

## **ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)**


### **135<sup>th</sup> ACCV Meeting – Public Comments**


Public comments are provided for informational purposes only. The comments posted on this site are submitted by members of the public and do not necessarily reflect the views or positions of the Advisory Commission on Childhood Vaccines, Health Resources and Services Administration, or the Department of Health and Human Services.


1. Received on 12/18 – Amy Pisani, CEO at Vaccinate Your Family
2. Received on 12/18 – Phyllis A. Arthur, Executive Vice President and Head of Healthcare Policy and Programs at Biotechnology Innovation Organization (BIO)
3. Received on 12/19 – Eli Briggs, Director of Public Policy at Infectious Diseases Society of America (IDSA)
4. Received on 12/19 – Candace Dematteis, Vice President of Policy and Advocacy at Partnership to Fight Infectious Disease
5. Received on 12/19 – James C. Appleby, CEO of Gerontological Society of America
6. Received on 12/19 – Jorey Berry, President and CEO at Immune Deficiency Foundation
7. Received on 12/19 – Jim Stansel, Executive Vice President and General Counsel & Kelly Falconer Goldberg, Vice President at Law/Senior Counsel at Pharmaceutical Research and Manufacturers of America (PhRMA)
8. Received on 12/22 – Adult Vaccine Access Coalition (AVAC)
9. Received on 12/22 – Alliance for Aging Research and 40+ Organizations
10. Received on 12/22 – Brigid K. Gloves, Vice President of Professional Affairs at American Pharmacists Association (APhA)
11. Received on 12/22 – Tom Daschle, Chairman at Coalition to Stop Flu
12. Received on 12/23 – Jester Jersey, Private Citizen



712 H Street NE, Suite 1507  
Washington, DC 20002

(202) 783-7034 

info@vaccinateyourfamily.org 

vaccinateyourfamily.org 

December 18, 2025

Pita Gomez, MPH  
Principal Staff Liaison  
Division of Injury Compensation Programs  
Health Resources and Services Administration  
5600 Fishers Lane, 8W-25A  
Rockville, MD 20857

Dear Advisory Commission on Childhood Vaccines Members,

Vaccinate Your Family is a nonprofit, nonpartisan organization with a three-decade history of working with policymakers, public health institutions, healthcare providers, and local communities to ensure that all Americans are protected from vaccine-preventable diseases.

At Vaccinate Your Family, we recognize the important role the Advisory Commission on Childhood Vaccines (ACCV) plays in supporting the National Vaccine Injury Compensation Program (VICP)—a program that is essential to our nation’s lifesaving immunization infrastructure. While we understand that the Commission will not be voting or making decisions at the upcoming December 29, 2025 meeting, we welcome the opportunity to opine on potential agenda items and opportunities to strengthen the VICP.

Despite the extensive safety profile of vaccines,<sup>1</sup> rare vaccine injuries do occur, and we strongly support systems that ensure proper compensation for these injuries. Since 1986, the VICP has helped ensure an adequate supply of vaccines, stabilize vaccine costs, and establish an efficient way to provide timely compensation for those who may have experienced a vaccine injury.

While the VICP’s design—intentionally less burdensome and complicated to navigate than the traditional court system—is supportive for the petitioners, there is opportunity to improve the program. The VICP has not been updated since its establishment. To improve upon the program, Vaccinate Your Family has developed the following recommendations which we have shared with lawmakers and policy partners broadly:<sup>2</sup>

---

<sup>1</sup> American Academy of Pediatrics. (2025). Vaccine Safety: Examine the Evidence. Accessed December 17, 2025. <https://www.healthychildren.org/English/safety-prevention/immunizations/Pages/vaccine-studies-examine-the-evidence.aspx>

<sup>2</sup> Vaccinate Your Family. (2025). State of the Immunion Report. Accessed December 17, 2025. [https://vaccinateyourfamily.org/wp-content/uploads/2025/03/VYF\\_2025\\_SOTI\\_Report.pdf](https://vaccinateyourfamily.org/wp-content/uploads/2025/03/VYF_2025_SOTI_Report.pdf)

- All adults should be eligible to file a claim given the recent innovations that have resulted in the development of adult vaccines.
- The number of judges and resources for the Department of Justice should be increased to keep pace with the expansion of vaccines available to the public since the VICP was initially created.
- COVID-19 vaccine injuries should transition from the Countermeasures Injury Compensation Program (CICP) to the VICP, and the VICP should be appropriately resourced to expeditiously adjudicate these claims.
- Awards should be increased to reflect inflation.
- Excise taxes for new vaccines should be quickly levied on the manufacturers.

These enhancements would help ensure that compensation continues to be quick and efficient for claimants and the program continues to evolve at the pace of vaccine innovation.

It is our understanding that the Secretary of Health and Human Services, Robert F. Kennedy, Jr., intends to alter the VICP. At Vaccinate Your Family, we are prepared to engage with the Health Resources and Services Administration (HRSA) and the ACCV on potential opportunities to streamline the VICP program with the goal of providing timely compensation for those who have valid claims and protecting our nation's vaccine supply. Looking ahead, we encourage the Commission to transparently engage the public in a timely manner, including the allowance and proper consideration of public comment and the timely posting of agendas.

Most Sincerely,

*Amy Pisani*

Amy Pisani, MS  
CEO, Vaccinate Your Family



Biotechnology Innovation Organization  
1201 New York Ave., NW  
Suite 1300  
Washington, DC 20005  
202-962-9200

December 18, 2025

Pita Gomez, Principal Staff Liaison  
Division of Injury Compensation Programs, HRSA  
5600 Fishers Lane, 14W-18  
Rockville, Maryland 20857

***For electronic submission***

**Re: BIO Comments on FR Doc. 2025-22982**

Dear Captain Grimes, ACCV Voting Members, and ACCV Secretariat:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments to the Advisory Commission on Childhood Vaccination (ACCV) in advance of the December 29, 2025 meeting. BIO appreciates that HRSA has scheduled these meetings to maintain transparency with the public in the operation of the Vaccine Injury Compensation Program (VICP). We encourage HRSA and ACCV to remain firmly committed to its long-standing *Guiding Principles for Recommending Changes to the Vaccine Injury Table*, reaffirm its commitment to measured, transparent processes consistent with the Federal Advisory Committee Act (FACA), and ensure any discussions, recommendations, and policy proposals are supported by scientific evidence and follow all statutory and regulatory requirements for notice and comment review.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 35 other nations. BIO membership includes vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to innovation and life-saving vaccines for all individuals.

Vaccines are among the most effective public health tools ever developed, providing extraordinary benefits that overwhelmingly outweigh their risks. At the same time, no medical intervention is without risk, and when people have vaccine-related injuries, those individuals deserve to be heard and to receive fair, timely, and appropriate compensation through VICP.

