA, but no vaccine or other drug is perfect, and we shouldn't have been surprised when a few months later reports emerged about young people presenting in emergency rooms with elevated heart enzymes following vaccination.

I subsequently joined a group of epidemiologists who analyzed the data that had been collected by Pfizer and Moderna in their randomized controlled trials prior to the emergency use authorizations, and we attempted to calculate the precise incidence for serious adverse events, or SAEs, in adults who receive these experimental vaccines. We discovered that in the Pfizer trial, there was one additional serious adverse event for every 556 people vac-

cinated, or about 1,800 for every million. Yet, the regulators at that time conveyed the impression that there were no major safety concerns. Our peer-reviewed study was published in the journal, Vaccine, in 2022.

At a personal level, as Dr. Wenstrup mentioned at the beginning, I took care of a young boy who suffered a cardiac arrest in our emergency room shortly after receiving his second COVID vaccination. I filed the VAERS report at the time, and I felt it was my civic duty. I had filed other VAERS reports previously, but when the patient died a week later, I tried to update the report, and the system is not set up to do that, which led me to believe that the system underestimates the incidence of more severe outcomes since many children and adults who are very sick and later die, they are going to get a VAERS report filed initially.

I do not know how many people are available at the FDA to followup on the more than 1.7 million VAERS complication reports that have been filed the past 3 years. But I feel strongly that we must work proactively in our public health system, both to accurately identify the true risks of all medications, including vaccines, but also that we must have the courage to trust Americans with this information in a spirit of ethical informed consent. Hopefully, we will ultimately know the true long-term risks and benefits of these vaccines that have been given now to nearly three-quarters of the world's population. Thank you again for the honor of meeting with you today.

Dr. WENSTRUP. Thank you. I now recognize Dr. Gortler to give an opening statement.

STATEMENT OF DAVID GORTLER, PHARM.D.
SENIOR RESEARCH FELLOW
PUBLIC HEALTH POLICY AND REGULATION
THE HERITAGE FOUNDATION

Dr. GORTLER. Thank you, Dr. Wenstrup, Dr. Ruiz, and Members. The views I express in this testimony are my own and do not necessarily represent any official position of the Heritage Foundation.

The drugs we take and the food we eat are the most regulated things in the world, despite many people thinking that it is things like guns or airplanes or cars. Since most people know at least a little bit about cars, I am going to use a car analogy to compare COVID mRNA injections to development of a new car. Let's say that it normally takes 10 to 12 hours to assemble a car, representing the 10 to 12 years that it takes to bring a vaccine to market. Let's also say that due to some sort of emergency, new cars would be jammed down the same assembly line in just 45 minutes instead of 10 to 12 hours, representing the relative 9 months it took to bring COVID RNA injections to market. Let's also suppose that those cars are something completely different from what you know as cars. I don't just mean the next cool-looking car. I mean something visibly and technologically unrecognizable.

Whatever advanced car you are picturing in your head right now, it is not that. It is something more complex. On top of the novel design of the car, all of the parts of that car are new. The new car being produced might not have wheels, a brake pedal, a windshield, for instance. Let's also say that it was not powered by elec-

tricity or combustion either. Instead, it uses your body as a fuel source. Not only are all the parts new, but the materials used to manufacture those parts are new, with decades of research showing them to often be extremely delicate, finicky, or toxic, representing the fully synthetic RNA nucleotide and lipid nanoparticle components. Of note, since the development and review time was reduced by over 90 percent, even if the slightest error was made to those ultra complex cars, the car might not work at all and/or could be extremely unsafe and/or highly unpredictable for you, your family, friends, and fellow drivers.

Let's also say that the new car was so novel and different from every other car on the road that it did not even meet the current definitions of car. Rather than call it what it was, the National Highway Traffic Safety Administration unilaterally altered its 100-year-old plus definition of a car on its website overnight without seeking outside input. This represents the CDC's fall of 2021 abrupt definition change of vaccines versus gene therapy.

If a curious material scientist or engineer wanted to perform research about the design and materials used in this new car and replace some critical technical information, 70 percent of the document would be grayed out with (b)(4) redactions, translating to "protects trade secrets and confidential commercial or financial information." In other words, the engineering blueprints and materials used to build that car were secret despite taxpayer dollars being used to research and produce those cars.

Let's compare that new car to an existing car. To keep expenses low, I personally prefer to drive a very specific older car, which is a true story, by the way. It is nowhere near as fancy or elaborate or laden with features, but it is inexpensive and quite safe, just like ivermectin, hydroxychloroquine, vitamin D, and other COVID treatments. Let's also say my old car was so safe and reliable that it won the Nobel Prize. While my 1995 Lexus LS400 never received a Nobel Prize for medicine, the Japanese inventor of ivermectin did in 2015.

Despite that, 1 day the government, who does not have congressional authority to recommend what available cars to buy or not buy and has never done so in the past, proclaims that my Nobel Prize-winning car should now only be driven by horses and cows, as per the FDA's famous tweet. Now, they are not recalling the car, but they are screaming from on high their unmistakable disapproval, mocking patients and physicians who drive it. Of note, the FDA has no congressional authority to recommend one drug or medical treatment over another and has never done so in the past. Several obsequious state pharmacy boards take it to the next level and use the FDA's implication to forbid the use of my traditional car to anyone other than horses or cows as 20,000 career FDA employees remain conspicuously silent.

Today, over a hundred studies published by over 1,100 authors conducted in over 140,000 patients in 29 countries show a statistically significant lower risk for mortality, ventilation, ICU, hospitalization, recovery incidents and viral clearance for ivermectin. Similarly, positive data is associated with the use of vitamin D and hydroxychloroquine. How peculiar is it that some of the same politicians who believe it is OK to legalize hard street drugs such as

heroin and methamphetamines have a cow when it comes to ivermectin, hydroxychloroquine, vitamin D, and other protocols to COVID? To the country's physicians and pharmacists who prescribed ivermectin or hydroxychloroquine, I would like to tell you right now, you were right. The pharmacy boards were wrong, period. I would bet you my prized 1995 LS400 on it.

To summarize, medical scientists not only have the right, but the duty to ask questions about the safety and unnecessarily complex pharmaceuticals jammed through an expedited review process when there are inexpensive, undebatably safe, and effective alternatives available. Academic medical discourse should be encouraged, not quelled. Thank you very much. I look forward to cultivating an academic exchange with everybody here.

Dr. WENSTRUP. Thank you. I now recognize Ms. Gentry to give an opening statement.

STATEMENT OF RENÉE GENTRY
DIRECTOR
VACCINE INJURY LITIGATION CLINIC
GEORGE WASHINGTON UNIVERSITY

Ms. GENTRY. Thank you, and good afternoon. Thank you to Chairman Wenstrup, Ranking Member Ruiz, and members of the subcommittee for this opportunity to discuss a critical national public health issue. This afternoon, I hope to be able to give you the perspective of the vaccine injured, a voice that often gets lost in the debate. My colleagues and I believe strongly in the importance that vaccines play in our society in eradicating diseases and curbing pandemics. Having said that, vaccine injuries while rare in the vaccinated population, are real.

Routine and pandemic immunization programs are the cornerstone of our public health policies. The success of those immunization programs relies on public confidence in vaccines. A critical component of vaccine confidence is ensuring that those rare individuals who are injured by vaccines have a reasonable and effective forum in which to make their claims and an experienced bar to represent them. The VICP needs modernizing to shift from the aspirations of 1986 when it was created to reflect the realities of 2024 and our current public health needs. Much has changed in the nearly 40 years this program has existed. Congress intended that the VICP provide individual petitioners a swift, flexible, and non-adversarial alternative to the often costly and lengthy traditional tort civil litigation system. You cannot file a lawsuit against a manufacturer or administrator of a covered vaccine without going through our program first.

While imperfect, the VICP was tremendously successful in its first 30-plus years. New vaccines were developed at such a rate that the program grew from six covered vaccines to 16. Very few petitioners rejected the decision of the vaccine court and filed suit against a manufacturer, and fewer still opted out of the program at the 240-day mark when they are permitted to pursue civil litigation if their claim has not been processed. This reality perfectly reflected Congress' intent that petitioners be compensated quickly and generously by making the VICP a reasonable and meaningful alternative to civil litigation.

Three procedural events have resulted in the VICP being overwhelmed at this point. The addition of the influenza vaccination in 2005 resulted in the pool of potential petitioners being exponentially increased as obviously the influenza vaccination is generally recommended to everyone, adults and children, every year as opposed to the typical childhood vaccines. In 2015, two additional vaccines were added, the HPV and meningitis vaccines, which once again opened the VICP up to additional potential claims. Finally, in 2017, two significant table injuries were added: SIRVA, the shoulder injury related to vaccine administration, which is associated with nearly all the covered vaccines on the vaccine injury table, and Guillain-Barre Syndrome, following the influenza vaccination.

