

TESTIMONY

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

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“ASSESSING AMERICA’S VACCINE SAFETY SYSTEMS, PART 1”

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Chairman Wenstrup, Ranking Member Ruiz, and distinguished members of the Subcommittee, it is an honor to appear before you today to discuss the Centers for Disease Control and Prevention's (CDC) ongoing work to monitor the safety and effectiveness of vaccines. My name is Dr. Daniel Jernigan and I serve as the Director for the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) at CDC. Our center is where CDC's Immunization Safety Office is organized, alongside other patient safety and healthcare quality programs.

For nearly 80 years, CDC has been the nation's leading public health service organization, putting scientific findings and data into action to support healthy people and communities. CDC prevents, detects, and responds to health threats at home and abroad to protect the nation's health, safety, and security. Vaccines are a cornerstone of this work, preventing debilitating illnesses and saving lives through the prevention of devastating diseases.

We cannot know for sure how many people would have succumbed to smallpox without the massive global vaccination program that led to smallpox eradication in 1977, but it is estimated that 150 to 200 million lives and billions of dollars in healthcare costs were saved. The eradication of smallpox through vaccination is considered by many to be one of the greatest public health achievements in history.

Polio once caused more than 21,000 paralytic cases at its peak in 1952. Following introduction of safe and effective vaccines, polio declined rapidly, and, as a result, wild poliovirus was eliminated from the United States in 1979. Since 1988, thanks to the polio vaccine, more than 18 million people globally who could otherwise have been paralyzed can now walk, and 1.5 million childhood deaths have been averted. The best way to maintain this public health achievement and keep people safe from polio is to establish and maintain high immunity in the population through vaccination.

CDC's successful Vaccines for Children (VFC) program highlights the importance of providing access to vaccines to reduce vaccine preventable diseases, like measles, mumps, and varicella. The VFC program helps ensure all eligible children receive recommended vaccines at no-cost for the vaccine. Almost half of all childhood vaccines administered in the United States are provided through the VFC program. CDC estimates that vaccination of children born between 1994 and 2021 will prevent 472 million illnesses and 29.8 million hospitalizations, help avoid 1,052,000 deaths, and save nearly \$2.2 trillion in total societal costs.

CDC built on the successes and lessons learned from the VFC program to build the public health infrastructure for the federal COVID-19 vaccination program. CDC, along with our federal, state, and local partners, rapidly and equitably rolled out COVID-19 vaccines across the nation starting in December 2020. It was the largest and most successful vaccination campaign seen in recent history, resulting in more than 676 million doses of COVID-19 vaccine administered in the United States during the public health emergency. According to a study by the Commonwealth Fund, as of November 2022, COVID-19 vaccines saved more than 3.2 million lives in the United States, prevented more than 18.5 million hospitalizations, and averted over \$1.15 trillion in healthcare costs. Clinical research and continuous public health monitoring demonstrate the safety and effectiveness of the COVID-19 vaccines.

Vaccine Safety Monitoring—A layered approach

CDC’s vigilant safety monitoring of all U.S. approved and authorized vaccines is an integral part of our mission to protect and promote public health. The agency is committed to providing timely, transparent, and high-quality information gleaned from this work to public health partners, healthcare providers, policymakers, and the public.

CDC works closely with partners, including the Food and Drug Administration (FDA) and others, to achieve a broad, complementary, and layered approach to help detect possible vaccine safety signals and prompt action to address potential issues. Each system in this approach is designed for a different purpose, differing in the information they collect, how that information is collected, and the types of analyses that can be done using that information. Analyzing possible vaccine safety signals with multiple systems allows us to maximize the benefits of each system and address information gaps that exist in each. The systems layered into CDC’s comprehensive approach for vaccine safety monitoring are the Vaccine Adverse Event Reporting System (VAERS); Vaccine Safety Datalink (VSD); and the Clinical Immunization Safety Assessment (CISA) Project. Two additional monitoring systems, V-safe and the COVID-19 Vaccine Pregnancy Registry, were created to support safety monitoring during the COVID-19 pandemic.

Vaccine Adverse Event Reporting System

The first of these layered systems, VAERS, is co-managed by CDC and FDA and serves as the nation’s early warning system to detect possible safety signals for all U.S. approved and

authorized vaccines. Under the emergency use authorizations for COVID-19 vaccines, healthcare professionals and manufacturers were required to report serious adverse events following vaccination to VAERS, even if the cause of the event is unknown. Serious events include, but are not limited to, death, hospitalization, disability, congenital anomaly, severe allergic reactions, and other neurological or immune conditions. Individuals and their families are encouraged to also submit VAERS reports for any adverse event that occurs after vaccination. It is important to note that VAERS is not designed to determine if a vaccine caused a reported adverse event or if, like most serious reported events, it was likely a coincidental event unrelated to vaccination. VAERS is designed to be sensitive and hypothesis-generating, and its signals can then be analyzed using other systems that are more specific and hypothesis-confirming.