Since its creation in 1986 through bipartisan legislation, the program has fulfilled this important goal. The VICP has ensured that people injured by certain vaccines are provided with a fair and efficient process for compensation. With an average time to adjudicate cases between two to three years, individuals avoid civil litigation, which could languish many more years, drain petitioners' resources, and have a much higher threshold for determining compensation.

The program has also allowed for continued innovation in vaccine discovery, leading to the development of novel products that protect against serious and deadly diseases and their consequences.

BIO recognizes that there is room for improvement in this program and supports updates that would speed petitioners review processes and improve overall experience with the VICP. Those updates must be grounded in evidence and science and informed by experts who are invested in the program's success and maintaining a robust public health infrastructure.

To that end, we urge the Commission to remain firmly committed to its long-standing *Guiding Principles for Recommending Changes to the Vaccine Injury Table*, which have ensured that deliberations are grounded in rigorous, peer-reviewed scientific and medical evidence, are transparent, and are trusted by the public (as cited in past ACCV materials). As instructed by these principles and central to the Commission's credibility and effectiveness is the careful weighing of evidence for and against proposed changes, evaluations of the strength of presented evidence and strength of data sources, and consideration of Institute of Medicine findings.

Historically, ACCV has demonstrated a strong commitment to measured, transparent processes consistent with the Federal Advisory Committee Act (FACA). This includes clear and timely meeting notices and agendas, robust opportunities for public comment, comprehensive meeting minutes and recordings, and well-documented presentations that evaluate the strength and limitations of available evidence. Timely rulemaking and sufficient comment periods are crucial aspects of the overall evaluation of scientific data for any changes that may be deliberated by ACCV to ensure that balanced scientific perspectives are considered. These practices have ensured that recommendations to the Secretary are well-reasoned, publicly accountable, and grounded in the totality of the evidence.

The addition of Shoulder Injury Related to Vaccine Administration (SIRVA) to the Vaccine Injury Table in 2017 – as documented in this 2021 notice – is an excellent example of how the thorough and transparent process of ACCV leads to well-supported policy outcomes. The addition of SIRVA followed a multi-year, evidence-based review involving nine HHS workgroups, consideration of IOM findings, publication of a notice of proposed rulemaking, a full six-month public comment period, and consultation with ACCV. Only after almost a year considering the 14 written comments and the remarks at the public hearing did HHS issue the final rule that added SIRVA to the table. This deliberate process ultimately produced a change that improved patient protections while preserving confidence in vaccine administration and access. Conversely, when a subsequent proposal was advanced in 2020 to remove SIRVA without new supporting scientific evidence, ACCV appropriately objected, citing its Guiding Principles and the absence of a sufficient evidentiary basis.

We respectfully emphasize that if any significant changes are to be made to the VICP, they must be transparent, supported by scientific evidence, and follow all statutory and regulatory requirements. This includes full consultation with ACCV with at least 90 days to make recommendations, publication of a notice of proposed rulemaking, and at least 90 days for public comment (42 U.S.C. 300aa-14(c)-(e)). Major or unsubstantiated policy shifts undertaken outside of these processes risk undermining patient protections, eroding public trust and confidence in vaccines and the program, destabilizing the environment necessary for continued innovation for life-saving vaccines, and, critically, doing a disservice to individuals who have experienced injuries linked to clinical evidence injuries and deserve timely compensation.

It is vital that the process to reform the VICP remains transparent, participatory, and apolitical, and seek input from experts in the scientific, academic and public health community as well as the public. Any reforms should result in a stronger program that helps Americans who have been injured and protects the ability for them to choose and access lifesaving vaccines here in the U.S. We thank the ACCV for their rigorous and transparent work over many years and look forward to the Commission's continued efforts to uphold and strengthen the VICP through its robust and thorough processes.

Sincerely,

/s/

Phyllis A. Arthur

EVP & Head, Healthcare Policies and Programs



**2025 – 2026  
BOARD OF DIRECTORS**

**PRESIDENT**

**Ronald G. Nahass, MD, MHCM, FIDSA**  
ID Care  
Hillsborough, NJ

**PRESIDENT-ELECT**

**Wendy S. Armstrong, MD, FIDSA**  
University of Colorado School of Medicine  
Aurora, CO

**VICE PRESIDENT**

**Maximo O. Brito, MD, MPH, FIDSA**  
University of Illinois at Chicago  
Chicago, IL

**SECRETARY**

**Erin Bonura, MD, FIDSA**  
Oregon Health & Science University  
Portland, OR

**TREASURER**

**Rana Chakraborty, MD, MS, PhD, FIDSA**  
University of Miami  
Miami, FL

**IMMEDIATE PAST PRESIDENT**

**Tina Q. Tan, MD, FIDSA**  
Northwestern University Feinberg School  
of Medicine  
Chicago, IL

**DIRECTORS**

**David M. Aronoff, MD, FIDSA**  
Indiana University  
Indianapolis, IN

**Adarsh Bhimraj, MD, FIDSA**

Houston Methodist Hospital  
Houston, TX

**Matifadza Hlatshwayo Davis, MD, FIDSA**

St. Louis, MO

**Robin H. Dretler, MD, FIDSA**

Georgia Metro Infectious  
Disease Consultants  
Atlanta, GA

**Michelle S. Cespedes, MD, MS**

HIVMA Representative  
Icahn School of Medicine at Mount Sinai  
New York, NY

**Kami Kim, MD, FIDSA**

University of South Florida  
Tampa, FL

**Upinder Singh, MD, FIDSA**

University of Iowa  
Iowa City, IA

**Anu Malani, MD, FIDSA**

Trinity Health Ann Arbor Hospital  
Ann Arbor, MI

**Heather Yun, MD, FIDSA**

South Texas Veterans Health Care System  
San Antonio, TX

**CHIEF EXECUTIVE OFFICER**

Chris Busky, CAE

4040 Wilson Blvd.  
Suite 300  
Arlington, VA 22203

[info@idsociety.org](mailto:info@idsociety.org)

703.299.0200

[IDSOCIETY.ORG](http://IDSOCIETY.ORG)

**Comments for Advisory Commission on Childhood Vaccines, Health Resources and Services Administration**

**Dec. 29, 2025**

The Infectious Diseases Society of America (IDSA) provides the following comments ahead of the December 2025 meeting of the Advisory Commission on Childhood Vaccines (ACCV.)

IDSA is a global community of 13,000-plus clinicians, scientists and public health experts working together to solve humanity's smallest and greatest challenges, from tiny microbes to global outbreaks. IDSA submits the following comments related to implementation of the National Vaccine Injury Compensation Program (VICP) on behalf of IDSA's members and the patients and communities they serve.

