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Chairman Massie, Ranking Member Correa and distinguished members of the Subcommittee, thank you for the opportunity to testify at today’s hearing. I am a pediatric infectious diseases (ID) physician. I have cared for a large number of children with COVID-19, advised the Centers for Disease Control and Prevention (CDC) and the Utah Department of Health on COVID-19 and served as the Pediatric Team Lead for the National Institutes of Health COVID-19 Treatment Guidelines Panel. Throughout my career, my research and public health work has focused on emerging infectious diseases and pandemic preparedness.

Decades of data underscore the enormous benefits of vaccines for multiple infectious diseases, which have significantly increased human life expectancy. 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 and why my family and I received COVID-19 vaccines as soon as they were available to us and remain up to date on our COVID-19 vaccinations. Unfortunately, the spread of misinformation and disinformation is weakening vaccine confidence and uptake — for the COVID-19 vaccine and other vaccines — leaving more individuals and communities at risk of serious illnesses.

I look forward to discussing 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 (including administration of the primary series and boosters) are safe and provide protection against severe disease, hospitalization and death. Numerous studies have demonstrated their benefit as they continue to prevent hospitalization and death as variants have emerged and subsided. Studies also demonstrate that they reduce the risk of long COVID 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 infections, hospitalizations and death.<sup>1,2,3,4</sup>

I worked countless hours caring for children who required hospitalization because they were severely ill with COVID-19 and MIS-C, including children with and without preexisting conditions. I saw children who, even after recovering from acute infection, were too weak to resume normal childhood activities. And, thankfully, I saw firsthand the significant difference our COVID-19 vaccines made in saving lives.

In addition to providing protection for individuals, COVID-19 vaccination has had tremendous societal benefits. By reducing COVID-19 hospitalizations and protecting health care workers from severe disease and, to a lesser extent, infection, COVID-19 vaccines helped preserve our health systems' capacity to care for patients with a wide array of health care needs. During surges of cases and hospitalizations, patients died in part because our health care systems and workforce were overwhelmed. There simply were not enough hospital beds and providers to meet the extraordinary demands, and workforce shortages were exacerbated if any of us became ill. In addition, let me remind you that workforce shortages have only been exacerbated after the pandemic with approximately 230,000 physicians, nurse practitioners, physician assistants and approximately 100,000 nurses having left the workforce since the pandemic.

Vaccines have been a key factor in facilitating a return to normalcy. They allowed us to safely return to our usual activities, such as going to work and school, eating in restaurants and patronizing other local businesses. They were of enormous benefit to our economy.<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 three out of four people globally) have received 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.

Concerns surfaced that mRNA vaccines cause heart problems. There have been rare instances of teenage boys and younger men experiencing myocarditis (heart inflammation), which happened in

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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>

about 20 out of 1 million doses in younger men.<sup>9</sup> For comparison, your odds of being struck by lightning in your lifetime are three times higher. We take this risk very seriously, but the benefits of vaccination outweigh this risk even in the highest risk group of teenage boys and young men. Most of the people who developed myocarditis responded well to medicine and rest and recovered quickly.<sup>10</sup> I cared for a few patients who had myocarditis following COVID-19 vaccination. Their cases were mild, and they recovered quickly, in marked contrast to some of the cardiac manifestations we saw from MIS-C due to COVID-19 infection where children required ECMO, that is, heart lung bypass, and even emergency cardiac surgery. 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 people 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, multicenter 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 Food and Drug Administration (FDA), CDC and both agencies' independent advisory bodies before being rolled out to the public. Health care workers like me 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. Ensuring vaccine safety does not stop when a vaccine is licensed. Our network of vaccine safety systems has continued to evaluate any potential issues now that over 650 million doses of vaccine have been given to Americans.<sup>14</sup>

In September 2021, FDA expanded its emergency use authorization for COVID-19 vaccines to include a single booster dose for certain populations at higher risk of developing severe illness due to COVID-19. This followed external expert input from the Vaccines and Related Biologic Products Advisory Committee. FDA analyzed safety and immune response data from a subset of participants from the original clinical trial of the Pfizer-BioNTech COVID-19 vaccine as well as real-world data on the vaccine's efficacy over a sustained period of time. Data were clear that the booster was safe and provided an enhanced immune response. Data further indicated that during the summer 2021 Delta surge, breakthrough cases were more common among individuals who had received their primary vaccine series earlier as compared to individuals who received their primary vaccine series more recently — demonstrating that the vaccine's protection waned overtime, and a booster was likely necessary to sustain protection. The decision to implement boosters, like many during the pandemic, had to be made with incomplete data and generated some appropriate debate. It

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<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>

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

<sup>14</sup> <https://usafacts.org/visualizations/covid-vaccine-tracker-states/>

proved to be absolutely correct. I grimly recall the winter of 2021-2022, in which the Omicron variant emerged and tore through our country, sending hospitalization rates soaring yet again, killing over 20,000 Americans each week and pushing our health care workforce to new levels of exhaustion. That winter was extremely difficult and would have been far worse without the booster protecting our health care workers and allowing us to continue doing our jobs with the confidence that we would be protected from hospitalization and death.

