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**Select Subcommittee on the Coronavirus Pandemic**  
**Assessing America's Vaccine Safety Systems, Part 2**  
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Chairman Wenstrup, Ranking Member Ruiz and distinguished members of the Subcommittee, thank you for the opportunity to testify at today's hearing, "Assessing America's Vaccine Safety Systems, Part 2." I am a pediatric infectious diseases physician, and my research has focused on the epidemiological aspects of viral vaccine development. 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. A large body of data demonstrate that COVID-19 vaccines are safe and effective in greatly reducing the risk of serious illness, hospitalization and death from the virus. That is why I recommend COVID-19 vaccines to all individuals who are eligible to receive them.

The decision to use any medical product, including vaccines, is essentially a risk-benefit analysis. Decades of data underscore the enormous benefits of vaccines, which have significantly increased our life expectancy. Early in my career I routinely saw children dying or suffering from severe, life-long health problems such as neurological and developmental challenges, hearing loss and blindness, due to infectious diseases for which we now have vaccines. We no longer see this very often thanks to the broad adoption of vaccines. We are now several decades removed from the realities I faced early in my career, and as a result some individuals may take the benefits of vaccines for granted. But vaccines remain critically important to protect individual and public health.

Any medical product carries some level of risk, and it is critical to have well-funded, robust surveillance systems in place to monitor for any potential adverse events and to have well-resourced, meaningful compensation programs for individuals who are harmed. Ensuring these programs function properly is an important component of extremely important broader efforts to boost vaccine confidence. The Vaccine Adverse Events Reporting System (VAERS) is explicitly designed to cast a very broad net to capture all potential adverse events that may occur following a vaccine. As such, it is critical to remember that most severe events captured through VAERS 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 are rare.

I look forward to exploring further how we can boost vaccine confidence and vaccine uptake, not only for COVID-19 vaccines, but for all medically recommended vaccines that play a crucial role in protecting individual and public health.

### **COVID-19 Vaccines are Safe and Effective**

COVID-19 vaccines are safe and provide protection against hospitalization and death. Numerous studies have demonstrated their benefit throughout the pandemic, as they continued to prevent hospitalization and death as variants emerged and subsided. In addition to their impact during acute disease, studies

demonstrate that they reduce the risk of post-infectious manifestations of acute COVID-19, including long COVID-19 and multisystem inflammatory syndrome in children (MIS-C). Vaccination benefits individuals who have immunity from prior COVID-19 infection by adding protection to residual infection-induced immunity against additional COVID-19 infection, hospitalizations and death.<sup>1,2,3,4</sup>

In addition to providing protection for individuals, COVID-19 vaccination has had tremendous societal benefits. COVID-19 vaccines have been central in reducing COVID-19 hospitalizations, preserving our health systems' capacity to care for patients with a wide array of health care needs and protecting our health care workers from burnout. Vaccines have been a key factor in facilitating a return to normalcy, including participating in routine activities that support our economy and lives, such as going to work and school, eating in restaurants and patronizing other local businesses.<sup>5,6</sup> COVID-19 vaccines also improved the overwhelming depression and anxiety experienced by many during the pandemic, by decreasing fear of COVID-19 hospitalization and death and by facilitating safe interactions with one another, decreasing loneliness and isolation.<sup>7,8</sup>

More than 5 billion people around the world (or 3 out of 4 people globally) have received mRNA COVID-19 vaccines. I would like to help dispel some myths about their safety. mRNA vaccines do not contain live virus and they do not alter a person's DNA. Instead, they are made of messenger RNA, which teaches your cells how to make an important piece of the coronavirus. After the mRNA delivers these instructions, our cells break down the mRNA and get rid of it. If we are exposed to the real virus later, our bodies will be better able recognize the virus and be better prepared to fight it off.

Some people have concerns that mRNA vaccines cause heart problems. 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).<sup>9</sup> Most of these people responded well to medicine and rest and felt better quickly.<sup>10</sup> This small risk is even less now that we have safety recommendations like spacing out vaccines for young men and women. **It is important to recognize that COVID-19 infection is much more likely to cause heart damage and other severe events than the vaccine.**<sup>11</sup> Myocarditis and pericarditis associated with COVID-19 in the United States became 15 times more frequent compared with pre-COVID levels.<sup>12</sup> A study of over 20 million

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<sup>1</sup> [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00801-5/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00801-5/fulltext)

<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9027152/>

<sup>4</sup> [https://www.cdc.gov/mmwr/volumes/73/wr/mm7308a5.htm?s\\_cid=mm7308a5\\_w](https://www.cdc.gov/mmwr/volumes/73/wr/mm7308a5.htm?s_cid=mm7308a5_w)

<sup>5</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9946727/#b1>

<sup>6</sup> <https://sjes.springeropen.com/articles/10.1186/s41937-021-00082-0>

<sup>7</sup> <https://www.economist.com/graphic-detail/2022/01/20/covid-19-vaccines-have-made-americans-less-anxious-and-depressed>