***Vaccine Injury Compensation Program***

VICP has helped for decades to protect our nation's lifesaving vaccine supply. Vaccines are some of the greatest public health tools and are responsible for some of the greatest gains in protecting millions of people from serious vaccine preventable diseases and increasing human life expectancy, and maintaining vaccine availability of all vaccines must remain a top priority in any updates to VICP. Serious vaccine injuries are very rare, and when they do occur, patients and families deserve the utmost care and compassion. While the VICP's design is aimed to be less burdensome and complicated for petitioners than going through the traditional tort system, the program has not been updated since its establishment in the 1980's and is overdue for review.

We welcome engagement with the Health Resources and Services Administration (HRSA) and ACCV on opportunities to enhance the VICP program, while maintaining the program's goals of ensuring an adequate vaccine supply in the United States and compensating scientifically based claims.

Although the ACCV does not plan to make any decisions at the upcoming meeting, IDSA strongly urges that more public engagement in the process is essential, including transparent and public agendas and opportunities for public comment from patients, scientists and health care providers with vaccine expertise. We also urge congressional oversight of VICP reform to help ensure that changes are aligned with the best available science and that the program remains financially solvent and able to protect vaccine access.

There are several areas where VICP could be improved and modernized:

- Expanding the adult vaccines considered by VICP.
- Implementing excise taxes on new vaccines in a timely manner to ensure that sufficient funding is available for VICP.
- Increasing award amounts to reflect inflation since the establishment of the program.
- Increasing the number of judges and Department of Justice resources available to VICP to improve efficiency and timely consideration of claims.
- Transitioning COVID-19 vaccines from the Countermeasures Injury Compensation Program to VICP.

***Vaccine Safety Monitoring***

- IDSA continues to support the ongoing monitoring of any adverse events associated with vaccines, especially those observed in infants and children. Currently, multiple systems within the federal government track vaccine safety, including Vaccine Safety Datalink, Vaccine Adverse Event Reporting System (VAERS), the Clinical Immunization Safety Assessment Project and the Sentinel Initiative.

It is critical to acknowledge that individuals report a wide array of events to VAERS that simply occur following administration of a vaccine, while further investigation finds in the majority of cases that these events are not related to a vaccine. To protect the public and preserve scientific rigor, these systems should be supported with sufficient resources to determine any credible safety signals related to vaccines and their findings widely shared with substantive evidence and recommendations made public.

Thank you for your attention to these comments. Please contact Eli Briggs, IDSA director of public policy, at [ebriggs@idsociety.org](mailto:ebriggs@idsociety.org) with any questions.



December 18, 2025

The Honorable Thomas J. Engels  
Administrator  
U.S. Health Resources and Services Administration

Submitted via email to [ACCV@hrsa.gov](mailto:ACCV@hrsa.gov)

Re: Engagement and Modernization of the Vaccine Injury Compensation Program (VICP)

Dear Administrator Engels:

The Partnership to Fight Infectious Disease (PFID) appreciates the opportunity to comment on the future of the Vaccine Injury Compensation Program (VICP). PFID is dedicated to protecting people from infectious diseases--particularly those most vulnerable, including infants, older adults, individuals with chronic conditions, and immunocompromised populations. Vaccines are among the most effective tools available to prevent serious illness, disability, and death, and a strong vaccine ecosystem is essential to safeguarding both individual and public health. As the ongoing measles outbreak, rising cases of whooping cough, emergence of a "super flu" strain, and declines in vaccination continue to threaten the public's health, reinforcing the U.S. vaccination system is more vitally important than ever.

The Vaccine Injury Compensation Program (VICP) has played a critical role for nearly forty years in protecting the United States' lifesaving vaccine supply while ensuring individuals with legitimate, scientifically supported vaccine injury claims have access to compensation. By providing a predictable and balanced framework, the VICP has helped sustain public confidence in vaccines and maintain a stable environment for vaccine access in the U.S.

We recognize and support changes to the VICP that modernize it while reinforcing the important role it plays in assuring Americans access to safe and effective vaccines. Accordingly, any changes should preserve the VICP's foundational goals: ensuring a safe, abundant, and reliable vaccine supply in the United States, and compensating claims that are grounded in sound science.

Specifically, we suggest consideration of VICP enhancements to:

- Increase the number of special masters and Department of Justice resources to improve efficiency and reduce delays.
- Update award amounts to reflect inflation and changes in economic conditions.
- Expand coverage to include all adult vaccines; and
- Implement excise taxes for newly recommended vaccines in a timely manner.

We stand ready to engage with HHS, HRSA, the ACCV, and other relevant stakeholders to help strengthen and modernize the VICP in a manner that preserves its integrity, fairness, and essential role in supporting the nation's immunization system.





Partnership to Fight  
Infectious Disease

Thank you for your consideration and for your commitment to ensuring that the VICP continues to serve the public interest by compensating those suffering vaccine injuries while assuring the public continues to have access to vaccines that protect against preventable, serious illnesses.

Sincerely,

Candace DeMatteis, JD MPH  
Vice President, Policy & Advocacy  
Partnership to Fight Infectious Disease

December 19, 2025

**To: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Program**

**Re: Comments to the Advisory Commission on Childhood Vaccines (ACCV)**

**Delivered via email: [ACCV@hrsa.gov](mailto:ACCV@hrsa.gov)**

The [Gerontological Society of America](http://www.geron.org) (GSA) honors aging across the life course and is the nation's oldest and largest interdisciplinary organization devoted to research, education, and practice in the field of aging. The principal mission of the Society — and its 6,000+ members — is to advance the study of aging and disseminate information among scientists, decision-makers, and the public. Our mission is to cultivate excellence in interdisciplinary aging research and education to advance innovations in practice and policy. We encourage interdisciplinary research collaboration and communication. We routinely convene stakeholders to discuss issues of importance and make recommendations to address the specific needs of older people.

**Vaccines are one of the greatest advances in human health in modern history, saving untold millions of lives here in the United States and worldwide.** In addition to preventing a staggering human cost of disease, vaccines have resulted in trillions of dollars in direct and indirect societal savings (Baker, 2025). We remain committed to protecting the health of the American public from preventable infectious diseases through the use of extensively studied vaccines that are thoroughly evaluated for use among the American population.

Since 2010, GSA has been dedicated to bringing an interdisciplinary team together to increase reverence for the lifesaving value of vaccines. Our nation has experienced major increases in longevity since 1900 due to improvements in public health. The dramatic gains in life expectancy during the 20<sup>th</sup> century are largely attributable to widespread childhood vaccination programs, which significantly reduced mortality from diseases such as diphtheria, measles, and polio. **We need to recall the importance of these life-saving vaccines and recognize the reverence with which they should be regarded.**

We write to express our **strong support for the Vaccine Injury Compensation Program (VICP) and urge the Advisory Commission on Childhood Vaccines (ACCV) to uphold the VICP's due process.** We are concerned that this meeting was scheduled hastily, with only five business days for written public comment during the holiday break.