The collective effect of these procedural changes was to triple the workload of the special masters in the vaccine court, the number of whom are still statutorily restricted to eight—eight special masters with a caseload, as of last Friday, of 3,618 cases. As a result, it is now the norm in the vaccine court to wait 2 years for a trial date after having already waited, in some instances, years for a record to be ripe for trial. There are simply no spaces on the court's docket. Today, through no fault of the special masters, vaccine-injured children and adults wait years, often without the ability to pay for critical time-sensitive therapies for the vaccine court to even be able to award compensation. To be clear, these crushing delays are not because vaccines are less safe but because the VICP's infrastructure has not been updated to reflect current public health policy, and we fully expect the ongoing development of new lifesaving vaccines. Children are not the only ones that get vaccinated anymore, as we all know.

Even more concerning is the fact that this reality does not yet reflect the addition of the COVID–19 vaccines, which I strongly believe are more suited to the VICP than the Countermeasures Program. Unlike the VICP, those injured by COVID–19 vaccines and restricted to the Countermeasures Program have no right to counsel, no right to appeal, no pain and suffering awards, and significant limitations on economic damages. I have not heard of a single person currently engaged with the Countermeasures Program for the COVID–19 vaccine that feels as though their voice was being heard. This is driving vaccine hesitancy in individuals who have previously been vaccinated and were pro-vaccine.

Finally, it is critical to distinguish the vaccine injured from the anti-vax. All of my clients were vaccinated. They suffered real and often catastrophic injuries that are supported by medical and scientific literature and expert opinion. The well-meaning, the often dismissive and critical comments of the pro-vaccine side directed at those individuals asserting vaccine injury also creates and bolsters vaccine hesitancy in those individuals who were previously vaccinated and are pro-vaccine. The vaccine injured that I and my colleagues represent are not anti-vax. That is a critical distinction that I hope you take with you as you look for solutions to the challenges the VICP currently faces. Thank you.

Dr. WENSTRUP. Thank you. I now recognize Dr. Maldonado to give an opening statement.

STATEMENT OF YVONNE "BONNIE" MALDONADO, M.D.
CHIEF OF THE DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF PEDIATRICS
STANFORD UNIVERSITY SCHOOL OF MEDICINE

Dr. MALDONADO. Thank you, and good afternoon. Chairman Wenstrup, Ranking Member Ruiz, and distinguished members of the subcommittee, thank you for the opportunity to testify. I am a pediatric infectious disease physician, epidemiologist, and vaccine researcher at Stanford University School of Medicine. I led the COVID–19 response at my institution, including scaling up testing capacity and clinical trials for vaccines and therapeutics, as well as caring for thousands of seriously ill patients.

The decision at its core to use any medical product is a risk-benefit analysis. Decades of data underscore the enormous benefits of vaccines. Early in my career, I routinely saw children dying or suffering from severe health problems due to infectious diseases. We no longer see these deaths and complications in the United States thanks to vaccines, and, as a result, some individuals may not understand the benefits that vaccines have provided, especially to our children. But vaccines remain critically important, as you have heard, and prevent tens of thousands of deaths from vaccine-preventable diseases every year.

COVID–19 vaccines are safe and provide protection against hospitalization and death and reduce the risk of long COVID and, in children, MIS-C. COVID–19 vaccination has also had tremendous societal benefits, including preserving our health system's capacity to care for patients and facilitating a return to normalcy. Early in the pandemic, there were rare instances of teenage boys and younger men experiencing heart inflammation, which happened about as frequently as being struck by lightning, about 1 in 10,000 vaccinations. Most of these people responded well to medicine and rest and felt better quickly. This small risk is even less now that we have safety recommendations like spacing out vaccines for young men and women. COVID–19 infection is also much more likely to cause heart damage and other severe events than the vaccine. A study of over 20 million people published this month found, for example, that COVID–19 vaccination significantly reduced post COVID–19 cardiovascular complications, including myocarditis, heart attack, and stroke.

COVID–19 vaccines were rigorously evaluated in large clinical trials, through which scientists gathered significant safety and efficacy data from diverse populations. Healthcare workers like myself were among the first to be vaccinated, demonstrating that experts across the country had great confidence in the vaccine safety and effectiveness. As I said, any medical product carries some risk, and it is critical to have robust systems in place to monitor for adverse events and compensate individuals who are harmed. These programs are a key component of broader efforts to boost vaccine confidence.

Sometimes rare events may occur after vaccination that are too rare to be identified within clinical trials. Vaccine Adverse Event Reporting System, or VAERS, is explicitly designed to cast a very broad net to capture all potential adverse events that may occur following a vaccine. Reports are investigated, and most severe

events are ultimately found to be unrelated to the vaccine. In other words, correlation does not equal causation, and severe adverse events associated with COVID–19 vaccines continue to be rare.

When investigations indicate a serious risk associated with a vaccine and vaccine policies and recommendations are updated accordingly, this indicates that our vaccine safety systems are working. One example is the investigation into reports of TTS, which we heard earlier, which led to a pause in the use of the Janssen COVID–19 vaccine and, ultimately, a recommendation for the preferential use of mRNA COVID–19 vaccines over the Janssen product, which is no longer used in the United States. In the rare event when an individual is harmed by a vaccine, it is important that they can receive compensation, which is the purpose of the Vaccine Injury Compensation Program, the VICP, and the Countermeasures Injury Compensation Program, CICP. COVID–19 vaccines are currently covered by the CICP, which has been underfunded as compared to the VICP. Bipartisan legislation has been proposed to move COVID–19 vaccines to the VICP and strengthen the Federal response.

In the years leading up to the COVID–19 pandemic, our public health system was chronically underfunded, which has negative repercussions across public health, including vaccine safety monitoring. While Congress appropriated emergency funding for the COVID–19 response, providing adequate funding for public health before an emergency occurs is critical to ensure that we have a sufficiently trained work force and infrastructure. Thank you again for the opportunity to testify and for your efforts to boost vaccine confidence and uptake.

Dr. WENSTRUP. Thank you. I now recognize myself for questions and a few comments.

You know, one of the things with COVID itself that makes it very difficult is there is so many people that got COVID and did not even know they had it. And so, if you are trying to say that it was safer to have the vaccine as opposed to getting COVID, it is very difficult because many patients got COVID and did not know. I did not know until I could not smell garlic salt. So, I just think we have to keep that in mind when we have a frank discussion about the benefits and risks of getting COVID, getting COVID at a certain age, getting COVID with certain comorbidities. All those things have to be discussed, but we can't ignore the fact that many people got COVID and did not even know it, so that is one thing. But Dr. Maldonado, do you think it is important to have a frank discussion with patients or, in your case, the parents of children to discuss the benefits and risks of virtually any medication, but especially vaccines?

Dr. MALDONADO. Absolutely. I believe that the bond between a physician and a parent and a patient is sacred and really should be transparent.

Dr. WENSTRUP. Yes, and I think that is one of the things that we missed. When we started putting out mandates, you eliminated the physician, and that is what a lot of people struggled with, which, in my opinion, has led to many people having vaccine hesitancy. When I say, "my opinion," it is because we are out with our constituents all the time and we get their opinion. And so that is

a difference between, say, just working in a lab or in an agency. You know, we are actually out with the people and understand what is going through their minds.

You know, during part one, I asked our government witnesses to acknowledge that they were, well, too general in their assertions that the vaccine was safe and effective. I said at the time, to the American public, many of them heard "100 percent safe and effective." That is what they interpreted that to be, but they never qualified their statement. You know, like any drug you see on TV, they say talk to your doctor. That wasn't happening. You had the government saying safe and effective, no qualifier, not talk to your doctor. And so, from what I understand, the FDA standard of safe and effective is actually very specifically defined. So Dr. Gortler, if you can very quickly let me know, does the FDA have different standards for EUA and full BLA approval? Could you explain the difference, if there is one?

Dr. GORTLER. Oh, sure, and Dr. Wenstrup, I appreciate the question. I would also like to point out that one of my colleagues, Dr. David Weisman, pointed out to me yesterday that the approval language in Europe is actually a little bit different where it says, "safe and effective." I think they precursor those words with maybe "safe and effective."

Dr. WENSTRUP. So, what about ours?

Dr. GORTLER. So, with ours, I believe the way the approval process works is, once it is authorized one way or another, it is authorized. You know, we heard, like, Operation Warp Speed, and, you know, Operation Warp Speed, while it was kind of, you know, a cool idea with underlying themes of, you know, the person who conceptualized it with Yale and ham radio and Star Trek, of course, I would have just liked to have seen something a little bit simpler.

Maybe I am a little bit of a Luddite, a Philistine, perhaps, but I would be interested in seeing what already exists in our toolbox that isn't quite as complicated. And for instance, just to let you know, the molecular weight of hydroxychloroquine is about the same molecular weight, size as Tylenol, about 300 daltons. In contrast to that, we do not know what the exact structure is, or the exact molecular weight is for the spike protein encoding for RNA, but just the spike protein alone is, like, 4,000 bases, which is about 200,000 daltons compared to about 300 daltons. I would have liked to have seen an Operation Warp Speed for things like ivermectin, hydroxychloroquine, vitamin D, maybe colchicine, midodrine, metformin——

Dr. WENSTRUP. Let me get to a different question or maybe get more specific. Are the systems that we have in place, in your opinion, adequate in ensuring the safety of COVID–19 vaccines?