<sup>8</sup> <https://www.nber.org/papers/w29593>

<sup>9</sup> <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/10-covid-klein-508.pdf>

<sup>10</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9555956/#:~:text=Overall%2C%20patients%20considered%20to%20be,vs%2056%20%5B86%25%5D%20of>

<sup>11</sup> <https://www.frontiersin.org/articles/10.3389/fcvm.2022.951314/full>

<sup>12</sup> <https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.123.321878>

people published this month found that COVID-19 vaccination significantly reduced post-COVID-19 cardiovascular complications, including myocarditis, heart attack and stroke.<sup>13</sup>

COVID-19 vaccines were studied in large, multi-center clinical trials through which scientists were able to gather significant safety and efficacy data across populations. Researchers took great care to ensure that clinical trial participants came from a wide array of communities that reflect the diversity of the U.S. population. COVID-19 vaccines were rigorously evaluated by the FDA, CDC and both agencies' independent advisory bodies before being rolled out to the public. Health care workers like myself were among the first to be vaccinated – demonstrating that medical and scientific experts across the country had a high level of confidence in the vaccines' safety and effectiveness.

### **Vaccine Safety Systems**

Sometimes, rare events may occur after vaccination that are too rare to be identified within clinical trials. These could include outcomes such as Guillain-Barré syndrome, stroke or myocarditis. Because background rates of these outcomes are very low, the only way to appropriately assess differences in risks of these outcomes is to measure relative risks in large populations. Therefore, vaccines continue to be assessed for safety in much larger populations (millions or tens of millions of people) after they are authorized or licensed for use. There are several infrastructures in place to investigate vaccine safety outcomes after vaccine authorization or licensure in the US, including the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD). Additional safety investigations and considerations are performed by FDA's BEST system and by using information from the Centers for Medicare & Medicaid Services.

VAERS is an open database that collects reports of adverse events following vaccination. Health care providers are required to report certain COVID-19 vaccine safety outcomes to VAERS, but anyone can report events to VAERS, including care providers, child care professionals and individual patients/laypeople. VAERS is not structured to formally investigate causal relationships between vaccines and potential safety outcomes (Dusto, May 2022). Instead, it is an early warning system used to generate hypotheses about vaccine safety that are then more thoroughly investigated.

VSD is composed of several large managed-care organizations in the U.S. Information from the electronic health records of individuals at these managed-care organizations is combined to investigate formally hypothesized relationships between vaccines and specific safety outcomes. These hypotheses may come from VAERS or medical literature.

Since June 2020, ACIP has convened 23 public meetings to review data on the epidemiology of COVID-19 and the use of COVID-19 vaccines. The ACIP COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and ethics, has held weekly meetings to review COVID-19 surveillance data, evidence for vaccine efficacy and safety, and implementation considerations for COVID-19 vaccines. In addition, the COVID-19 Vaccines Safety Technical Work Group (VaST), consisting of independent vaccine safety experts and established to provide expert consultation on COVID-19 vaccine safety issues, has reviewed safety data from the COVID-19 vaccination program during weekly meetings.

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<sup>13</sup> <https://heart.bmj.com/content/early/2024/01/24/heartjnl-2023-323483.info>

It is important to remember that just because a health event occurs after a vaccination, a report to VAERS in no way indicates that the event was caused by vaccination. Correlation through VAERS does not equal causation. This is why additional investigations are critical, and those investigations have consistently found that serious adverse events associated with COVID-19 vaccination are 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 effectively. For example, in April 2021, CDC and FDA recommended a pause in use of the Janssen COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome (TTS), a rare condition. ACIP rapidly convened two emergency meetings to review reported cases of TTS and issued a warning regarding clotting events after vaccination, particularly in women ages 18-49. Through ongoing safety surveillance, including reviewing reports from VAERS, additional cases of TTS following vaccination with the Janssen COVID-19 vaccine were identified. In December 2021 ACIP held another emergency meeting and made a recommendation for the preferential use of mRNA COVID-19 vaccines over the Janssen vaccine.<sup>14</sup>

In the rare event when an individual is harmed by a vaccine or other medical countermeasure, it is important that they have the opportunity to receive compensation, which is the purpose of the Vaccine Injury Compensation Program (VICP) and the Countermeasures Injury Compensation Program (CICP). COVID-19 vaccines are currently covered by the CICP, which has been underfunded as compared the VICP. Bipartisan legislation has been proposed to move COVID-19 vaccines to the VICP and strengthen the federal response for the rare instances in which individuals are harmed.

Some individuals have criticized federal vaccine safety and vaccine injury compensation systems. I agree that we must ensure our vaccine safety and injury compensation systems are robust. Their ability to function optimally helps reassure the public of vaccine safety and is a critical component of a broader and necessary effort to boost vaccine confidence. Unfortunately, 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 significant and critically needed emergency funding to support the COVID-19 response, it is equally critical to prepare for the next public health event. Providing adequate funding for public health before an emergency occurs is critical to ensure we have a sufficient trained workforce and infrastructure in place for a successful response. An ounce of prevention is worth a pound of cure and applying this lesson now will help us ensure a more efficient and equitable response to future outbreaks and pandemics.