We strongly encourage the ACCV to ensure that its work is grounded in evidence-based practice and informed by peer-reviewed science. Doing so not only strengthens the credibility of your efforts but also promotes transparency and accountability—critical elements for advancing policies and practices that protect and improve public health. While there are substantive updates that would improve the program, any changes to the VICP must comply with the notice-and-comment requirements and provide meaningful opportunities for public stakeholder input. The VICP plays an integral role in public trust and vaccine confidence, and modifications must be made through traditional and transparent processes.

We appreciate the work of the National Vaccine Injury Compensation Program within the Health Resources and Services Administration and the Advisory Commission on Childhood Vaccines. For additional information, please contact Patricia D'Antonio, Vice President of Policy and Professional Affairs at [pdantonio@geron.org](mailto:pdantonio@geron.org).

Sincerely,



James C. Appleby, BSPHarm, MPH, ScD (Hon)  
Chief Executive Officer

#### References

Baker, M. (2025, June 5). *Vaccine Protection and Productivity: The Economic Value of Vaccines* - AAF.  
AAF. <https://www.americanactionforum.org/research/vaccine-protection-and-productivity-the-economic-value-of-vaccines/>

December 19, 2025

Pita Gomez, Principal Staff Liaison  
Division of Injury Compensation Programs, HRSA  
5600 Fishers Lane, 14W-18  
Rockville, Maryland 20857

***For electronic submission***

**RE: ADVISORY COMMISSION ON CHILDHOOD VACCINES MEETINGS, DECEMBER 29, 2025  
[FR Doc. 2025-22982]**

To the Advisory Commission on Childhood Vaccines,

On behalf of the [Immune Deficiency Foundation](#), thank you for the opportunity to provide comments to the Advisory Commission on Childhood Vaccines (ACCV) for its upcoming meetings on December 29, 2025. As you review the National Vaccine Injury Compensation Program (VICP), we urge caution against expanding the Vaccine Injury Table without clear scientific evidence showing a causal link between receipt of a vaccine and subsequent injury. Introducing changes that are not evidence-based diverts resources from some immunocompromised people who depend on the program's sustainability to receive fair and reliable compensation.

We intimately understand the importance of VICP's mission to ensure that individuals who experience real vaccine-related injuries are adequately compensated. Our organization represents people with primary immunodeficiency (PI), a group of more than 550 rare, chronic conditions in which part of the body's immune system is missing or does not function correctly. For these individuals, live-attenuated vaccines—which offer long-lasting or even lifetime protection from infectious diseases for healthy people—can be dangerous.

Members of the PI community depend on the vital support offered by the VICP in rare but real instances when immunization leads to injury. One such case was David Salamone, who was born with [X-linked agammaglobulinemia \(XLA\)](#), a life-threatening PI that prevents the body from producing antibodies needed to fight infection. David, who passed away in 2018 at the age of 28, received a routine oral live-attenuated polio vaccine at just four months old, before his XLA diagnosis. In extremely rare cases among individuals with immune deficiencies, the weakened live virus in the live-attenuated polio vaccine can revert to a more dangerous form. Since his XLA was undiagnosed, David became one of the last polio patients in the United States.

Thanks to the advocacy efforts of his father, John Salamone, the Centers for Disease Control and Prevention (CDC) changed the national vaccine schedule to include only the inactivated, nonviable polio vaccine. This form of the vaccine does not use live virus and cannot cause polio in people with immune deficiencies. Despite his son's injury, John remains steadfast in his support of broad vaccination to protect immunocompromised loved ones. He explained,

“Public trust in vaccine safety leads to widespread immunization, the most effective shield to protect the immunocompromised. Science—not speculation—must guide decisions to ensure programs like VICP remain for those who need it, while encouraging life-saving immunization practices.”

For the patients we represent, VICP reinforces the promise that vaccines are designed to safeguard—not endanger—health, offering peace of mind to the public when receiving immunizations. Protecting the immunocompromised requires widespread community uptake of routine and seasonal vaccines.

In the United States, seventy-two million people—about one in five—are immunocompromised and face an elevated risk of infection. This includes:

- [Fourteen million people age 64 or younger who are immunocompromised](#).
- All fifty-eight million adults age 65 and older, whose immune systems naturally weaken with age.

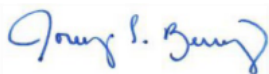
When healthy Americans immunize, they shield those for whom some vaccines may be unsafe or ineffective, allowing them to fully participate in school, work, and public life without fear of exposure. For people with a severe PI, like XLA, who cannot receive live-attenuated vaccines, VICP sustains balancing trust in vaccine safety and providing compensation in the rare cases of harmful outcomes.

To safeguard the integrity of the VICP, we urge ACCV to ground its upcoming discussions in science-based evidence and prioritize preserving resources for those who have truly been injured by vaccines. By promoting widespread vaccination, providing an immunization safety-net, and listening to the voices of people most vulnerable, like the PI community, ACCV can strengthen public trust while ensuring fair compensation in the extraordinary circumstance of vaccine injury.

We welcome the opportunity to engage with ACCV to improve the program’s efficiency, raise injury awards, and collaborate on reforms where the voice of PI patients can inform policy decision-making. Together, we can uphold VICP as a vital resource in the rare case of real immunization injury, while protecting the immunocompromised and the broader public who rely on their loved ones to vaccinate for their own protection.

For questions or additional follow up, please contact Lynn H. Albizo at [labizo@primaryimmune.org](mailto:labizo@primaryimmune.org).

Sincerely,



Jorey Berry,  
President & CEO  
Immune Deficiency Foundation

**By Electronic Mail**

December 19, 2025

Pita Gomez, MPH  
Principal Staff Liaison  
Division of Injury Compensation Programs  
Health Resources & Services Administration  
5600 Fishers Lane, 14W-18  
Rockville, Maryland 20857  
[ACCV@hrsa.gov](mailto:ACCV@hrsa.gov)

**Re: Advisory Commission on Childhood Vaccines  
(ACCV) Public Meetings**

Principal Staff Liaison Gomez:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) submits this comment in advance of the ACCV’s public meetings for calendar year 2025 to emphasize the importance of the Vaccine Injury Compensation Program (VICP) and the ACCV in the United States vaccine ecosystem. PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure that patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than \$850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

**I. Vaccines are a Powerful Tool for Public Health.**

Vaccines are one of the most effective public health tools we have, and they play a critical role in helping to prevent some of the most dangerous diseases. Vaccines eradicated smallpox, helped the United States achieve elimination status for polio, and protect millions of people from serious and potentially deadly diseases every year. One of the great public health victories of the last several decades was the elimination of measles in the United States – an achievement now at risk due to declining vaccination rates driven by misinformation. Over the last 30 years in the United States, childhood vaccines have prevented more than one million early deaths and saved \$2.7 trillion.<sup>1</sup> From saving lives to promoting healthy aging, vaccines play an important role in building a healthier future for Americans.