CDC and FDA staff continuously assess VAERS data for vaccine adverse event reports. This includes review of individual reports, aggregate analysis of VAERS data, and review of case series data when indicated for possible safety concerns. As VAERS reports are received, CDC and FDA staff monitor for potential vaccine safety concerns or unusual patterns of rare and serious adverse events. If a serious adverse event is reported, VAERS staff from CDC and FDA can request additional information such as medical records, death certificates, or autopsy reports from the healthcare provider of record. If multiple reports indicate similar potential safety concerns, CDC and FDA staff can investigate further by incorporating VAERS data and data from CDC's and FDA's other monitoring systems. This analysis helps us determine if the occurrence, or risk of occurrence, is higher than expected when compared to the general population or for previous vaccines.

Vaccine Safety Datalink

The second of these layered safety monitoring systems, the VSD, is a collaboration with participating health systems using real world electronic health record data from over 12.5 million people to perform robust, near real-time monitoring of vaccine recipients to identify and further characterize potential vaccine safety concerns. VSD allows CDC and its partners to evaluate adverse events and conduct studies to address gaps in vaccine safety knowledge. Information regarding adverse events from VAERS may prompt analysis and review of VSD data, which – unlike VAERS data – is capable of estimating the risk of an adverse event. In addition to using

large volumes of electronic health record data to conduct epidemiologic analyses, VSD also allows for medical chart review of cases to verify diagnoses.

Clinical Immunization Safety Assessment

A third system, the CISA Project, is a collaboration between CDC, medical research centers, and other vaccine safety experts to better understand adverse events following immunization at the individual patient level. The CISA Project conducts clinical research to better understand vaccine safety and provides expert medical consultations to U.S. healthcare providers with complex vaccine safety questions about their patients, to assist with decisions about immunization. The CISA Project has provided key medical expertise on adverse events like anaphylaxis, myocarditis, and thrombosis with thrombocytopenia syndrome (TTS) as a service to healthcare providers in the United States.

V-safe

V-safe is a smartphone-based safety monitoring tool developed initially for the COVID-19 vaccination program to supplement the existing vaccine safety monitoring systems. It allows vaccine recipients to use their phones to send personal health check-ins after receiving a vaccination. V-safe provides crucial information in near-real time to monitor potential short-term side effects and other health impacts after vaccination. Enrollment and participation are voluntary. An updated version of V-safe was released in October of 2023, allowing reporting for the RSV vaccine and with added functionality that allows participants to use a computer, tablet, or smartphone to enroll and participate. COVID-19 vaccine reporting is also available on the updated V-safe tool.

COVID-19 Vaccine Pregnancy Registry

Finally, the COVID-19 Vaccine Pregnancy Registry has allowed V-safe participants who reported they were pregnant around the time of vaccination to volunteer to provide additional information after vaccination. The pregnancy registry monitors pregnancy and infant outcomes both before and after birth over time, providing data after COVID-19 vaccination. Like V-safe, participation in the Pregnancy Registry is voluntary and, while enrollment has concluded, we continue to evaluate outcomes data from the registry.

Vaccine Safety Monitoring in Action—COVID-19

CDC and its federal partners rigorously monitor safety among vaccines used in the United States after approval or authorization. These efforts are particularly important for promoting vaccine confidence and improving outcomes for those who may experience a rare adverse event. The COVID-19 vaccine distribution and related vaccine safety monitoring efforts were the largest of their kind in U.S. history. Both CDC and FDA continue to monitor the safety of COVID-19 vaccines in a thorough manner that reflects the scale of the COVID-19 vaccination effort, and both agencies will continue to provide appropriate guidance related to safety signals for COVID-19 vaccines.

CDC has acted quickly and transparently in response to potential safety signals detected by CDC's vaccine safety monitoring systems, including for COVID-19 vaccines. For example, myocarditis, an inflammation of the heart muscle, is a known condition that can occur during a COVID-19 infection. Beginning in April 2021, through ongoing monitoring and analysis of data from VSD and VAERS, we found an increase in rare cases of myocarditis following COVID-19 vaccination that demanded further deep-dive analysis. We found rates of myocarditis after COVID-19 vaccination were highest among males in their late teens and early 20s, usually following the second dose of an mRNA COVID-19 vaccine. In May 2021, CDC used this information to quickly update our clinical considerations for healthcare providers with information on this rare adverse event and advise providers on determining the risk of additional vaccinations. CDC's evaluation found that most patients with heart complications after COVID-19 vaccination responded well to medicine and rest and felt better quickly. And importantly, subsequent studies have consistently found that the risk of myocarditis is higher following COVID-19 infection than following COVID-19 vaccination. CDC and FDA are continuing to monitor for and evaluate reports of myocarditis after COVID-19 vaccination.

