

**MYTHS SURROUNDING SIRVA AND SYNCOPE AND HHS' PROPOSED RULE
TO REMOVE THESE INJURIES FROM THE VACCINE INJURY TABLE**

TRUE OF FALSE

1. THE PROCESSING OF SIRVA AND SYNCOPE PETITIONS SLOWS DOWN THE PROCESSING OF PETITIONS INVOLVING CHILDREN: **FALSE**
2. THE VACCINE ACT WAS NEVER INTENDED TO COVER ADULTS, ONLY CHILDREN, AND THAT IS WHY CONGRESS CALLED IT THE NATIONAL CHILDHOOD VACCINE INJURY ACT: **FALSE**
3. REMOVING SIRVA AND SYNCOPE FROM THE VACCINE INJURY TABLE MEANS NO SIRVA OR SYNCOPE CASES CAN EVER BE BROUGHT IN THE PROGRAM AGAIN: **FALSE**
4. IF SIRVA AND SYNCOPE CASES ARE REMOVED FROM THE VACCINE INJURY TABLE, AND CASES MUST BE PROCESSED AS CAUSATION IN FACT CASES, THE WORKLOAD BURDEN ON HHS, DOJ, THE COURT, AND PETITIONER'S BAR WILL DECREASE: **FALSE**
5. HHS HAS NEVER CONCEDED SIRVA CASES AS BEING ACTUALLY CAUSED BY VACCINES AND THAT IS WHY HHS HAD TO ADD SIRVA TO THE VACCINE INJURY TABLE BEFORE THEY WOULD PAY ANY SIRVA CASES: **FALSE**
6. THE VACCINE FUND WILL SAVE MONEY BY REMOVING SIRVA AND SYNCOPE FROM THE VACCINE INJURY TABLE: **FALSE**
7. PEOPLE WHO OPPOSE HHS' PROPOSED RULE SHOULD BE CONSIDERED "ANTI-VAXXERS:" **FALSE**
8. THE OFFICE OF SPECIAL MASTERS (THE VACCINE COURT) HAS NEVER MADE INSTITUTIONAL CHANGES TO ACCOMMODATE THE INFLUX OF SIRVA AND SYNCOPE CASES SO THAT THEY COULD BE PROCESSED IN AN EFFICIENT AND SPEEDY MANNER: **FALSE**
9. THE VACCINE COURT AND/OR THE GOVERNMENT HAS IDENTIFIED A NUMBER OF SIRVA AND SYNCOPE CASES INVOLVING FRAUD: **FALSE**
10. SIRVA CASES ARE NOT SERIOUS OR LIFE-CHANGING INJURIES AND ESSENTIALLY INVOLVE INSIGNIFICANT INJURIES: **FALSE**
11. HHS ONLY RECENTLY DECIDED TO COMPENSATE SYNCOPE CASES: **FALSE**
12. THE AMOUNTS PAID OUT OF THE VACCINE TRUST FUND FOR SIRVA AND SYNCOPE CASES, AND THE ASSOCIATED ATTORNEYS' FEES IN THOSE CASES, HAVE THE POTENTIAL TO DRAIN THE TRUST FUND: **FALSE**
13. IF HHS' PROPOSAL BECOMES FINAL, PETITIONERS WILL HAVE TO SUE THEIR OWN DOCTORS AND THEIR OFFICES FOR SIRVA AND SYNCOPE: **TRUE**