Every vaccine is carefully developed through rigorous research and clinical trials and undergoes thorough review by scientific and regulatory experts before it is approved for use.

---

<sup>1</sup> F. Zhou et al., [\*Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program – United States, 1994–2023\*](#), MMWR Morb Mortal Wkly Rep 2024;73:682–685.

Even after approval, vaccines are continuously monitored using real-world data to ensure they continue to safely prevent serious disease and protect the population. While all medical products may have the risk of side effects, the most common side effects of vaccines are very mild and transient, such as pain or swelling at the injection site. The overwhelming benefits of vaccination outweigh the risks, as shown by thousands of peer-reviewed studies involving hundreds of thousands of people and continuous monitoring after approval.<sup>2</sup>

## II. **A Strong Vaccine Infrastructure Protects Americans from Infectious Disease Outbreaks, Upholds U.S. Leadership in Innovation, and Strengthens National Security.**

The current vaccine infrastructure in the United States dates back to 1986, when Congress took bipartisan action to enact the National Childhood Vaccine Injury Act (NCVIA).<sup>3</sup> In the 1980s, there was a massive increase in product liability suits filed against manufacturers of vaccines against diphtheria, tetanus, and pertussis (DTP). A 1985 report from the Institute of Medicine emphasized that the effects of product liability suits disincentivized vaccine research and development and threatened the nation's vaccine supply.<sup>4</sup> The same report also called for the creation of a commission to “monitor all aspects of immunization efforts in the United States,” “help to educate and inform the public, physicians, and government decision makers about the effects of various immunization actions and policies,” and “[w]hen necessary . . . become an impartial broker to promote the availability of needed vaccines and to coordinate collaborative activities for which no suitable mechanism exists.”<sup>5</sup> In response, under the NCVIA, Congress created a no-fault compensation system—the VICP—and established the ACCV to help implement it.

Since 1986, the VICP and ACCV have helped to stabilize the vaccine market, facilitate compensation to claimants pursuing legitimate vaccine-related injuries, and encourage the availability of an adequate supply of safe and effective vaccines. The VICP provides a streamlined process intended to resolve vaccine injury claims efficiently. Individuals who claim they were injured by vaccines recommended for routine use by children or pregnant women can seek compensation, without undergoing the lengthy and costly legal burdens often experienced in civil litigation and without needed to prove fault as would be required in a typical civil lawsuit. Since 1986, the VICP has compensated thousands of injury claims while helping to safeguard the stability of our nation's vaccine supply. **It is important to emphasize that the VICP does not shield manufacturers.** Individuals can still pursue civil lawsuits against a vaccine manufacturer if they are dissatisfied with the judgment issued under the VICP.

The ACCV also plays a critical role in the United States vaccine ecosystem by providing advice and recommendations to the Secretary of HHS on the VICP and more broadly promoting the availability of an adequate supply of safe and effective vaccines. The ACCV's statutorily mandated composition ensures independent and balanced perspectives. Of the nine members appointed by the Secretary, two must be pediatricians with expertise in the health care of

---

<sup>2</sup> Children's Hospital of Philadelphia, [Vaccine Science: Common Questions about Vaccine Liability](#) (Jan. 24, 2024).

<sup>3</sup> Pub. L. 99-660, 100 Stat. 3755 (1986).

<sup>4</sup> See Institute of Medicine, [Vaccine Supply and Innovation](#) (1985).s

<sup>5</sup> S. Rep. 99-483, Report to Accompany S. 827, at 15 (99th Cong.) (quoting the Institute of Medicine Report).

children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines (and a third must be a health professional with similar expertise); two must be legal representatives of children who have suffered a vaccine-related injury or death (and a third must also be a representative from the general public); one must be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death; and one must be an attorney whose specialty includes representation of vaccine manufacturers.<sup>6</sup>

We note the importance of the ACCV convening and acknowledge that consistent with the statute and the ACCV's charter, it should meet at least four times per year.<sup>7</sup> While the VICP could potentially benefit from targeted improvements, it is critical that any proposed changes are carefully evaluated and consider the long-term impacts of changing a system that has served public health so well. Weakening the current vaccine infrastructure would jeopardize patient access to FDA-approved vaccines and leave communities more vulnerable to preventable diseases.

It is important to understand that progress isn't permanent. When vaccination rates fall, diseases thought to be in the past, like measles and whooping cough, can and do return. Preserving access to vaccines is not just about convenience—it protects individuals, helps prevent the spread of disease and bolsters national security. Moreover, continued innovation ensures vaccines remain available as a critical tool to protect Americans from both longstanding and emerging health threats.

Respectfully submitted,

/s/

---

Jim Stansel  
Executive Vice President & General Counsel

/s/

---

Kelly Falconer Goldberg  
Vice President  
Law/Senior Counsel for Biopharmaceutical Regulation

---

<sup>6</sup> Public Health Service Act (PHSA) § 2119(a)(1). The ninth member must also be an attorney.

<sup>7</sup> *Id.* § 2119(c).



**To:** Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Program  
**Re:** 2025 ACCV Public Meetings  
**Date:** December 19, 2025

**Delivered** via email to [ACCV@hrsa.gov](mailto:ACCV@hrsa.gov)

On behalf of members of the Adult Vaccine Access Coalition (AVAC), we write in response to the December 16, 2025 notice published in the *Federal Register* announcing the Advisory Commission on Childhood Vaccines (ACCV) public meetings for calendar year (CY) 2025.

AVAC's broad membership consists of over eighty organizational leaders in health and public health committed to addressing the range of barriers to adult immunization and raising awareness of the importance of adult immunization. AVAC works towards common legislative and regulatory solutions that will strengthen and enhance access to adult immunization across the health care system. Our priorities and objectives are driven by a consensus process with the goal of enabling the range of stakeholders to have a voice in the effort to improve access and utilization of adult immunizations.

Immunizations are one of the greatest public health accomplishments in human history. Worldwide, vaccines have successfully eradicated deadly viruses such as smallpox, and virtually eliminated many other debilitating conditions, such as polio. In the United States, once rampant viruses, such as measles, chickenpox and whooping cough have become isolated events. However, vaccines can only be effective in protecting individuals, families and our communities, if a large majority of people choose to receive them. An important element for widespread participation in this vital public health intervention is confidence, in the safety of vaccines themselves, as well as in the systems designed to identify and protect individuals should a rare adverse event occur.

As you know, outbreaks of common vaccine-preventable conditions take a toll on the lives and health of individuals, families, loved ones and caregivers each year and compel us to remain vigilant. The Vaccine Injury Compensation Program (VICP) is a critical part of our U.S. immunization system that provides a patient-centered pathway to compensation for individuals injured by certain vaccines. To provide a fair and prompt alternative to the courts for individuals and families affected by vaccine injuries, Congress established an



expeditious, no fault compensation program, funded by an excise tax on manufacturers, with bipartisan support in 1986.<sup>1</sup>

Since FY1988, there have been 29,381 petitions with the VICP.<sup>2</sup> Meanwhile, billions of vaccines have been safely administered in the U.S. to individuals across the life course. For more than 3 decades, the VICP program has helped ensure injured individuals receive fair and efficient compensation, it helped stabilize the vaccine supply in the U.S. and has also helped spur innovation in new vaccines.