Another example of the vaccine safety monitoring system in action was with the identification of several cases of thrombosis with thrombocytopenia syndrome (TTS) detected in patients who received the Johnson & Johnson (J&J)/Janssen COVID-19 vaccine. TTS is a very rare, but life-threatening, condition that causes blood clots in large blood vessels and low blood levels of platelets. The J&J/Janssen COVID-19 vaccine was recommended for use by the Advisory Committee on Immunization Practices (ACIP) on February 28, 2021, and, as of April 12, 2021,

6.8 million doses had been administered in the United States. Six cases of TTS were reported through VAERS in patients who received the J&J/Janssen COVID-19 vaccine over the six weeks since the vaccine had been authorized for use. A causal relationship between TTS and receipt of the J&J/Janssen COVID-19 vaccine was supported by review of individual patient laboratory and medical records of potential cases identified from VAERS reports, with support from the CISA Project's clinical experts. On April 13, 2021, CDC quickly issued a broad Health Alert Network announcement that detailed the findings and recommended an immediate pause on the administration of J&J/Janssen COVID-19 vaccines while CDC and FDA continued evaluating the signal. Findings were presented at multiple ACIP public meetings and were published in the biomedical literature. These data informed national vaccine policy, contributing to the preferential recommendation by ACIP to use mRNA COVID-19 vaccines over the J&J/Janssen COVID-19 vaccine.

CDC and FDA investigate any signal of potential concern. That means that vaccine safety monitoring may also identify possible safety signals that, upon further analysis, do not ultimately represent an actual safety concern stemming from the vaccine. For example, in January 2023, CDC and FDA issued a joint statement following the detection of a possible safety concern for ischemic stroke events in the 21 days after bivalent COVID-19 vaccination in older adults using data from VSD. As additional data became available and further analyses were performed, the initial finding decreased and other studies looking into this issue have provided no clear and consistent evidence of a safety problem with ischemic stroke related to bivalent COVID-19 vaccines.

To date, CDC staff have analyzed data from over a million VAERS adverse event reports from healthcare providers, patients, and their families to monitor for new and emerging safety concerns. CDC has also received near real-time health reports in response to surveys sent to the more than 10 million V-safe users asking about their after COVID-19 vaccination experiences. In addition, CDC and VSD sites have conducted active population-based monitoring of the over 12.5 million patients at those sites, constituting both individuals who received COVID-19 vaccines and those who did not. CDC and CISA Project experts have provided over 1,300 clinical consultations to healthcare providers on vaccine safety issues affecting patient care.

Transparently Providing Rapid and Rigorous Vaccine Safety Information

In addition to its monitoring systems, CDC also provides technical assistance to and shares relevant vaccine safety data and analyses with state and other federal agencies. Through these partnerships, CDC can more comprehensively monitor, investigate, and respond to concerns related to vaccine safety. CDC and other experts have also presented data and other research regarding the safety of COVID-19 vaccines at more than 30 public ACIP meetings to provide further information to healthcare providers and the public. In addition, CDC provides the public and healthcare providers with short summaries of vaccine studies and a link to the corresponding free PubMed Central article, when available. This website includes a section dedicated specifically to COVID-19 vaccines.

COVID-19 Vaccines are Safe and Effective

The COVID-19 pandemic challenged the world, and the rollout of hundreds of millions of doses of COVID-19 vaccines to the American public challenged CDC to undertake the most comprehensive and intensive vaccine safety monitoring effort in U.S. history. The rigorous approach that CDC and our partners bring to vaccine safety monitoring reflects a commitment to protecting the health of all Americans. Our efforts to provide timely and well-researched vaccine safety information to clinicians, policymakers, and the public through evidence-based recommendations, published studies, and engagement with interagency and external partners highlight our commitment to transparency as a core value. The conclusions from the data collected as part of this historic effort is clear—COVID-19 vaccines are safe and effective.

A January 2023 study analyzing electronic health data from VSD, the largest vaccine-safety study of its kind, found that death rates among people who received COVID-19 vaccines were lower than for people who had not received the COVID-19 vaccines. Vaccine effectiveness data continue to show that vaccination against COVID-19 is the safest and most effective way to avoid severe hospitalization and death from COVID-19. After extensive review of the data on the safety and effectiveness of COVID-19 vaccines, CDC continues to encourage people to stay up-to-date with recommended COVID-19 vaccines, including the 2023-2024 updated COVID-19 vaccine for those who are eligible. COVID-19 vaccination continues to be the best way to protect against serious illness.

I greatly appreciate the opportunity to elaborate on CDC's role in conducting robust and reliable vaccine safety monitoring and communicating vaccine safety information to healthcare providers, decision-makers, and the American public. I look forward to your questions.