Dr. GORTLER. The question is for me, sir?

Dr. WENSTRUP. Yes.

Dr. GORTLER. No, they are not, and I can explain why. I do not think the collection systems are adequate for the following reasons. As a physician, you will know, and there are other physicians in here, a normal physician visit is usually billed out as a code, not ICD–10, but whatever the code is. It is 99213 for a 15 minute——

Dr. WHELAN. CPT.

Dr. GORTLER. A CPT code—thank you—is a 99213, and 99213 pays a physician something like $75 to be able to, you know, interview, assess, diagnose, and prescribe. And if a patient were to report an adverse event during one of those events, a physician wouldn't really have the time to collect it and go on the phone and spend an hour with the FDA MedWatch system. Likewise, a pharmacist is also someone who receives quite a bit of safety complaints. But a poor pharmacist, you know, working behind the counter at one of these grueling chain pharmacies, you know, they have metrics by their employer, and their metrics are to hammer as many round pegs in a round hole as fast as they can, and there is no protocol. There is no way to reimburse for them to be able to report adverse events.

And so, because of that, there was a study funded by the AHRQ that came through out of Harvard that found that it is only the very, very low digits, like 1 percent, the very, very low single digits of adverse events ever reported to VAERS, and I think there needs to be a better collection method. There needs to be more vigilance about reporting by healthcare professionals. Does that answer your question?

Dr. WENSTRUP. Thank you. Yes, it does, and, yes, we also have concerns of reported versus verified significant event, et cetera, and that is the type of stuff we want to be better at. Dr. Whelan, do you believe that it is appropriate to house all of the potential updates and corrections to VAERS on a non-public data base?

Dr. WHELAN. I think that there is a lot of trust involved in the medical community, but also for the general public, that something is happening behind the scenes when you can't see it right out in front. And I think, two, that people were very aware that you did not have the kind of followup on vaccination generally that we expect, for instance, from our pediatricians, where you got a nurse who is going to call the following week and make sure that your child is doing OK. And, I mean, my own strong feeling is that we really needed a much more proactive surveillance mechanism, and I think that many of us understand that the FDA was under enormous pressure and also that it was an overwhelming task. And just judging by the number of VAERS reports that there have been and knowing how challenging it can be to actually file a VAERS report, the task could have been even vastly larger than the large task that it already is.

I mean, you have to have some level, I think, of internal dialog that takes place. But I think ultimately, as you alluded earlier, you have to be able to create some level of trust among people, and I think the system currently does not cultivate that.

Dr. WENSTRUP. Yes. Look, there is no doubt it is a challenge, you know. You might have 10 adverse events from vaccines in a year, and then all of a sudden you have a pandemic and a new vaccine, and the numbers are huge. How do we prepare for that? And those are some of the things that we wanted to discuss here. I will say, Dr. Whelan, the government witnesses in part one of this told us that all serious reports to VAERS are followed up on, and there is not a timeline on that statement. But do you believe that the government is adequately following up on all serious reports to VAERS, and what might we do to improve on that?

Dr. WHELAN. I do not have any high-level view of how often and how closely they followup, but in my own anecdotal experience, there was not a sense of urgency. Because I was a co-author on this paper, I had an opportunity to speak directly with Dr. Marks, who spoke at your previous hearing, and they were in the process of sort of, you know, critiquing our work. When I mentioned that I had had this patient who died, the whole tenor of the discussion completely changed. But even then it was a whole month before I was able to speak with somebody, and I have never received any followup about it later. I am not sure that they ever obtained the records on that particular case, so we were kind of left with the sense that if there was followup, they didn't do much in the way of follow through afterwards.

Dr. WENSTRUP. Thank you. Just a quick question for Ms. Gentry because I think in your opening statement you made many good points in your concerns for the compensation systems in place. And can you give us some idea of how we should change how our system works currently?

Ms. GENTRY. The VICP specifically?

Dr. WENSTRUP. Oh, we can start with that. Yes.

Ms. GENTRY. Sure. I think certainly the main thing with the VICP that we have seen is that it just needs to be modernized. I mean, this was originally the National Childhood Vaccine Injury Compensation Program. And as we all know, adults routinely get vaccines now, and they have always been covered, but it needs to be expanded. Certainly, when I say "infrastructure," we need to have an increase in special masters, to be sure.

HHS and the Department of Justice that represents the Secretary in these cases needs to have adequate compensation or adequate funding rather to make sure that they can do that. We see long delays at HHS in processing petitions because they have so few reviewers to do that. And they were also deployed during COVID away from it, so I think there is certainly some delays in that. That needs to be updated. We are still looking at compensation from the 1980's for these cases, so you are looking at a death case being capped at $250,000 in the VICP. Pain and suffering is capped at $250. There are, thankfully, no caps on economic damages in the VICP, which is great. Those rare individuals with serious injuries have additional care, life care plans that can come into effect. That is critical.

From the standpoint of the Countermeasures Program, you know, when you don't hear much about it, it usually means it is doing fairly well, and when it starts to have an issue is when you start to hear about it. And I think the first big hit that it took was with the H1N1 vaccine back in 2009, and those cases went into to the Countermeasures Program. That was a big chunk of cases, but nowhere near what we are seeing with COVID. And that vaccine came over because it was included in the formulation for the seasonal flu vaccine.

The COVID vaccine, though, I just think it is not the appropriate program for it. We saw Commander Grimes speak at your last hearing, and he gave the burden of proof in the Countermeasures Program. The burden of proof in the Countermeasures Program is higher than in our program, and you do not have attorneys or ex-

perts or anything like that, so I think that is a really difficult burden to meet. And when I speak of causation, I appreciated in your last hearing that both you and Ranking Member Ruiz, we have talked about words matter, so I want to be clear with my words. When I speak of causation in these cases, I am talking about legal causation in the vaccine court, not medical certainty, not a causal analysis as Dr. Maldonado spoke of. We will never have epidemiology in support of our cases because they are rare events. That is what you want them to be is rare events.

So, when I speak of legal causation, it is still much harder in legal causation to prove causation in the Countermeasures Program than in the Vaccine Program than the VICP. I try to use the "Vaccine Program" and "Countermeasures," a little less alphabet soup, but that is very difficult. And when you do not have right to counsel, it is incredibly difficult to prove, particularly if you are injured or you are sick or your family member is sick, to do that.

So, I think there is no improvement that can be made to the Countermeasures Program that would make it appropriate for COVID–19 vaccine cases. There are improvements that could certainly be made to the Countermeasures Program for everything else. Statute of limitations can certainly be increased and different things like that on compensation, but that would be my recommendation for those improvements.

Dr. WENSTRUP. I appreciate that. I now recognize Dr. Ruiz for questions.

Dr. RUIZ. Thank you. During last month's hearing, we heard from Federal officials at the FDA, CDC, and HRSA, who are tasked with overseeing America's various vaccine safety systems. Their testimony walked us through the multi-step process that ensures vaccines available to the American public are safe and effective as possible. Dr. Maldonado, I would like to get your perspective on how these systems worked for the COVID–19 vaccines. Is it true that COVID–19 vaccines underwent rigorous evaluation for safety and effectiveness as part of the FDA's emergency use authorization and approval process?

Dr. MALDONADO. Yes. I won't go through the various phases, but the process by which the Federal Government oversees regulation of vaccine, clinical and other products, devices, as well as other biologics is quite rigorous and very well defined in terms of steps that are laid out for industry and others to participate in these. And the steps taken for the COVID–19 vaccines were similar to those that were used for all the other vaccines that have been studied over the many decades that we have these programs in place. Obviously they were accelerated because of the nature of the pandemic that we were in, but the processes were followed.

Dr. RUIZ. And what did clinical trial data collected as part of these processes show about the safety of the COVID–19 vaccines?

Dr. MALDONADO. Well, as we know, there were adverse events, and that is where our VAERS, VSD, and V-safe systems, among others, really took those into account. But overall, as we went through the process and as I testified earlier, as safety events were identified, they were explored more deeply. And again, within the constraints of the work force and the volume of the claims that were coming through, they were addressed, with the highest pri-

ority being to the most important safety considerations. But certainly, they were addressed as they went forward, the example being the J&J, for example, and other issues. But in general, the safety issues were the most common ones that we see with vaccines, which are pain at the site of injection, fever, swelling, and myolysis. But again, at the other end of the spectrum were the more serious things, like TTS, et cetera.