We appreciate the important work of the National Vaccine Injury Compensation Program within the Health Resources and Services Administration (HRSA) and the Advisory Commission on Childhood Vaccines (ACCV). Any departmental efforts to update and enhance aspects of the VICP program should be based in science and follow the well documented processes that provide transparency and ample opportunity for public input. Thank you for your consideration.

---

<sup>1</sup> [42 USC CHAPTER 6A, SUBCHAPTER XIX, Part 2: National Vaccine Injury Compensation Program](#)

<sup>2</sup> [HRSA Data and Statistics 09012025](#)

December 19, 2025

Pita Gomez

Principal Staff Liaison

Division of Injury Compensation Programs

Health Resources and Services Administration

5600 Fishers Lane

14W-18, Rockville, Maryland 20857

**RE: December 2025 Meeting of the Advisory Commission on Childhood Vaccines**

To members of the Advisory Commission on Childhood Vaccines,

As organizations representing public health, older adults, patients, family caregivers, consumers, physicians, and other health care providers, we write to express our strong support for the Vaccine Injury Compensation Program (VICP) and urge the Advisory Commission on Childhood Vaccines (ACCV) to uphold the VICP's due process. We are concerned about this meeting being scheduled hastily, with only five business days given for written public comment over the holiday break.

The VICP was created to uphold the "grand bargain" by ensuring that, in exchange for broad vaccine access and liability protections for manufacturers, individuals who experience rare but serious vaccine-related injuries have access to compensation. The program is integral to vaccine infrastructure, and allows Americans to protect one another by taking vaccines, while also ensuring that biopharmaceutical companies continue to invest in vaccine clinical development.

[The VICP has been heralded as a success. As of 2023, almost 9,500 people have been paid more than \\$4.5 billion since the program's 1988 inception.](#) As stated by Dr. Reed Grimes—Director of the Division of Injury Compensation Programs in the Health Resources and Services Administration (HRSA)—at the [December 2025 ACIP meeting](#) (minutes forthcoming): "In the last five years, 77-78 percent of adjudicated claims have resulted in compensation, reflecting the program's deliberate policy choice to err on the side of fairness and efficiency for claimants while preserving vaccine confidence and supply."

While there are substantive updates that would help improve the program, any changes to the VICP must follow the requirements for notice and comment periods and allow for meaningful opportunities for public stakeholder input. The VICP plays an integral role in public trust and vaccine confidence, and modifications must be made through traditional and transparent processes.

Our organizations are also very concerned about efforts to add autism or autism symptoms to the Vaccine Injury Table. The VICP program was built on the principle of compensation

without causation, a fragile balance designed to sustain both trust and supply, and adding autism would collapse that distinction entirely. Federal estimates suggest up to 48,000 children could qualify immediately under a “profound autism” standard at an initial cost of nearly \$100 billion, followed by annual totals of about \$30 billion a year — [dwarfing the current \\$4 billion trust](#), a new analysis finds.

In addition, [multiple studies conducted in several different countries have demonstrated that there is no causal association between vaccines or their preservatives and autism spectrum disorder \(ASD\)](#). Vaccines do not change the timing of the onset of ASD symptoms, nor do they affect the severity of ASD symptoms. Vaccines are one of the greatest success stories in all of medicine, and the continued, baseless push to suggest otherwise needs to stop.

Sincerely,

Alliance for Aging Research  
Alliance for Women’s Health and Prevention  
American Families for Vaccines  
America’s Physician Groups  
American Association for Geriatric Psychiatry  
American Association of Psychiatric Pharmacists (AAPP)  
American Behcet's Disease Association (ABDA)  
American Geriatrics Society  
American Pharmacists Association  
Arkansas Immunization Action Coalition (Immunize Arkansas)  
Big Cities Health Coalition  
CaringKind, The Heart of Alzheimer's Caregiving  
Families Fighting Flu  
Gerontological Society of America  
Global Coalition on Aging  
Global Healthy Living Foundation  
HealthHIV  
HealthyWomen  
Illinois Public Health Association  
Immunize Kansas Coalition  
Immunize Wisconsin  
Infectious Diseases Society of America

Looms For Lupus  
Louisiana Families for Vaccines  
Lupus Foundation of America  
Mississippi Chapter of the American Academy of Pediatrics  
National Association of Nutrition and Aging Services Programs  
National Association of School Nurses  
National Coalition for LGBTQ Health  
National Consumers League  
National Foundation for Infectious Diseases  
National Hispanic Health Foundation  
Neuropathy Action Foundation  
Northern Utah Immunization Coalition  
Partnership to Fight Infectious Disease (PFID)  
RetireSafe  
Village to Village Network  
Voices of Alzheimer’s



December 22, 2025

Pita Gomez  
Principal Staff Liaison  
Division of Injury Compensation Programs  
Health Resources and Services Administration  
5600 Fishers Lane,  
14W-18, Rockville, Maryland 20857

**Re: [\[FR Doc. 2025-22982\]](#) Meeting of the Advisory Commission on Childhood Vaccines**

To members of the Advisory Commission on Childhood Vaccines,

The American Pharmacists Association (APhA) is pleased to submit comments to the Health Resources and Services Administration (HRSA) on the meeting of the Advisory Commission on Childhood Vaccines (ACCV).

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Pharmacists and pharmacy personnel administer immunizations across the lifespan and are integral providers in vaccine access in the United States. During the 2025-2026 respiratory season, pharmacists and pharmacy personnel have administered over 30 million adult influenza vaccines and almost 16 million RSV vaccines for adults 50 years and older.<sup>1</sup>

*Vaccine Injury Compensation Program (VICP)*

The implementation of the Vaccine Injury Compensation Program (VICP), established under the National Childhood Vaccine Injury Act of 1986, created a streamlined, no-fault process for individuals injured by immunization. This program continues to provide the public with an accessible avenue for injury compensation while giving manufacturers and immunizers confidence to continue supporting vaccination efforts, ensuring a stable vaccine supply, and advancing public health in local communities. APhA supports the VICP as it compensates those

---

<sup>1</sup> CDC, *Influenza Vaccinations Administered in Pharmacies and Physician Medical Offices\*, Adults, United States*, FluVaxView (Dec. 22, 2025). Available at: <https://www.cdc.gov/fluvoxview/dashboard/adult-vaccinations-administered.html>.

injured by immunization and reduces the liability of health care professionals arising from adverse effects associated with the appropriate administration of properly manufactured vaccines.

