American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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The Honorable Brad Wenstrup
Chairman
House Oversight Select Subcommittee
on the Coronavirus Pandemic
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Raul Ruiz
Ranking Member
House Oversight Select Subcommittee
on the Coronavirus Pandemic
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Wenstrup and Ranking Member Ruiz:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, I write to thank the subcommittee for holding a hearing on the nation's vaccine safety monitoring systems and to reiterate that our nation's immunization program, arguably the most robust in the world, has helped save millions of American lives from vaccine preventable illness and related death.

As pediatricians, we are extremely grateful that this vaccine safety system helped authorize and effectively monitor a COVID-19 vaccine for use in children. COVID-19 poses a serious health risk to infants, children, and adolescents, with thousands hospitalized during the height of the pandemic and, unfortunately, more than 1,800 children between the ages of 0 and 18 dying from COVID-19 though June 2023. The introduction of a COVID-19 vaccine for children was a game changer that provided the benefits of the vaccine to reduce the number of children who became seriously ill. On top of preventing severe disease and hospitalization, a recent study from the Children's Hospital of Philadelphia found that vaccination even provides moderate protection against long COVID in children. As we move forward, we hope that more Americans recognize the effectiveness of COVID-19 vaccines so we can grow the vaccination rate among all age groups.

The development and widespread use, in the United States and globally, of safe and effective vaccines has been one of the greatest achievements in science, medicine, and public health—saving lives, preventing disabilities, contributing to improvements in life expectancy, and reducing health care costs. This massive achievement in public health relies on the robust and expansive vaccine safety monitoring system that has been created over the last half century in the United States.

Prior to licensure, all vaccines in the United States undergo rigorous immunogenicity (e.g. the ability of a foreign substance, such as an antigen, to provoke an immune response) and safety testing, which helps ensure that vaccines are safe and effective before they are approved by the Food and Drug Administration (FDA) and recommended for use by the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and

Prevention (CDC)). Importantly, the monitoring system does not stop with the approval of a vaccine. On the contrary, the United States has established a rigorous post-market surveillance system to continue to capture data to ensure that vaccines are safe and effective and respond to any safety signals that may arise.

In fact, if not for our nation's robust vaccine safety monitoring system, we would not have the number of vaccines we have available today to help control infectious diseases like measles, mumps, rubella, diphtheria, and polio, prevent cancer caused by human papillomavirus infection, and quickly respond to world-wide pandemics like COVID-19.

Despite the millions of illnesses prevented and the number of lives saved through vaccination, adverse events after vaccination can occur and they must be reported, tracked, and investigated. One key element of vaccine-safety science is to determine if adverse events are occurring coincidentally or whether they may be caused by the vaccine (and how commonly this may be occurring). With rare exceptions (e.g., vaccine-associated paralytic polio), the adverse events are not clinical syndromes unique to a vaccine and may be caused by an extensive list of diseases of interest. For events that are caused by the vaccine, it is important to quantify that risk (e.g., how much of the disease burden may be attributed to the vaccine), determine if there are any subpopulations at increased risk, and identify the biological mechanism responsible for the adverse reaction.

Because of these incidents, the United States has created systems for people to report adverse events, established structures and methods to research and thoroughly document these events, and a compensation system to provide redress for these events. For instance, the Vaccine Adverse Event Reporting Systems, better known as VAERS, which is jointly administered by the CDC and the Food and Drug Administration (FDA), is a surveillance system that allows people who believe they or their family members or their patients have experienced an adverse event to report them to a centralized database. Because VAERS is based on submissions by the public and can be susceptible to unverified reports, misattribution, and inaccurate data, it is important for the claims that are reported to be scrutinized for their accuracy and to help determine what type of events need to be investigated.

In addition to VAERS, the Vaccine Safety Datalink Project (VSD), a collaborative project between CDC's Immunization Safety Office, integrated healthcare organizations, and networks across the United States, monitors the safety of vaccines and conducts studies about rare and serious adverse events following immunization. The VSD conducts vaccine safety studies based on questions or concerns raised from the medical literature and reports to VAERS and other vaccine safety systems. In fact, there are 13 VSD sites that provide clinical, methodological, and data expertise; 11 currently are data-providing sites and the remaining sites provide subject matter expertise.