Dr. RUIZ. Yes. And we talked in more detail about the various systems that were in place to identify adverse reactions, and we talked about how VAERS was the most nonspecific in the sense that it was where patients could write in about anything that they felt, any symptom, any occurrence that they felt was related to the vaccine and that would overcount what one individual would think was related. And in fact, many of the patient-driven were investigated and were not found not to be associated with COVID, but we have to cast a wide net like that so that we can identify any possibility of a true, serious adverse effect. And with Johnson & Johnson, of course, they found that and they made modifications with a recommendation. So once the COVID–19 vaccines were brought to market, multi-layered surveillance systems operated by the CDC monitored for adverse events.

Dr. Maldonado, has data collected through the surveillance systems genuinely reaffirmed the safety of the COVID–19 vaccines?

Dr. MALDONADO. Yes, they have. Generally, they have reaffirmed the safety, but also reaffirmed whether or not SAEs, or serious adverse events, were truly related or not related to the vaccines, and those are done by separate methods. That is by verifying through massive surveillance efforts. Again, no surveillance system is perfect, which is why you need multiple layers of surveillance and strengthening of those surveillance systems over time. The other way to do it is to confirm by using other datasets, for example, Medicare claims datasets, emergency room visit datasets. There are numerous other datasets where you can take large populations and verify what you see in your surveillance through these——

Dr. RUIZ. In the medical and public health world, we want to know, we want to verify, we want to identify the adverse effects so that we can make the adjustments, the changes, the recommendations, find the populations who are contraindicated from taking that vaccine, et cetera. So, you know, I see how we take it very seriously and want to identify them so we can rule them out in order to give the best recommendations as possible. And is it true that in cases where an elevated risk of adverse events has been detected, such as with the J&J vaccine, our Federal public health officials have used this data to swiftly update their vaccination recommendations?

Dr. MALDONADO. Yes, absolutely that is the case, and it just happened recently with the followup of the potential for a risk of stroke from the COVID–19 vaccine, which was a signal that was identified and further investigated and found not to be a true signal.

Dr. RUIZ. OK. But they are taken seriously, and they are looked into further, correct?

Dr. MALDONADO. Yes, they are.

Dr. RUIZ. OK. So, it seems like that is the system that we want, is to be hyper vigilant and then do the investigation to determine to make the changes or adjustments. But overall, the vaccine has shown in a population health base to be safe and effective, correct?

Dr. MALDONADO. Yes, with the data that has come from a multiple surveillance systems.

Dr. RUIZ. And so, has any data collected through CDC surveillance systems drawn into question your recommendation as a physician that patients should receive the COVID–19 vaccine?

Dr. MALDONADO. No, I think the data has been very supportive of my decision to counsel my patients.

Dr. RUIZ. OK. Thank you. And in the case that rare but serious adverse events occur after vaccination, such as severe allergic reaction, HRSA operates a system to evaluate claims and adjudicate them for compensation. Ms. Gentry, you represent patients who have gotten vaccinated and experienced these serious adverse events as they navigate this system, and thank you for doing that. What role does the efficient processing of these claims and meaningful compensation when appropriate play in encouraging patients to receive safe and effective vaccines and reducing vaccine hesitancy across the United States?

Ms. GENTRY. Thank you. I think it is absolutely critical that they have that. I mean, the whole system was designed to be faster than the 240 days. And prior to the three events that I talked about, procedural things, we were processing claims at the vaccine court, some claims in under a year. I think it is very critical, and what you are seeing also with the COVID cases is the frustration of the delays. It is starting to turn people who, again, are pro-vaccine and got the vaccine and want to do the right thing turning away from it——

Dr. RUIZ. Yes. So——

Ms. GENTRY [continuing]. And being very concerned. It is very disconcerting.

Dr. RUIZ. So, it is a systematic issue that needs to be fixed, and——

Ms. GENTRY. Absolutely, in both programs.

Dr. RUIZ. Yes, and I am very in support of making sure that the claims are processed faster and that we update the compensation amount when appropriate to ensure that people are adequately compensated. That is something that I think we can have bipartisan consensus on.

Now, I would like to turn my attention to the physician-patient relationship during the COVID–19 pandemic. As I have stated before in previous Select Subcommittee hearings, the relationship between a patient and their doctor is sacred, a cornerstone of healthcare delivery that is rooted in trust, empathy, and the oath to do no harm. As a physician, it is something I deeply valued when I treated and cared for my patients in the emergency department. And for our Nation's physicians who served on the frontlines of the COVID–19 pandemic, I know it is something they deeply value too.

Yet, over the past year, we have had hearings in this committee on the patient-doctor relationship during COVID and heard allegations that the government overreach and so-called one-size-fits-all

vaccine requirements eliminated the decisionmaking power of patients and physicians. I would like to dwell on this a little further. Dr. Maldonado, were requirements a clinically appropriate tool to encourage vaccine uptake, and how did they help to save lives and prevent severe hospitalizations in the United States?

Dr. MALDONADO. So, I was also the Chair of the Committee on Infectious Diseases for the American Academy of Pediatrics during the period of the pandemic. It just happened to occur at the same time. And I found that our relationship with the 67,000 pediatricians who we represent in the American Academy were highly supportive of the programs and processes that we had in place and actually worked very closely with us on a daily basis during this pandemic to help message not only to providers in, for example, rural areas that had poor access to information, but also to those providers' patients. So, I found that during the pandemic we had a stronger relationship with our providers and patients than I have seen actually in my career.

Dr. RUIZ. So, physicians weren't left out in these recommendations for requirements. In fact, they gave their input, and they supported them?

Dr. MALDONADO. Our opinions were sought out, and when we requested, for example, discussions with, say, Dr. Marks, Dr. Wharton, and others from CDC, FDA, and others, we were at the table, and we were able to put in our opinion in as frontline providers around what would work for our providers and what would work for our patients in terms of communication. And it all has——

Dr. RUIZ. So, you were consulted on even how to better communicate with patients regarding the vaccine and the requirements.

Dr. MALDONADO. Yes, I——

Dr. RUIZ. And you gave your input, and the association gave their input, too?

Dr. MALDONADO. Yes, I believe that our input was solicited on a regular basis.

Dr. RUIZ. And do you agree with the allegation that doctors were sidelined, and that the physician-patient relationship was disregarded in the discussion surrounding COVID–19 vaccine requirements?

Dr. MALDONADO. I did not find that to be the case either at the local level or at the national level in the patients that——

Dr. RUIZ. How did you communicate with your patients during this time, and was there any scenario where you advised for any contraindicated reasons not to take the vaccine and what to do about it?

Dr. MALDONADO. So, what I will say is all of us probably here at the table, we worked probably 24/7 for those, you know, several years. And much of that time was spent in communicating with families, with adults, who also wanted advice for their own selves, and not only their children, in dealing with numerous town halls, webinars. I remember we were on Zoom for a lot of this too, but in person as well seeing patients. We set up large clinics where we could actually see people, talk to them in English, Spanish, Tagalog, whatever language we needed to really get to people so that they could ask the questions that they needed to have answers for.

Dr. RUIZ. Thank you. Before I conclude, I would like to make one thing clear, which is that the physician-patient relationship is not one that occurs in spite of our government's public health institutions. Rather, it is a relationship that is complemented and fortified and perhaps even enhanced by the tireless work of our Nation's public health officials and experts, particularly during times of crisis because let's face it, we need each other. We need everybody in our communities to pull through in a crisis. And we need to be able to work with one another in a very trusting relationship, getting all the input that we need, and then use science to determine the right course of action so that we are not leaving it up to ideology, we are not leaving it up to partisanship, we are not leaving it up to chance, because, ultimately, science and epidemiology is the ruling out of chance in our recommendations to determine patterns that we can get close to the truth in order to provide the best recommendations that we can. And so that is why I see, because of these studies in science, that we are in a much better place. And so, with that, I yield back.

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

Ms. MALLIOTAKIS. Thank you very much. I want to thank our witnesses today for being here to discuss a very critical issue, vaccine safety. And I know many of my constituents have concerns about the government's handling of the COVID–19 vaccine rollout, the communication issues that there were, and the adequacy of our safety monitoring systems. And today, I hope we can have an open and transparent discussion about how to improve these programs to better protect public health, restore trust, and ensure accountability as we move forward, so I appreciate your insights and your recommendations.

My question is for Dr. Whelan. In your testimony, you discussed your research that re-analyzed the Pfizer and Moderna clinical trial data and found a higher risk of serious adverse events compared to a placebo. Did your analysis reveal any safety signals or increased risk of cardiovascular issues like myocarditis, especially in the younger vaccine recipients? And based on your findings and your expertise as a pediatric rheumatologist, do you believe the risk of myocarditis after COVID–19 vaccination has been adequately investigated and communicated to the public, particularly for young males?

Dr. WHELAN. So, thank you for that question. The study that we performed was based on the original Pfizer and Moderna vaccine data in adults, so it didn't address children. And the studies in children which used populations that were considerably smaller and not powered to find the kind of signals, you know, that were apparent in the data for the adults. There were significant problems with the studies as they were performed or, rather, the data as it was reported. And I think that the value added for our group was that we went in, we re-analyzed the data with objective criteria—it hadn't been done that way previously—and we discovered that there was some flaws in the way that both Pfizer and Moderna reported their data that hid some of the adverse effects.