### *Vaccine Injury Table*

ACCV's charter, filed July 21, 2024, describes the committee's duty to recommend changes in the Vaccine Injury Table.<sup>2</sup> The table establishes consistent eligibility criteria for compensation, specifying the vaccine type, the type of injury, and injury onset. Petitioners seeking compensation outside of the table's eligibility criteria must prove medical evidence of causation. The table simplifies the claims process, reduces legal costs, and promotes equitable access to compensation.<sup>3</sup>

The "Guiding Principles for Recommending Changes to the Vaccine Injury Table" emphasize that the scientific and medical credibility of a proposed change is critical. Recommendations should draw on the Institute of Medicine (now the National Academy of Medicine) and other reliable data sources. Members of ACCV are also encouraged to review findings from Omnibus Proceedings under VICP when evaluating relevant injuries, as these consolidated cases provide precedent and scientific context.

APhA appreciates ACCV's continued commitment to and consideration of reputable and credible scientific and clinical evidence when proposing changes to the Vaccine Injury Table. If ACCV proposes to make changes to the VICP Injury Table, APhA encourages ACCV to ensure those decisions are grounded in general scientific consensus. Significant changes to this table may lead to an increase in scientifically unsubstantiated claims to the program, limiting the resources available to those experiencing a true vaccine injury. Additionally, an increase in claims for injuries unrelated to vaccines has the potential to reduce vaccine availability, stall vaccine innovation, and increase overall health care costs to account for an expected rise in health care professional liability fees. With these things considered, patient access may be diminished due to health care professionals determining that offering immunizations is a risk to their practice.

### *Potentially Expanding VICP to Unrelated Conditions*

The revitalized efforts to associate autism with vaccines have not gone unnoticed; this unsupported claim, if applied to the Vaccine Injury Table, would effectively bankrupt the

---

<sup>2</sup> *Charter*, Health Resources & Services Administration (Jan. 2025). Available at: <https://www.hrsa.gov/advisory-committees/vaccines/charter>.

<sup>3</sup> *Covered Vaccines*, Health Resources & Services Administration (Dec. 2025). Available at: <https://www.hrsa.gov/vaccine-compensation/covered-vaccines>.

program.<sup>4</sup> This would not only break the initial promise of the program, but also undermine years of scientific literature in the United States and abroad that show no causal association between autism spectrum disorder (ASD) and vaccines or their preservatives.<sup>5</sup> The Omnibus Autism Proceeding, the compilation of over 5000 injury claims filed as 6 test cases sought to establish a mechanism linking vaccines and autism, is also precedent to reject this notion of correlation, as the courts ruled there was no causal link and against injury compensation.<sup>6,7</sup>

### *Pharmacists as Immunizers*

Pharmacies are the predominant location for individuals to get their routine and seasonal vaccines. VICP has allowed pharmacists to confidently provide vaccinations without fear of litigation as they protect patients from transmittable infectious diseases. Among other advancements, this protection has fostered the expansion of pharmacist-administered immunizations. It has also benefited surrounding communities by providing accessible, community-based locations where patients can conveniently receive vaccine services. VICP is essential to sustaining vaccine confidence and uptake, as clinicians rely on liability protections to maintain immunization centers in the United States, including at pharmacies and other community-based locations.

Thank you for the opportunity to submit comments to HRSA on the meeting of the Advisory Commission on Childhood Vaccines. If you have any questions or would like to meet with APhA and our nation's pharmacists, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at [cwhetzel@aphanet.org](mailto:cwhetzel@aphanet.org)

Sincerely,



Brigid K. Groves, PharmD, MS  
Vice President, Professional Affairs

---

<sup>4</sup> Peter Grossi, *An Outline on How Adding Autism to the National Vaccine Compensation Program Would Likely Destroy It*, 32 Virginia Journal of Social Policy and the Law 1 (2025). Available at: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=5425514](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5425514).

<sup>5</sup> *Statement on CDC's Changes to Guidance on Vaccines and Autism*, National Academies (Nov. 23, 2025). Available at: <https://www.nationalacademies.org/news/statement-on-cdc-s-changes-to-guidance-on-vaccines-and-autism>.

<sup>6</sup> Jennifer Keelan and Kumanan Wilson, *Balancing Vaccine Science and National Policy Objectives: Lessons from the National Vaccine Injury Compensation Program Omnibus Autism Proceedings*, American Journal of Public Health (Oct. 17, 2011). Available at: <https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2011.300198>.

<sup>7</sup> *Docket of Omnibus Autism Proceeding*, United States Court of Federal Claims (Jan. 2011). Available at: <https://www.uscfc.uscourts.gov/docket-omnibus-autism-proceeding>.



December 22, 2025

Pita Gomez, MPH  
Principal Staff Liaison  
Division of Injury Compensation Programs  
Health Resources and Services Administration  
5600 Fishers Lane, 8W-25A  
Rockville, MD 20857

Dear Advisory Commission on Childhood Vaccines Members,

The Coalition to Stop Flu appreciates this opportunity to comment ahead of the 2025 meetings of the Advisory Commission on Childhood Vaccines (ACCV).

## **I. Introduction to the Coalition to Stop Flu**

The Coalition to Stop Flu is a multi-sector advocacy coalition dedicated to ending deaths from seasonal and pandemic influenza, often called “the flu.” Our thirty members represent a unified voice for the influenza ecosystem and include public health and patient advocacy organizations; academic, scientific, and research organizations; health care professional organizations; emerging biotech companies; health care distributors; and vaccine, antiviral, and diagnostic manufacturers.

The Coalition’s federal policy agenda is aimed at saving lives, saving money, and protecting public health by enhancing the U.S. influenza ecosystem, including through proper authorization, funding, and implementation of federal influenza and adjacent programs.

## **II. Children Are at High Risk of Severe Outcomes from Influenza**

Influenza is one of our country’s most predictable, preventable public health crises. The Centers for Disease Control and Prevention (CDC) estimates that every year in the U.S., influenza results in 6,300–52,000 deaths, 120,000–710,000 hospitalizations, and 9.3–41 million illnesses.<sup>1</sup> Children – especially those younger than two – are at higher risk of severe outcomes from the flu, including pneumonia, encephalopathy, and death.<sup>2</sup> In the 2024–2025 season, 288 children died from flu in the U.S., tying the record for pediatric deaths set during the 2009 H1N1 pandemic.<sup>3</sup> Ninety percent of those children were not fully vaccinated against influenza, and roughly half had no preexisting conditions.<sup>4</sup>

---

<sup>1</sup> CDC, “About Estimated Flu Burden,” <https://www.cdc.gov/flu-burden/php/about/index.html> (Nov. 13, 2024).

<sup>2</sup> CDC, “Flu and Children,” <https://www.cdc.gov/flu/highrisk/children.html> (Sept. 5, 2024).