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 about the large benefits and low risks associated with vaccination and the data underpinning the vaccines' use. As a pediatric ID physician, I had the opportunity to educate many of my health care colleagues about COVID-19 vaccines, and together we counseled our patients, their families and the public.

### **Individual and Societal Benefits of Vaccination (Non-COVID)**

The benefits of vaccines for individuals, families, communities and society as a whole are tremendous. CDC estimates that vaccination of children born between 1994 and 2021 in the U.S. will prevent 472 million illnesses, help avoid 1,052,000 deaths and save nearly \$2.2 trillion in total societal costs (that includes \$479 billion in direct costs).<sup>15</sup> Vaccine-preventable diseases can be very costly resulting in doctor's visits, hospitalizations and premature deaths. Additionally, national, state and local outbreak responses also take a lot of time and resources. Through vaccinations, the U.S. saves billions of dollars. Even prior to COVID-19, it was estimated that vaccines prevented up to 6 million deaths every year worldwide.<sup>16</sup> Infectious diseases that accounted for major mortality and morbidity in the early 20th century in the U.S. showed over a 90% decline in incidence by 2017 due to high uptake of vaccines for diphtheria, tetanus, pertussis, measles, mumps, rubella and polio.<sup>17</sup>

Prior to the availability of the *Haemophilus influenzae* type b (Hib) vaccine, Hib caused 20,000 cases each year of serious and often fatal invasive disease in children, especially those under 5 years of age. The inclusion of Hib vaccine in the routine infant/childhood vaccine schedule beginning in 1990 has decreased Hib disease in the pediatric population by 99% with less than 50 cases occurring in children under 5 years of age each year (with all cases occurring in unvaccinated or under-vaccinated children). My daughter was born in 1990 while I was a pediatric ID fellow, and we were seeing a horrible case of Hib almost every week with several deaths. As a parent, I was terrified of Hib. When the first case of Hib vaccine arrived at our hospital pharmacy, we brought her in that day to get vaccinated.

Thanks to vaccines, we have eradicated smallpox and are close to eradicating polio. When a sufficiently high proportion of the population is vaccinated, some vaccines can generate herd immunity — which prevents ongoing transmission of the pathogen thus protecting individuals who are too young to be vaccinated or medically unable to receive a vaccine or mount a sufficient

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<sup>15</sup> <https://www.cdc.gov/vaccines/programs/vfc/protecting-children.html>

<sup>16</sup> Ehreth J. (2003). The global value of vaccination. *Vaccine* 21 596–600.

<sup>17</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7371956/>

immune response. High vaccination rates and the resultant herd immunity is an important societal benefit that protects our most vulnerable, including infants and young children.

### **Dangers of Vaccine Misinformation and Disinformation**

Unfortunately, the increasing spread of vaccine misinformation and disinformation through various mechanisms — including social media — is the main driver of increased vaccine hesitancy for COVID-19 vaccines and importantly, other vaccines. In 2019, the World Health Organization identified vaccine hesitancy as one of the top 10 threats to human health.<sup>18</sup> Considerable research has found evidence of how misinformation and disinformation about vaccines have reduced vaccine uptake.<sup>19</sup> Misinformation generally refers to a claim that is false or inaccurate due to a lack of scientific evidence and is shared without an intention to cause harm. Disinformation refers to the deliberate creation and dissemination of false information with an intention to cause harm.

Uptake of the updated COVID-19 vaccine has lagged due in large part to vaccine hesitancy fueled by misinformation and disinformation, leaving millions of individuals without optimal protection. Just over 22% of adults have received the most recent updated COVID-19 vaccine. Rates of vaccination for influenza and respiratory syncytial virus (RSV) are also far too low, with just 48% of U.S. adults receiving the influenza vaccine for the 2023-2024 flu season and just 24% of eligible adults (ages 60 and over) receiving the RSV vaccine.<sup>20</sup> As of Jan. 20, 2024, CDC estimated that 47.8% of children had been vaccinated for influenza, which is 3.5 percentage points lower than the same time last season.

Inadequate vaccine uptake for respiratory viruses like COVID-19, influenza and RSV leads to higher rates of hospitalizations and deaths. This winter, with COVID-19 levels far lower than previous winters, about 2,000 to 2,500 people in the U.S. still died every week due to COVID-19.<sup>21</sup> In our most recent 2023-2024 flu season, CDC estimates there have been 390,000 hospitalizations and 25,000 deaths in the U.S. Each year in the U.S., an estimated 60,000 to 120,000 older adults are hospitalized and 6,000 to 10,000 die from RSV infection. At least 178 children died of flu this season. We have the tools — vaccines — to dramatically decrease these hospitalizations and deaths.