Ms. MALLIOTAKIS. Would you care to share an example?

Dr. WHELAN. I don't know that this was an intentional thing, and I don't know that the FDA was even aware that this was going on, but, for instance, the Pfizer population, their data was reported in a form that included a very large number of people who had only gotten a single vaccination and people who did not have adequate followup afterwards.

Ms. MALLIOTAKIS. Uh-huh.

Dr. WHELAN. So, the number of people that we analyzed were just the individuals who received two vaccinations and received at least 2 months of followup afterwards. What that did was it contracted the total population that we studied by about 5,000 individuals. And all of a sudden, this significant signal emerged, which showed that, you know, the Pfizer vaccine had associated adverse events that, at least by pediatric standards, were pretty high.

So, with regard to, you know, finding myocarditis in young people, I did get phone calls from around the country from providers who were anxious about, you know, young people that came into the emergency room with elevated troponin values and so on. We really don't know what the long-term consequences of having myocarditis as a teenager are, but it was pretty scary, of course, you know, when a child is coming into the emergency room with chest pain and then it turns out that they have got elevated troponin levels, which suggest, you know, that they might be having a heart attack. So——

Ms. MALLIOTAKIS. Well, it is interesting because myocarditis is one of the vaccine injuries that are actually being compensated for, but I think you made a really good point in terms of the followup for long-term effects, right? We really don't know what the long-term effects of not just myocarditis, but also of the vaccine itself. So, in your opinion, how could the vaccine safety surveillance systems be improved to better detect and characterize rare but serious adverse events?

Dr. WHELAN. As I alluded before, I think that the system was under resourced, and I don't fault the individuals involved. I have discussed this with Dan Jernigan, who spoke to the committee last month. And I think they were just approached with an impossible task, which was, you know, how do you vaccinate an entire country and adequately followup on, you know, the individual vaccinations? I just think that they really needed to have an army of people who could have gotten in there and started calling people who got vaccinated and then find out exactly, you know, what was that person experiencing.

Ms. MALLIOTAKIS. So in my last, like, 20 seconds, I just want to ask Dr. Gortler a question. You have written about the FDA's dependence on vaccine manufacturers for certain safety assessments, which some view as a conflict of interest that could compromise the integrity of the approval process and undermine public trust. In your expert opinion what are the most critical weaknesses in the government's vaccine safety surveillance systems? What specific steps could the FDA take to reduce reliance on manufacturers and increase transparency to strike a balance between promoting vaccine confidence while allowing space for addressing legitimate concerns openly?

Dr. GORTLER. So, the one-word answer is transparency, period. The FDA isn't perfect, and when they do things that are a little bit shortcoming, I don't have a problem, you know, speaking up and saying something about it. But when you look at the lack of information, both in the label and the technical documentation of how its manufactured, how the mRNA shots, in particular, are evaluated for safety, there is just too much information missing. Honestly, I don't know if I can blame the FDA for the transparency or some component of the emergency use authorization or the PREP Act that doesn't allow that information in there. But there is information conspicuously lacking, not only from the label, comparing it to other drugs that utilize RNAs as a mechanism of action, especially because this drug is so much more complex.

I mentioned there are about 4,000 base pairs. Another drug, Onpattro, which is also an RNA technology, contains all the information you need, you know, molecular weight, number of strands, you know. It even shows a picture of the structure, and that is only 20 base pairs. And so, we don't have the transparency for something that is a lot more complex, per the introduction that I talked, the car reference. Thank you.

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

Mr. MFUME. Thank you very much, Mr. Chairman. I want to thank you and Ranking Member Ruiz for calling today's hearing. Obviously, I want to thank all four of our witnesses for traveling here to share your thoughts and your understandings, your recommendations, and your suggestions. As an aside, Dr. Whelan, let me thank you for referencing Dr. Jonas Salk, who was an indirect hero of mine. I was in the second grade when the polio vaccine was first approved and distributed. And I say "hero" because it was a small Black school on the edge of the Chesapeake Bay that had attached to it a small, underfunded nursery. And I remember my mother taking me to that nursery as a young person, under the age of 5, and going back the next 2 years and not seeing any of those kids because so many of them had contracted the virus and had passed away, so Salk was a big hero. In fact, my second and third grade teachers collaborated and threw a party to tell us why the polio vaccine was important and how it was going to save lives. So let me get away from that side talk for just a moment, but thank you for what you did toward the end of his life. It is very important. It is not lost on me.

I want to talk about a couple of things, and on this committee, I have tried to be straightforward about what it was like then because the further we get away from the pandemic, recollections fade, memory serves us less. But fear was the order of the day, absolute stark fear, and it was fear among all of us. It was pain. It was anguish. There was death, and obviously there was a great deal of sorrow that some people are still experiencing. People wanted help then and they wanted it right away, and they looked to all of us, whether we were in government or not or, as you are in medicine or not, to figure it out because they thought that they were going to find themselves stricken or losing a loved one.

So, today is a cautionary tale. That is why these hearings are important. We can learn what we did, what we didn't do, how do we

do it better, how do we fix it, what were our shortcomings, what do we own up to. But back then, 4 years ago, caution went out the window, and as a result of that, many of the things that we are talking about today developed.

Ms. Gentry, I really want to land on where you were because victims concern me, and being able to find a way to get compensation is important. And I am not here as a commercial for the Trial Lawyers Association, but I can tell you that people who don't have a voice who were somehow, or another injured by the vaccine and unable to get injury compensation just concerns me, and I hope it concerns all of us. The VICP shortage of masters tells me that things don't move through the courts as they should for many of them. The litigation backup concerns me because it says it is only probably going to get worse unless we put resources to it. It is kind of like what Dr. Whelan said about the systems that are in place. They probably were meant well, but we didn't do the right thing to resource them.

And so, this litigation and the appeal process, can you take just a moment to talk about the time problems that come about and the cap problems that really get in the way of everything?

Ms. GENTRY. Certainly, and in my written testimony, I talk about the various lengths of time. So, when you file a claim in the VICP right now, in a regular lawsuit, you file a lawsuit and there is an answer. In our program, we file a petition and there is the rule for response. Right now, it is taking between 12 and 16 months for HHS to do that because of the lack of reviewers on that end, so that is just the beginning. That is when everything is in. If you have a table case, which means you have a presumption of causation based on certain specified injuries in the vaccine injury table, those will move slightly faster, but in those cases, you are still looking at times upwards of a year in some circumstances to get a decision, again, just for the sheer volume of cases.

If you have a non-table case, which is going to proceed as what we call a causation in fact case, it is going to look more like a regular lawsuit, even though I would stress these are no-fault compensation claims. So, you are not proving fault in this. It is just legal causation. In those circumstances, you may have several rounds of expert reports that go back and forth.

Mr. MFUME. I see.

Ms. GENTRY. And nothing in our program is anything less than 60 days at a time. It could take 2 years to get to the point of a trial, 2 years to get to the trial.

Mr. MFUME. Yes. I have got to reclaim my time. I am sorry. We have a limit here, unlike the Senate, where they just go on forever.

Ms. GENTRY. It is long, yes.

Mr. MFUME. But this is why I want to go back to what Mr. Ruiz said that we could probably find bipartisan consensus on trying to figure out how we make that better. And I heard someone say that the severe events are rare and not always captured by clinical trials. Let's not forget that clinical trials are inadequate. They are not diverse. They don't come up with the right sort of findings. And year after year, we talk about finding a way to expand them, and we don't expand them at all, so we get results that are inadequate and cures that don't always cure.

My time is up. I just want to thank all of you for what you are doing. Ms. Maldonado, I wanted you to talk about equity and your opinions, but I don't know if the Chair is going to allow any more time. So, thanks to all of you for being here.

Dr. WENSTRUP. We can certainly make a request for the record.

Mr. MFUME. Yes. And my request would be to Dr. Maldonado to tell the committee how, in her opinion, we can enhance equity in future pandemic responses and rollouts of vaccine initiatives to ensure that the most vulnerable among us have access to the care that they need. And I say that particularly because of the fact that in the U.S., mortality and morbidity rates, Mr. Chairman, were the highest among Black communities, Hispanic, Asian-American, Pacific Islanders, at-risk populations. And those communities deserve equity or at least a response about how we get to equity in terms of servicing them and in terms of their followup.

I yield back, and I thank you for your consideration, Mr. Chair.

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

Mrs. LESKO. Thank you, Mr. Chair, and thank you to all the witnesses. This has been very interesting and informative.

I am glad to hear that we actually may have bipartisan support in helping the victims because the system is obviously broken, and I just want to emphasize that by saying what happened to my office, OK. So as of January 1 of 2024, this year, the total number of CICP COVID claims filed was 12,854. I have a constituent that had a very severe reaction to the COVID vaccine. He filed a claim. He hasn't heard anything. He hasn't heard anything back.