<sup>3</sup> CDC, Weekly U.S. Influenza Surveillance Report: Key Updates for Week 49, Ending Dec. 6, 2025, <https://www.cdc.gov/fluview/surveillance/2025-week-49.html>; Reinhart, K. et. al., Influenza-Associated Pediatric Deaths — United States, 2024–25 Influenza Season, 74 Morbidity & Mortality Weekly Report 565, 565–69 (2025), <https://doi.org/10.15585/mmwr.mm7436a>.

<sup>4</sup> CDC, Weekly U.S. Influenza Surveillance Report: Key Updates for Week 37, Ending Sept. 13, 2025, <https://www.cdc.gov/fluview/surveillance/week-37.html>; Reinhart, K. et. al., Influenza-Associated Pediatric Deaths — United States, 2024–25 Influenza Season, 74 Morbidity & Mortality Weekly Report 565, 565–69 (2025).





### **III. Despite Strengthened Supply Chains, the U.S. Influenza Market Remains Fragile**

In 2004, the United States suffered historic flu vaccine shortages due to bacterial contamination at the plant of the country's major supplier, Chiron, which was located in Britain.<sup>5</sup> Just prior to the announcement that British regulators were suspending Chiron's license, GAO issued a report warning about the consolidation of suppliers, noting that "[c]hallenges persist in ensuring an adequate and timely flu vaccine supply."<sup>6</sup> Subsequent reports cited low profit margins and the complexity of production as a reason for the scarcity of manufacturers licensed in the U.S., and noted that prior manufacturers had exited the market after facing financial losses.<sup>7</sup>

Following the 2004 shortages, the federal government and private industry made substantial investments to strengthen the U.S. flu vaccine supply chain. Today, the U.S. has four major suppliers of annual flu vaccine and a stable supply chain. However, this market remains fragile. Vaccines represent less than five percent of global pharmaceutical sales and are dwarfed by revenue in other product categories like oncology and rare disease.

### **IV. A Robust VICP is Essential to Preserving Flu Vaccine Access**

The National Vaccine Injury Compensation Program (VICP) is a critical program to protect and serve patients in the extremely rare case of vaccine injury, as well as ensure stable vaccine markets and vaccine costs. HRSA notes that the program 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."<sup>8</sup> The program provides a pathway for patients to receive compensation on a quicker timeline than traditional legal cases with less expense and using a lower evidentiary standard. However, VICP has not been significantly updated since it was created and has been challenged in recent years by significant case backlogs.

The Coalition urges ACCV to maintain the core components of the program while considering updates that would improve access, more fairly compensate patients, decrease wait times, and improve the consistency of decisions. This includes:

- Increasing resources for the program;
- Expanding the number of Special Masters;
- Requiring additional transparency around case decision-making;
- Increasing award amounts to reflect inflation; and
- Expanding coverage to include all vaccines routinely recommended to adults.

Finally, the Coalition urges ACCV to consider the impact of all proposed changes on vaccine access, based on the statutory directive to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."<sup>9</sup>

---

<sup>5</sup> Andrew Pollack, "With Few Suppliers of Flu Shots, Shortage Was Long in Making," N.Y. Times (Oct. 17, 2004).

<sup>6</sup> GAO, "Federal Challenges in Responding to Influenza Outbreaks" (Sept. 28, 2004).

<sup>7</sup> See, e.g., Erika Seiguer, "Issue Brief: Protecting the Nation's Health: Ensuring a Stable Supply of Influenza Vaccine," Commonwealth Fund (July 2005).

<sup>8</sup> HRSA, "National Vaccine Injury Compensation Program" (Dec. 2005), <https://www.hrsa.gov/vaccine-compensation>.

<sup>9</sup> 1986 National Childhood Vaccine Injury Act (Public Law 99-660).





\* \* \*

Thank you for the opportunity to provide input on this critical issue. If you have any questions or would like any further information, please do not hesitate to contact Niki Carelli, Coalition Executive Director, at [niki@db-3.co](mailto:niki@db-3.co).

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Daschle". The signature is stylized with a large, sweeping "T" and "D".

Tom Daschle  
Chairman, Coalition to Stop Flu

Written Public Comment for the Health Resources and Services Administration's  
Dec. 29th, 2025 Meeting of the Advisory Commission on Childhood Vaccines

Thank you to the Advisory Commission on Childhood Vaccines for allowing me to provide both a written and oral public comment for the this meeting. I am a vaccine advocate who has traveled the country to help raise health awareness and vaccine rates, particularly that of children, in the last few years.

As the measles outbreak continues across the country unimpeded for almost a year now next month, threatening the United States' measles elimination status that it has since achieved in the year 2000, and with growing cases of whooping cough and other vaccine preventable diseases on the rise thanks to low vaccination rates, rather than place the blame on the current government administration, I would like to place the blame on some vaccine advocacy groups. More specifically, Voices for Vaccines(VFV), which is a part of the Task Force for Global Health(TFGH). Both are based out of Atlanta, Georgia.

In 2023, I was tasked with traveling the country for a little more than two months during that summer, from June to August, with the understanding that I would be meeting up with fellow vaccine advocates, including health influencers and vaccine advocates. I had some conventions that I would be attending and would be filling the days in between with vaccine advocacy volunteer work, and would be traveling through ten states in the process. We had spoken numerous times & months prior via Zoom before the travels, as I would not have time to do so while traveling.

At first, things went well, as I had met the executive director of VFV, who was located in Minnesota, along with other local vaccine advocates in the Twin Cities. Unfortunately, that was the only really useful part of the advocacy. A contact I was supposed to meet with in Ohio turned out to be located in Columbus, more than 200 miles away from Cleveland, where I had specifically told VFV I would be traveling to for an event. Because of this, I was not able to make contact with the advocate I was supposed to connect with because they were not located anywhere near me. Instead, that person connected me to someone closer, who only spoke with me by phone. This did nothing to help vaccine advocacy efforts in the least.

During the trip, when I stopped by Atlanta, I was then asked by the director I met earlier on the trip if I would be interested in stopping by the TFGH's HQ in Decatur. I was asked on Jul 31. I wrote back the same day and said that I was. Yet I did not hear back until 4 days later from the same director. The communications coordinator was hardly keeping the conversation open the whole week. By the time I got to the building Aug. 4<sup>th</sup>, a Friday, there was hardly anyone in the building- the desk staff went to the bank & I had to wait nearly an hour before one of the staff gave me a tour of the building. Again, this did not help vaccine advocacy & I had not met with any media like VFV & the TFGH had promised. At best they had wasted my time & at worst hey had lied to me. They've also let down the vaccine community as a whole.

If the Advisory Commission is truly interested in helping young Americans, then they should not follow the example of Voices for Vaccines or the Task Force for Global Health by lying to people. Doing so only risks the health of the most vulnerable who are in need of vaccines to fight vaccine-preventable diseases & tarnished important bodies like yours who carefully scrutinize vaccine safety. Thank you for your work.