14. NURSES AND OTHER MEDICAL PROFESSIONALS WHO ADMINISTER VACCINATIONS IN DOCTOR'S OFFICES WILL BE SUED FOR SIRVA AND SYNCOPE IF HHS' PROPOSAL IS ACCEPTED: **TRUE**
15. IN PASSING THE VACCINE ACT, CONGRESS INTENDED VACCINE ADMINISTRATORS AND MANUFACTURERS TO BE SHIELDED FROM LIABILITY, EVEN IF THEY WERE NEGLIGENT: **TRUE**
16. IF HHS' PROPOSAL BECOMES FINAL, PETITIONERS WHO SUFFER SIRVA AND SYNCOPE WILL BE BRINGING LAWSUITS AGAINST BEHEMOTH COMPANIES THAT ADMINISTER VACCINES, SUCH AS WALMART, COSTCO, CVS AND WALGREENS, AS WELL AS DRUG MANUFACTURERS LIKE SANOFI AND MERCK, ALL OF WHOM ARE REPRESENTED BY LARGE LAW FIRMS: **TRUE**
17. IN PASSING THE VACCINE ACT, CONGRESS MADE CLEAR THAT THEY WANTED HHS ITSELF TO SUE NEGLIGENT VACCINE ADMINISTRATORS AND MANUFACTURERS RATHER THAN INDIVIDUAL CITIZENS WHO RECEIVED A SINGLE VACCINE AND SUFFERED SIRVA OR SYNCOPE: **TRUE**
18. THE ONLY WAY TO GET SIRVA IS TO RECEIVE A VACCINE: **TRUE**
19. THE VICP IS ONLY ONE SMALL PIECE OF THE OUR GOVERNMENT'S APPARATUS TO SET NATIONAL VACCINE POLICY: **TRUE**
20. THE SCIENCE SUPPORTING SIRVA AND SYNCOPE AS VACCINE INJURIES HAS BECOME STRONGER OVER THE YEARS, EVEN AFTER THE PUBLICATION OF THE NATIONAL ACADEMY OF MEDICINE REPORT IN 2012: **TRUE**
21. HHS ENTHUSIASTICALLY ADDED SIRVA AND SYNCOPE TO THE VACCINE INJURY TABLE IN 2017 AFTER STUDYING THESE ISSUES SINCE THE NATINAL ACADEMY OF MEDICINE STUDY THAT WAS PERFORMED IN 2012: **TRUE**
22. THE VACCINE COMMISSION IS BOUND TO APPLY THE FOLLOWING PRINCIPLE IN DECIDING WHETHER TO MAKE ADDITIONS OR DELETIONS FROM THE VACCINE INJURY TABLE: THAT WHERE THERE IS CREDIBLE EVIDENCE TO BOTH SUPPORT AND REJECT A CHANGE TO THE TABLE, THE CHANGE SHOULD, WHENEVER POSSIBLE, BE MADE TO THE BENEFIT OF PETITIONERS: **TRUE**
23. HHS HAS BEEN WORKING ON THE INITIATIVE TO REMOVE SIRVA AND SYNCOPE FROM THE VACCINE INJURY TABLE FOR YEARS, BUT ONLY MADE THEIR INITATIVE PUBLIC WITHIN THE LAST 90 DAYS: **TRUE**.

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April 14, 2020

Honorable Alex M. Azar II
Secretary of Health and Human Services
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330 C Street, SW
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Mr. Thomas J. Engels
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Health Resources and Services
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By Email and First-Class Mail

OPEN LETTER TO THE SECRETARY OF HHS AND HRSA ADMINISTRATOR

Re: HRSA Proposed Vaccine Rulemaking Making Dramatic Changes in Scope of the National Vaccine Injury Compensation Program

Dear Secretary Azar and Administrator Engels,

The Health Resources and Services Administration (“HRSA”) has recently released a Notice of Proposed Rulemaking (“NPRM”) that will make detrimental changes to the Vaccine Injury Compensation Program and negatively impact our nation’s vaccine policy. The NRPM recommends, among other things, the removal of Shoulder Injury Related to Vaccine (“SIRVA”) and syncope from the Vaccine Injury Table.

I strongly urge Administrator Engels to reject the Proposed Rulemaking recommended by your subordinates. Their proposal is ill-conceived and will do severe damage to our national health policy.

Should Administrator Engels proceed in signing this severely flawed NPRM, I call on Secretary Azar to reject the Administrator’s recommendation and stop the adoption of the Final Rule.

By way of background, I spent 30 years as an attorney at the Department of Justice working on cases in the Vaccine Injury Compensation Program (“VICP”). I was actually the very first attorney hired by the government to defend VICP claims back in the 1980s. Over the years, I have worked closely with all the Directors of HRSA’s Division of Injury Compensation Programs at HHS (this letter will refer to HRSA and HHS interchangeably) including Drs. Geoffrey Evans, Vito Caserta, Melissa Houston, Rosemary Johann-Liang, and Narayan Nair.

All of these outstanding medical professionals will vouch for my integrity and dedication to the VICP. For three decades, I also worked daily with the highly talented attorneys in HHS' General Counsel's Office regarding vaccine-related matters.