So my staff, who is sitting in the back, called or contacted the CICP legislative affairs person and said, OK. What is the update on this person? They couldn't give him any update. He asked, how many of the claims have you processed, you know, have you done, and the answer was, "We don't have that information." I mean, how can you not have that information? This is absolutely ridiculous, and, Mr. Chairman, I think this is a really big problem if they don't even have the information of how many claims they have processed or they have awarded. I mean, $41,000, I believe, has been awarded in the CICP, and, you know, with how many claims: 12,854 claims. I mean, that is, like, nothing.

All right. Well, that is my rant. But then I do have another question, and that is, Dr. Whelan, you had testified that you had a boy in your care that died. You had done an initial report and then you tried to followup. Am I correct? And then say, you know, he passed away, and they didn't update it. You didn't hear anything? Is that accurate?

Dr. WHELAN. Yes, it is.

Mrs. LESKO. OK. Well, I have a story also of a New York man who suffered from—and I can't even pronounce this—H-L-H after the COVID vaccine. His initial report was classified as life threatening. Then his second report filed after his death was classified as hospitalized. After their initial complaint inquiring about why his report is not indicated as a death, his family subsequently received the following email: "Good afternoon. Thank you for contacting the Vaccine Adverse Event Reporting System, VAERS, Program. Thank you for taking the time to file the report. VAERS data

available to the public include only the initial report data to VAERS. Updated data, which contains data from medical records and corrections reported during followup, are used by the government for analysis. However, for numerous reasons, including data consistency, these amended data are not available to the public." And then the family subsequently sent an automated message at the end of 2023 to update their VAERS report on his condition saying he is dead, and the family has just been totally distressed because, you know, it is not reported accurately.

And so, do you have any suggestions? I mean, I know you haven't gotten anything back. Do any of you have any suggestions in how we can improve this process? It sounds like it is absolutely messed up.

Dr. GORTLER. If I may, Ms. Lesko. I am also from the state of Arizona. My family has lived there since the 1940's, and I live in Rio Verde. The information that is contained in VAERS is not complete. The information you can download online is not complete, and it can be complex to do. I personally had to learn how to do SQL programming and use data bases and buy some expensive software to get all the information to be able to view, but there is information which is also not submitted electronically.

I mean, this is an unrelated matter. Right now, one of the things I am looking at are the safety of puberty modulating drugs, and I want to tell you about a story that I had when I called the FDA to request some of that information. When you look at all adverse events over a long period of time, I found about 70,000 hits. And I am not sure what those hits are made up of, but when I spoke with the director at the FDA, the head of FOIA, my first request got lost. And my second followup when I asked for it, I said, I would like this information, and he said, well, that is going to take us about 30,000 hours to get to you, and then he asked me for $1.2 million just to be able to review those data, just to be able to go over them.

But it boils down to what one of the other Congresswomen was saying: it is transparency. There is a lack of transparency, and there is too much information that is redacted, and in order to redact that information, it takes time, right? It would take $1.2 million in salaries and 30,000 hours for those employees to have it. But if someone who is, you know, familiar with the rules of HIPAA in keeping medical records a secret, I don't understand why they have to be redacted. I could just sign a form saying, OK, I promise not to release this information," and that is that. And so, there is a blockade, there is, like, an embargo in trying to get this information so that drug safety people like myself can at least take a look at it and see what to make of it, see if there is a pattern, and cross-reference it to clinical trials, et cetera. Thank you.

Mrs. LESKO. Thank you all of you. It has been very interesting. And it is very interesting, Ms. Gentry, of what you said, and what the deficiencies are in the number of people that are processing, and that you think that the COVID vaccine should go under VICP. I didn't realize that under CICP, they couldn't have an attorney. I didn't realize that until you said it.

Ms. GENTRY. Well, obviously, there is no right to counsel, that people have their attorneys, but it is not a court process, so there is not really much that the attorneys can do.

Mrs. LESKO. Got it. Thank you.

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

Ms. TOKUDA. Thank you, Mr. Chair. Strengthening our Nation's vaccine safety systems is critical for us to advance public health—I think we can all agree on that—whilst especially addressing deficiencies in our Nation's compensation programs so that those who experience rare, yet serious adverse events can receive the compensation and care they need. That is important, you know, to bolster vaccine confidence in our country.

Yesterday, our committee received a letter from the American Academy of Pediatrics, noting that, "It is imperative that Congress increase funding so that the United States can maintain the world's most robust and effective vaccine safety monitoring system and help improve public understanding of and confidence in our vaccine safety system." Mr. Chairman, permission to enter this into the record.

Dr. WENSTRUP. Without objection.

Ms. TOKUDA. Thank you. And I think based upon the previous speaker's comments, she would actually agree with the American Academy of Pediatrics' recommendations, that they need to increase funding so that we can increase capacity to address a number of these NVICP claims, as noted in their letter that we will be putting in.

Since Fiscal Year 2012 to 2021, claims have increased more than fivefold, from 402 claims in 2012 to 2,057 in 2021, and that the steep increase is largely, in part, due to the influenza vaccine being administered to adults. In fact, more than 92 percent of those claims in the last 2 fiscal years were filed for adults, with 74 percent of all claims being filed for alleged injuries from the influenza virus. Unfortunately, while you have seen this dramatic increase, their budget has barely increased from $6.5 million to $11.2 million during the same period, and so clearly, funding for capacity is required for us to maintain these systems.

You know, I could not agree with them more in terms of the matter and importance of improving public confidence, as I think all of us agree. In our vaccine safety systems, we need to continue to support and enhance these vaccine safety monitoring and post market surveillance systems currently in place. We must handle each opportunity to discuss this matter with care because the consequences if we don't, quite frankly, are far too great. And since the start of the pandemic, we have seen growing distrust in vaccines overall. And while misinformation about COVID–19 vaccines have proliferated online, it has had ripple effects, as we know, and perhaps unintended consequences across our Nation's broader public health. A recent survey from the Annenberg Public Policy Center found that the proportion of respondents who believe in the safety of vaccines fell from 77 percent in April 2021 to 71 percent in the fall of 2023. And while a decrease of 6 percent may not sound like a lot, it does have serious and real consequences for our Nation's health.

As we hold today's hearings, the United States is at the precipice of losing our measles elimination status that we gained in 2000 due to repeated outbreaks of the disease that have popped up across the country from Florida to Ohio, to Missouri, to California. So far this month, we have already seen 58 cases of measles, many of which have occurred among unvaccinated children. That is just as many cases as there were during the entirety of 2023. This is especially concerning as 250,000 kindergarteners nationwide haven't received their updated measles immunizations, leaving them unprotected from this deadly disease. Dr. Maldonado, why is any decrease in immunization levels, big or small, troubling for our overall public health?

Dr. MALDONADO. Well, thank you for allowing me to talk about this. This is something that we talk about with our families as providers. There is still, again, that sacred trust, and I think our families really continue to trust, at least in the pediatric population. I am sure that is true in other fields, but this is my field. And I think that our ability to have doubled our lifespan since 1900 in large part is due to clean water, sanitation, and vaccination. We have made remarkable progress in our ability to stay alive and to be healthy.

And several generations have never seen these diseases that I have cared for in the past. And so, it is understandable that people think, well, they are not here. Why should I take a vaccine? It is going to hurt my child's arm. They are going to be uncomfortable. What is the good? And the good is that these diseases are not eliminated. I was on the panel that sought the certified elimination of measles in 2000. It is very sad to see that we may head away from that after 20 remarkable years. These diseases kill. They cause neurologic damage and developmental delay. I have seen all of this on a regular basis. I don't see it anymore, and I don't want to see it again. These diseases will come back, and they will come back with a fury if we don't continue to vaccinate, and especially if we don't continue to build that trust and confidence that families have in our ability to provide the safest care and be transparent about that.

Ms. TOKUDA. And real quick in the brief time I have, how have you seen medical misinformation impact patients in the field, directly resulting in some of these things we are experiencing?

Dr. MALDONADO. Is that a question? I am sorry. Yes, absolutely. Young people get their information from social media, and there are good things and bad things about that, but we need to make sure that, again, we don't just dismiss it, but listen and understand——

Ms. TOKUDA. So, we could essentially see measles, you know, elimination status removed because of medical misinformation, misinformation online, in the community?

Dr. MALDONADO. Absolutely.

Ms. TOKUDA. Thank you. I yield back.

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

Dr. JOYCE. Thank you for convening this hearing today and to our panel for taking part in this. This is an important followup to the hearing that this subcommittee held last month, where we

heard from government witnesses responsible for overseeing Federal vaccine safety systems. We now have the opportunity to hear from experts who have directly interacted with these systems and that, in many cases, found them to be woefully inadequate.