### **Boosting Vaccine Confidence and Uptake**

Since the COVID-19 vaccines first became available, health care professionals and our public health partners have worked together on multifaceted campaigns to boost vaccine confidence and uptake. In my own community I was proud to be part of highly collaborative efforts to educate individuals throughout the community about the high benefits and low risks associated with vaccination and the data underpinning the vaccines' use. As an ID physician, I had the opportunity to educate many of my

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<sup>14</sup> [Use of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices — United States, December 2021 | MMWR \(cdc.gov\)](#)

health care professional colleagues about COVID-19 vaccines, and together we counseled our patients and the public.

Among the tools used earlier in the pandemic to boost vaccination rates were vaccine requirements for certain populations. Requirements for influenza vaccines among healthcare workers and for routine childhood vaccines in order to attend school have long been in effect and have been very successful at rapidly boosting vaccination rates. COVID-19 vaccine mandates for health care workers, emergency first responders, federal workers, school staff, university students and staff, and other groups have garnered high levels of compliance and boosted COVID-19 vaccine uptake.<sup>15</sup> Among U.S. adults vaccinated from June to September 2021, 35% reported that a major reason they got vaccinated was to participate in recreational activities that required proof of vaccination, and 19% said their employer's requirement was a major reason.<sup>16</sup> Mandates contributed to increased vaccine uptake, easing the pressure on our health care facilities, enabling us to provide the best care to our patients at the time of greatest risk from COVID-19 disease. As the pandemic evolved, policies have changed accordingly. At this time, most of the public has some level of immunity to COVID-19—due to vaccines, prior infection, or both—and therapeutic options help reduce the risk of hospitalization and death in higher risk patients. Widespread COVID-19 vaccine requirements are no longer appropriate and no longer in place.

The benefits of COVID-19 vaccination continue to be significant, though uptake of the updated vaccine has lagged. Similarly, rates of routine childhood immunizations are dropping. In the 2019–2020 school year, 95% of children had received vaccinations for MMR, DTaP, polio, and varicella. In the 2020–2021 school year, that number decreased to 94%, and it decreased again in 2021–2022 to 93%. While pandemic-related disruptions in access to routine care are likely responsible for some of the initial decreases, it is very distressing that vaccination rates are not fully rebounding now that the public has largely resumed pre-pandemic activities. So far in 2024, the US has seen 58 measles cases in 17 jurisdictions, according to the CDC — the same number of cases seen in all of 2023 — and some were spread locally. In fact, the US is in danger of losing its measles elimination status, which we have held for more than 20 years. This is important because measles, a disease that many physicians and members of the public have never seen, is highly contagious and can cause severe complications.

Measles and other vaccine preventable diseases are just that—preventable. In a nation as highly resourced as the US, we have no excuse to allow a resurgence of measles nor preventable hospitalizations and deaths due to COVID-19, influenza or other vaccine preventable diseases. We must work together to boost vaccine confidence by investing in our health care and public health systems, including our vaccine safety systems.

We also have to invest in our health care workforce, as local physicians and other community-based health care professionals are trusted messengers for reliable vaccine information. Unfortunately, far too many people in the US still do not have access to a primary care physician. Primary care physicians frequently rely upon infectious diseases (ID) clinicians to provide expert information on ID issues, including vaccination. This is particularly true for newer vaccines and during outbreaks or pandemics. Unfortunately, nearly 80% of US counties do not have a single ID physician, and pediatric ID physicians are even more scarce. Even worse, ID recruitment is lagging. In 2023, only 50.8% of ID physician training

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<sup>15</sup> <https://www.forbes.com/sites/tommybeer/2021/10/04/covid-19-vaccine-mandates-are-working-heres-the-proof/?sh=54a3b6972305>

<sup>16</sup> <https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-september-2021/>

programs filled, while most other specialties filled all or nearly all of their training programs. Many medical students and residents consistently report interest in a career in ID, but high medical student debt consistently drives more new physicians to more lucrative specialties. ID is the 4<sup>th</sup> lowest compensated specialty, as their services are poorly valued by payers (including Medicare) and much of their work is not billable. IDSA urges Congress to improve ID physician reimbursement and fully fund the Bio-Preparedness Workforce Pilot Program, which will reduce the financial barriers to ID recruitment and retention to help ensure we have the workforce necessary to address the current and future ID needs. These steps will help ensure the US has the workforce we need to provide education and programs to boost vaccine confidence and prepare for and respond to future outbreaks and pandemics.

### **Conclusion**

I greatly respect the important role of this subcommittee to review our nation's response to the COVID-19 pandemic and I am deeply grateful for the opportunity to testify. We must critically assess our COVID-19 response so that we can improve our public health infrastructure and ensure our readiness for the next pandemic. Vaccines are one of the greatest tools we have to protect public health from COVID-19 and other preventable diseases, and we must all work together to boost vaccine confidence to ensure that the benefits of vaccination can be fully realized.