Along with VAERS and VSD, other vaccine safety monitoring systems currently in use in the United States include V-Safe, the Clinical Immunization Safety Assessment Project (CISA), the National Healthcare Safety Network, FDA's Biologics Effectiveness and Safety System (BEST), FDA's Sentinel Initiative, the Centers for Medicare and Medicaid Services (CMS) Health Records Database, Genesis, and systems utilized by the Department of Veterans Affairs, Department of Defense, and Indian Health Services.

These vaccine safety monitoring systems were recently tested and on full alert during the COVID-19 pandemic. This network of vaccine safety monitoring worked as designed, with constant coordination between the FDA, CDC and other government agencies, health care systems, insurance claims data, and both healthcare provider and patient reports. As a result, officials were able to quickly identify any signal that could indicate there was a problem with the safety of COVID vaccines. One example of this occurred in 2021, when Johnson & Johnson's vaccine was found to cause a rare clotting disorder known as thrombosis with thrombocytopenia, or TTS. This signal was important in helping healthcare providers identify patients with TTS and treat them more effectively. It also resulted in the Johnson & Johnson vaccine not considered for full FDA approval. Soon after, another safety signal was discovered that determined that mRNA vaccines could potentially cause myocarditis and pericarditis in young men. By January 2022, there were 1,626 reported cases of myocarditis among 192,405,448 vaccinated people. This demonstrates the strength of our vaccine safety monitoring systems that it is sensitive enough to quickly detect a condition that occurs in 0.000845 percent of people.

When adverse events are caught and determined to have resulted from the administration of a vaccine, it is important that patients and their families are compensated. That is why the AAP championed and has been a long-time supporter of the National Vaccine Injury Compensation Program (NVICP), a no-fault alternative to the traditional legal system for resolving vaccine injury petitions. As you may recall, the NVICP was created in the 1980s, after lawsuits against vaccine companies and health care providers threatened to cause vaccine shortages and reduce U.S. vaccination rates, which could have caused a resurgence of vaccine preventable diseases.

Funded by a federal excise tax on vaccines that are covered by the program, there are no age restrictions on who may file a petition with the VICP. Petitions may be filed on behalf of infants, children, and adolescents, or by adults receiving VICP-covered vaccines. To ease the filing process, there are certain adverse events that have been deemed compensable and are included in a vaccine injury table, where, once determined to have occurred, a judge, known as a Special Master, determines the amount to be compensated. If the adverse event is not on the vaccine injury table, the person filling the claim must go through an adjudication process to demonstrate that the event was caused by a vaccine.

Throughout most of the history of the NVICP, there were usually anywhere between 250-400 claims filed each year, However, in recent years, that number has ballooned to thousands of claims filed. In fact, NVICP claims increased more than fivefold from 402 claims filed in Fiscal Year (FY) 2012 to 2,057 claims filed in FY 2021. The steep increase is claims filed is due in large part to the influenza vaccine being administered to adults. In fact, more than 92 percent of claims in the last two fiscal years were filed for adults, with 74 percent of all claims filed for alleged injuries from the influenza vaccine.

However, while claims have risen dramatically in recent years, the funding to administer the program through the Health Resources Services administration (HRSA) barely doubled from $6.5 million to $11.2 million during the same period. While the number of petitions has increased, the number of staff to administer the claims has not risen to the same level. Because of this, the AAP has called for increased funding for HRSA to hire more officials to administer the NVICP program and process the

increasing number of claims in a timely manner. This will be even more important when claims from the COVID-19 vaccines are moved from the Countermeasures Injury Compensation Program (CICP), where they are currently covered, to the NVICP.

In addition to the AAP's support for increased funding for NVICP, the Academy also encourages Congress to increase funding for the vaccine safety monitoring programs mentioned previously. While VAERS, VSD and other programs have worked to discover safety signals and help ensure the safety of our vaccine supply, more funding can help the programs expand their capacity to gather data, streamline and make it easier for people to report adverse events, increase the speed of communications between agencies, and encourage continual improvements in data analysis.

Throughout the history of vaccines, there have always been concerns raised by the public about vaccine effectiveness, safety, and necessity. Because vaccine safety is an integral part of any immunization program, vaccine safety will continue to be a component of the immunization dialogue. 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.

Sincerely,

Benjamin D. Hoffman, MD, FAAP
President