Physicians are on the frontline during any public health emergency, and the Federal response should be guided by the firsthand experience of healthcare providers. Instead, the current administration failed to provide an adequate mechanism for doctors to raise concerns about vaccine safety. Reports of serious injuries were ignored, causing serious damage to the public trust, I might add, fracturing the doctor-patient relationship. As a doctor myself, I also worry that not all adverse vaccine events were accounted for, whether because a healthcare practitioner did not know where and how to report an event, or because the system that they reported it to were not properly monitored.

The doctor-patient relationship needs to be reemphasized as we discuss how to restore public confidence in vaccines. To accomplish this, we must seriously examine the failures of our vaccine safety system and reform these systems to better support patients and to better support doctors. Doctors must have the most up-to-date information on any potential vaccine side effect in order to appropriately counsel patients. Our current vaccine safety mechanisms are insufficient to accomplish this goal, and patients ultimately suffer the consequences.

Dr. Whelan, what reforms are necessary to ensure vaccine injuries are being monitored proactively, and that when problems do arise, that they clearly are communicated to the doctors and the patients in a timely fashion?

Dr. WHELAN. Thank you for that question, Dr. Joyce. I should start by just saying I don't see that the Biden Administration has done things any differently than the previous administration, and I think big wheels move slowly. So, my sense is there is more of an institutional ennui than there is any kind of malintent on the part of, you know, the current administration.

But I do think that, as Dr. Maldonado was saying, you know, doctors want to be heard. They want to know that their concerns are being taken seriously. As I said earlier, I believe that there should be a more robust system for following up vigorously after people get vaccines and that we don't put the burden on the individual to report, you know, the things that they are experiencing, but rather, that the system really express an interest in finding these kinds of adverse events.

Dr. JOYCE. Can you speak about the benefits of ongoing and effective communications for physicians on the frontline and those who are responsible for providing healthcare guidelines?

Dr. WHELAN. I run a center at UCLA dealing with children who have neuroimmune problems, so I see a lot of kids that have autism and OCD and tic disorders. And so, I am confronted constantly with this question, you know, should my child be vaccinated, and I also have a lot of kids in our practice who have not been vaccinated at all. So, it is really an interesting balancing act because, on the one hand, I want to be sensitive to the concerns that these families have. I also want to, you know, express sensitivity to the fact that we really don't know a lot about where au-

tism comes from. And so, I can't make a categorical statement to the family that vaccines played no role, although I share unhesitantly the data that we have so far. And I also think that, as Dr. Maldonado alluded to, you have to be able to communicate to people that things like measles have the capacity to permanently damage the immune system of that child and could potentially kill them.

Dr. JOYCE. And during the COVID crisis, did you see an accentuation of children or young adults with autism who were exposed to or received the COVID–19 vaccine?

Dr. WHELAN. So, that is a very interesting question. Did the vaccines play any role? Interestingly, in the Pfizer trial on 11-to 15-year-olds, there was an increased incidence of psychiatric hospitalizations.

Dr. JOYCE. I think this is an important point, and as a physician and as a parent of a child with autism, I am aware of that information. And I think that information needs to be shared, and I think we need to explain that to parents. I think it needs to be explained to healthcare providers, and, particularly, it is information that we have a responsibility of sharing to those who deal with an autistic child. I thank you for that candid information. Mr. Chairman, my time has expired, and I yield back.

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 the witnesses for being with us today.

In the written testimony and during today's hearing one of the majority's witnesses has referenced redactions in documents that FDA produced through FOIA, and I would like to take a moment to round out that discussion. While I profoundly appreciate the important role that taxpayer funding played in the research that propelled development of the COVID–19 vaccines, we must recognize that this feat of modern science was a partnership between the Federal Government and industry. And we have to acknowledge that there are proprietary elements to the manufacturing process that are fundamental to encouraging and ensuring robust market participation for manufacturers of not just vaccines, but a wide variety of medical products essential to our public health.

In the course of responding in good faith to investigations, it is commonplace for commercially sensitive information, such as the exact composition of products to be redacted, and FOIA cases are no different. The redaction of this proprietary information has no bearing on the robust process that the FDA conducts to evaluate the safety of vaccines and countless other medical products before they are brought to market. And for what it is worth, the ingredients of the vaccines are included on the products' labels and available for anyone and everyone to evaluate for themselves, as many preeminent researchers, including those at the University of Cincinnati, have already done.

With that, I would like to turn back to the suggestion that COVID 19 vaccine policies infringed on the doctor-patient relationship. Much to the contrary, several of America's leading physician societies have conveyed their strong support for COVID–19 vaccines, and, in various cases, have filed briefs memorializing their

support for pandemic-era COVID–19 vaccine requirements. For example, ahead of the Select Committee's first vaccine safety systems hearing, six leading medical associations representing nearly 600,000 physicians issued a joint statement reiterating that, "COVID–19 vaccines are one of the most effective public health tools we have to prevent spread of the virus, hospitalizations, and deaths." This is consistent with the views many of America's leading medical societies expressed when legal challenges were mounted against vaccine requirements.

The American Medical Association led dozens of other groups, including the American Academy of Pediatrics and the American Academy of Family Physicians, in filing amicus briefs in support of these policies in cases such as BST Holdings v. OSHA, Kentucky v. Biden, and Georgia v. Biden. In their amicus brief for BST Holdings versus OSHA, the AMA stated that halting enforcement of Federal vaccine requirements would "severely and irreparably harm the public interest" due to the "grave danger to public health" that COVID–19 posed.

Dr. Maldonado, would America's major physician societies have filed these briefs in support of the vaccine requirements if they felt that these policies infringed on the doctor-patient relationship?

Dr. MALDONADO. No.

Ms. ROSS. Thank you. With my remaining time, I would like to discuss written testimony submitted to the Select Committee from Professor Richard Hughes at George Washington University Law School. Professor Hughes is one of the Nation's preeminent experts in systems we are examining today, and his statement explains the importance of vaccine injury programs in ensuring a robust market of vaccine manufacturers and an orderly processing of claims, albeit imperfect. He also reminds us of the importance of keeping today's conversation rooted in the facts and not letting opinions about proven safety and effectiveness of COVID–19 vaccines mislead the discussion. Mr. Chairman, I ask unanimous consent to submit Professor Hughes' written statement to the record.

Dr. WENSTRUP. Without objection.

Ms. ROSS. Thank you, Mr. Chairman, and I yield back my time.

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

Ms. GREENE. Thank you, Mr. Chairman. Nothing creates vaccine hesitancy like ignoring people when they are reporting problems with vaccines that they are being mandated and forced to take; vaccines that they have to take in order to keep their job; vaccines that they have to take in order to be able to go to restaurants, go into stores, go into public places; vaccines the doctors are telling them to take. But yet when they are screaming from the rooftops something is wrong with the vaccines, I am telling you that creates vaccine hesitancy. The other problem is, is when you get censored on the internet, or you get permanently banned on social media when you are a victim of a vaccine injury or a doctor trying to report what you were seeing in your patients from vaccines.

[Chart]

Ms. GREENE. This chart right here, this represents vaccine reports from all vaccines since 1990, 34 years. This represents reports on the COVID–19 vaccines since December 2020, less than 4

years. Something is wrong with the vaccines, and just because people are walking around and they have been vaccinated and they are not reporting a problem, doesn't mean other people aren't having problems, and this has been virtually ignored. Not only has it been ignored, it has also been censored and banned and labeled misinformation. This was a coordinated effort with the White House, the Surgeon General, the CDC, the Department of Homeland Security, CISA, Stanford, and the Virility Project.

As a matter of fact, real people with real problems got censored, such as Maddie de Garay. Maddie was a young child who developed severe symptoms and still has a feeding tube today. She is a very sick child. That happened from the COVID vaccine, but her mother was taken off of the internet when she tried to report the problem. Can you imagine trying to report a problem with your child who is having a real vaccine injury, but yet social media takes you off and the White House says it is OK and Department of Homeland Security says it OK, and they label it misinformation?

We can talk about funding these government programs and throwing more money at these government programs, but that isn't going to change the fact that vaccines should have never been forced on all these people to begin with. And if we want to talk about diseases like measles being transmitted among Americans, then perhaps we should talk about border security and stopping people who are unvaccinated from coming across our border and allowed to come into our country and then supporting them with taxpayer funds. I think that is a serious issue.

Dr. Maldonado, you are from Stanford. I am assuming you participated in the censorship program of so-called vaccine misinformation. I have got documents here showing Stanford ran a censorship program with the White House, commissioned by Bill Gates Foundation, tasked specifically with censoring content that would drive vaccine hesitancy, including true stories of vaccine injury, because this project led to the severe censorship of many people, including my own personal Twitter account, by the way, that was banned for an entire year because I apparently spread COVID information, things like information about myocarditis among our military members, neurological problems being reported. And I said that people shouldn't be forced to take a vaccine, especially like when Dr. Wenstrup talked about he didn't even know he had COVID until he couldn't smell garlic. That was the case for many people, including myself. I hardly had any symptoms when I had COVID. I certainly didn't need a vaccine. I have never had the vaccine, and I have never gotten COVID since.