Similarly, rates of routine childhood immunizations are dropping. In the 2019-2020 school year, 95% of children 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%. In some 12 states, measles vaccine coverage is now below 90%.<sup>22</sup> 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 resumed pre-pandemic activities.

The consequences of inadequate vaccination rates are serious. So far in 2024, the U.S. has seen 151 measles cases, compared to 58 in 2023. So far this year, there have been 11 measles

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<sup>18</sup> <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>

<sup>19</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9301555/>

<sup>20</sup> <https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-adults.html>

<sup>21</sup> [https://covid.cdc.gov/covid-data-tracker/#trends\\_weeklydeaths\\_select\\_00](https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00)

<sup>22</sup> [https://www.medscape.org/viewarticle/1000685\\_3](https://www.medscape.org/viewarticle/1000685_3)

outbreaks (defined as three or more related cases), compared to four outbreaks in 2023.<sup>23</sup> In fact, the U.S. is in danger of losing its measles elimination status, which we have held for more than 20 years. This is important because measles is incredibly contagious, makes people very sick, and can cause severe complications and significant health care and public health costs. Measles kills about 1 in every 1,000 children who contract the disease, and causes serious disability in another 1-2 in 1,000. It can cost hundreds of thousands of dollars for our health care and public health systems to respond to and contain a single case of measles.

Measles and other vaccine-preventable diseases are just that — preventable. In a nation as highly resourced as the U.S., 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.

### **Vaccine Safety Systems**

Any medical product carries some level of risk. Compared to other medical products, vaccines are exceedingly safe, but health problems can occur after vaccination. Sometimes, 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 there are background rates of these outcomes, the primary way to appropriately assess any association of these outcomes with vaccines 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 is a robust group of overlapping tools in place to investigate vaccine safety outcomes after vaccine authorization or licensure in the U.S., including the Vaccine Adverse Event Reporting System (VAERS), V-safe, CISA and the Vaccine Safety Datalink. Additional safety investigations and considerations are performed by FDA's BEST system and by using information from the Centers for Medicare & Medicaid Services and the Department of Defense.

To cast the broadest net possible and serve as an early warning system, VAERS accepts any report of a possible health event around the time of vaccination. 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, vaccine policies and recommendations are updated. 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. The Advisory Committee on Immunization Practices (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 to 49. Through ongoing safety surveillance, including reviewing reports from VAERS, additional cases of TTS following vaccination with the

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<sup>23</sup> [https://www.cdc.gov/measles/data-research/index.html#:~:text=Measles%20cases%20in%202024&text=There%20have%20been%2011%20outbreaks,58\)%20were%20outbreak%2Dassociated.](https://www.cdc.gov/measles/data-research/index.html#:~:text=Measles%20cases%20in%202024&text=There%20have%20been%2011%20outbreaks,58)%20were%20outbreak%2Dassociated.)

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>24</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.

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

Increasing vaccine confidence and uptake will improve our nation's health. Before the next outbreak or pandemic, we must restore trust in vaccines to strengthen our preparedness and ensure that our population is able to fully leverage the lifesaving power of vaccines. There are several steps the federal government can take to help boost vaccine confidence, access and uptake for routine vaccines, COVID-19 vaccines and future vaccines to combat new threats:

- Increase funding for U.S. vaccine infrastructure, led by CDC, to increase vaccine rates among uninsured and underinsured adults and children, respond to outbreaks, educate the public, improve vaccine communications, establish partnerships and improve vaccine information systems that help track vaccination.
- Fund research on vaccine hesitancy and vaccine communications strategies. Invest in evidence-based vaccine communications to increase public awareness about vaccination and combat misinformation and disinformation.
- Ensure first-dollar coverage of all medically recommended vaccines under Medicaid, Medicare and commercial insurance to minimize financial barriers to vaccination.
- Strengthen recruitment of physicians in all communities — particularly ID physicians with expertise on vaccines and vaccine-preventable diseases — and provide transparent data on vaccines and communications tools to further empower physicians to talk with their patients and communities about vaccination. Physicians are widely regarded as trusted messengers on vaccine-related topics, particularly when physicians are located within the community they are advising. ID physicians in particular play a critical role in educating other physicians and the public. Unfortunately, nearly 80% of U.S. counties do not have a single ID physician, and last year only half of ID physician training programs in the U.S. filled. High medical student debt and low reimbursement relative to other specialties are key barriers to ID physician recruitment.

Once again, I greatly appreciate the Subcommittee's attention to the important issue of vaccination, and I thank you for the opportunity to testify. IDSA welcomes the opportunity to work

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<sup>24</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 \(cdc.gov\)](#)

with you to help prevent serious disease, hospitalization and death due to COVID-19 and other infectious diseases.