While some people in our society are more susceptible to COVID because of maybe certain conditions that they have, not everyone should have been forced to take a vaccine. And certainly, people should be heard when they suffer a vaccine injury, and they want to tell others about it on their own personal social media accounts. Just a small example of this. Stanford identified and directed the White House to censor two COVID vaccine injured clinical trial participants, true stories of injury, one of whom is a child trapped in a wheelchair with a feeding tube; Stanford, an institution that actively suppressed the repeated cries for help from those who were injured by these shots is now being sued for it. As an example, it

is pretty interesting that a witness from Stanford brought in by the Democrats today who participated in censoring these true stories is going to give the witness testimony about vaccine hesitancy and about our hearing today on all of these reports.

I really don't have any questions today, Mr. Chairman. What I would like to echo is, is that there are so many people that have suffered injuries from these vaccines, and there are continuing problems, and now this vaccine is recommended by the CDC for children. There are also serious issues with blood clots that are being completely ignored, and it is not misinformation. Not at all. And so, for all the people that no one ever listens to about vaccines and that were suppressed and censored and banned on social media when they reported it, I would like to speak up for them. Their voices deserve to be heard, and a lot of them deserve a lot more money than the $41,000 that has been awarded to vaccine victims. I yield back. Thank you.

Dr. WENSTRUP. Thank you. I now recognize Mrs. Dingell from Michigan for 5 minutes of questions.

Mrs. DINGELL. Thank you, Mr. Chairman. Right now, we are at a pivotal moment for vaccine confidence in the United States. In recent years, we have witnessed a startling decline in immunization levels across the board, and I am deeply concerned about what this means for our Nation's ability to respond to public health threats in the future, especially today as the CDC issues an alert over rising measles cases and is urging families traveling to a measles-affected country to get vaccinated. And as I was sitting here, my Washtenaw County Health Department just sent a notice that another child has measles in Washtenaw County. I think that is a problem.

And listening to my colleague, the last victim of polio just died who lived in an iron lung. I am not old, but I am seasoned. I am really glad we were required to get polio vaccines, and I am somebody who, by the way, can't get a flu shot. We have got to focus on what we can and should do to strengthen our vaccine safety systems, which are crucial tools for promoting vaccine confidence. As I have said during our previous hearings, we need to do this by approaching people with compassion, empathy, make sure their questions are answered with trustworthy, accurate information that breaks through some of the noise that can come through, and they know if they are at risk, they have got a doctor to talk to.

Many of my colleagues here have heard me tell my own story of my experience with Guillain-Barre syndrome following a flu shot, but because I have got Guillain-Barre doesn't mean people should never get a flu shot. We need to put this all in perspective. And I asked a lot of questions before I got my COVID vaccine, and I was scared to death, but I got it, and I am alive, and I am here. And as we discuss these topics today, I personally appreciate the importance of patients knowing that meaningful compensation is available if they experience a severe adverse event and need it.

So Ms. Gentry—and we are going to run out of time, and we have got votes—can you answer this question? Why are efficient and adequately resourced compensation programs for patients who experience adverse events an important tool for improving vaccine confidence?

Ms. GENTRY. Because it makes them feel comfortable getting the vaccine, that, if something happens in those rare events, that they will be taken care of and compensated.

Mrs. DINGELL. So, I understand that Congress has an important role to play in strengthening these programs and streamlining the process of compensating patients with vaccine-related injuries. For example, under the current statute, in order to move the COVID–19 vaccines from the Countermeasures Injury Compensation Program to the more appropriate Vaccine Injury Compensation Program, Congress must pass an excise tax. And to facilitate the more timely processing of claims before the VICP, Congress can increase the number of special masters to adjudicate the claims and increase the cap on damages provided, including to account for inflation. A number of these reforms or more are included in two bipartisan pieces of legislation led by Congressman Lloyd Doggett, H.R. 5142 and 5143.

Mrs. DINGELL. Ms. Gentry, how would these reforms and others proposed in these two bills improve the processing of claims brought forward by people who experience serious adverse events from vaccines?

Ms. GENTRY. It would bring the infrastructure up to date in those programs and allow those claims to be processed. You would have more special masters to process claims, modernize the program to where it is supposed to be in 2024, and allow the excise tax which the manufacturers want to pay.

Mrs. DINGELL. Thank you. Now, Dr. Maldonado, do you agree that reforms, like increasing the number of special masters to process claims and ensuring that damages paid out reflect inflation, will strengthen how the Vaccine Injury Compensation Program operates?

Dr. MALDONADO. Yes, I do.

Mrs. DINGELL. And, Dr. Maldonado, do you agree that strengthening compensation programs for people who experience rare—I was one—but serious vaccine adverse events is an important tool for fortifying vaccine confidence?

Dr. MALDONADO. Yes, it is.

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

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

Dr. MILLER-MEEKS. Thank you, Mr. Chair, and I thank our witnesses that are here today. I am both a physician, a military veteran, and former director of the Iowa State Department of Public Health, so this is an important hearing. And vaccine hesitancy is certainly important, although it is also not new, but I think the COVID–19 pandemic has exacerbated vaccine hesitancy and reticence. Ms. Gentry, when a new vaccine is approved and marketed and you may have answered this—what steps are required to ensure access to liability compensation under the VICP program, and what happens if a new vaccine is not added to the list of taxed vaccines?

Ms. GENTRY. To get a new vaccine on, well, first, the ACIP has to make a recommendation for routine administration to children under the age of 5. The Secretary has to take that and make a recommendation to add it to the table, and then it goes to the regu-

latory processes. At the same time, the excise tax has to be instituted on that. If it is not, it is not there.

Dr. MILLER-MEEKS. And do you believe CICP is adequate for adjudicating COVID–19 vaccines claims?

Ms. GENTRY. No, I do not.

Dr. MILLER-MEEKS. Thank you for that. Do any of you believe that the CDC's reluctance to identify and, in fact, deny adverse reactions related to the COVID–19 vaccine and I will specifically point out to myocarditis and pericarditis—and a MMWR that the CDC put out saying that there was no greater risk. And I think looking at the data and looking at the data from overseas, to me, looking at that data, that is not true. Does that, in fact, affect the adjudication of claims, or does that have no bearing on the adjudication of claims?

Ms. GENTRY. Generally speaking, we never have epidemiological support because vaccine injuries are rare, so it is very difficult for us to get an increased rate of incidence. If you see that, the vaccine is generally pulled before we would ever get that, so the significant thing for us is that is not our burden of proof in the program. And again, I am speaking of legal causation and not scientific certainty and causation in that term.

Dr. MILLER-MEEKS. And like Representative Dingell, when I was Director of the Iowa Department of Public Health, soon into my first year, my Public Information Officer got her flu vaccine, and within several days, she called me up, on a Sunday. She was in the hospital. I went to go see her. It was obvious to me she had Guillain-Barre. I asked about her vaccination. She had just received her vaccination.

So, I would say these conditions, they may be uncommon, but I would not say that they are rare. Is the compensation for injuries related to vaccines, is the compensation enough? Someone that has Guillain-Barre and is paralyzed and on a ventilator and then out of work for months. It was about 6 months I was helping her to work remotely. That, to me, does not seem like a mild injury and would bear compensation, and for any other medication or drug, there certainly would be compensation.

Ms. GENTRY. Yes, Guillain-Barre syndrome would be a typical vaccine injury that we get compensated. You may have a life care plan that is substantial compensation in addition to lost wages, but the pain and suffering is still limited at 250.

Dr. MILLER-MEEKS. And what advantages do claimants to the VICP have that CICP claimants do not because you answered that in the negatory?

Ms. GENTRY. Correct. For one, it is an actual court process in the VICP. You have right to counsel. You are not responsible for attorney's fees. You have appropriate ability to appeal cases. You have full compensation and not restrictions on compensation, at least for economic damages and future care.

Dr. MILLER-MEEKS. Thank you very much. I thank all of our witnesses. I thank the Chair for this important hearing, and I yield the balance of my time.

Dr. WENSTRUP. Thank you. Listen, I would like to thank all of you for being here today, and I am sorry you were squeezed between vote series. Here, typically at this time, the Ranking Mem-

ber and I would make some closing statements. Well, part of that is thanking you all for your testimony and your written testimony as well. I think it has been very valuable what each of you has had to offer into the conversation today. And moving forward, I encourage all of you to reach out with us further if any concerns you may have or recommendations you may have in the future.

I am going to suggest because of this squeeze on time that the Ranking Member and I submit our closing statement for the record, and we will be glad to share those with you and make them public.

In closing, I would like to thank our panelists once again for your testimony.

With that and without objection, all Members will have 5 legislative days within which to submit materials and to submit additional written questions for the witnesses, which will be forwarded to the witnesses for their response.

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

[Whereupon, at 4:40 p.m., the Select Subcommittee was adjourned.]