After having worked on thousands of cases in which I represented HHS, I retired from DOJ after 30 years of work with the VICP. I spent my entire professional career advancing the goals of the Vaccine Program: to make vaccines readily available and as safe as possible. I am staunchly pro-vaccine. As a government attorney proudly representing HHS for thirty years on many vaccine issues, I believe vaccines save lives. I understand that Congress enacted the Vaccine Act and created the Vaccine Trust Fund to compensate those who experience rare reactions that we know occur, and to ensure that pharmaceutical companies continue to develop and manufacture vaccines, and to further ensure that vaccine administrators continue to administer them.

In the interest of full disclosure, I retired from my government job in 2017, and in 2018, I was lured out of retirement by my wife, Leah Durant, and I now work at a small firm that she owns that, among other things, brings vaccine petitions in the VICP. The firm she founded started taking VICP cases after she suffered a severe SIRVA injury herself. I now personally represent 10 VICP petitioners who allege certain vaccines caused their injuries including brachial neuritis, Guillain-Barre syndrome ("GBS"), and SIRVA.

HRSA's current proposal to remove SIRVA and syncope from the Vaccine Injury Table is a 180-degree reversal of sound health care policy that HRSA debated exhaustively just three short years ago. At the conclusion of that process, HRSA enacted the Final Rule adding these two injuries, and others. In the years prior to enacting the 2017 Final Rule that added SIRVA, syncope, and GBS to the Vaccine Injury Table, HRSA and its advisors, consisting of world-renowned medical experts and legal professionals, worked tirelessly to review the medical, legal, and policy considerations associated with adding these three injuries to the Vaccine Injury Table. The pros and cons of adding these injuries to the Vaccine Injury Table were then openly discussed at public meetings for the sole purpose of seeking input from health care policymakers and the general public. Given that very public effort to alert others of changes to the Vaccine Injury Table three years ago, it shocks the conscience that the current proposal to reverse those changes is not open for discussion in ANY public manner.

HRSA has steadfastly refused to discuss the matter in any way. Indeed, despite repeated calls for more information by members of the Advisory Commission for Childhood Vaccines ("ACCV"), an entity *required* by Federal law to vote on the merits of any proposed deletions to the Vaccine Injury Table, HRSA remains silent. On top of that, HRSA has refused to meet with or brief Commission members in any way.

I am currently a member of the Vaccine Section of the Advisory Council of the United States Court of Federal Claims. The Court of Federal Claims houses the Office of Special Masters, also known as the nation's "Vaccine Court." At the last meeting of the Advisory Council on April 6, 2020, the issue of the Proposed Rulemaking was placed on the agenda set by the Court. Numerous members of the Vaccine Advisory Council, including myself, asked the representatives of HHS (a lawyer from HRSA) and DOJ numerous questions about the Proposed Rulemaking. HHS and DOJ repeatedly refused to answer *any* questions whatsoever, as they

reported that they were under strict instructions not to discuss the issue. Over and over the HRSA lawyer said she was only permitted to bring questions back to her leadership rather than make any comments about the proposed changes to the Vaccine Injury Table. This lack of transparency and refusal to engage in any form of dialog about removing Vaccine Table Injuries which comprise well more than 50% of all vaccine cases filed in the Vaccine Program, stands in very sharp contrast to HHS' approach over the past 30 years when I represented the Vaccine Program, including as recently as 2017.

HRSA's efforts to reverse vaccine policy has been kept secret from our nation's most important vaccine policy makers. I have confirmed that HRSA made no effort to discuss, or even inform, the CDC's prestigious Advisory Committee on Immunization Practices ("ACIP") or HHS' own advisors at the National Vaccine Advisory Committee ("NVAC") that changes to the Vaccine Injury Table were being proposed.

What HRSA is now proposing is a huge health policy mistake. It puts liability back on vaccine manufacturers (companies that develop and produce vaccines like Sanofi, Merck, and others) and vaccine administrators (doctors, physician's assistants, nurses, medical techs, pharmacists, and pharmacy techs) for SIRVA and syncope injuries, and the results of this misguided reversal will have our nation revert back to where we were in the 1980s when so many manufacturers and administrators were leaving the vaccine industry due to high litigation costs. Please do not allow this to happen.

The policy reasons being put forth by HRSA in the Proposed Rulemaking are not sound. Having worked as a lawyer for the VICP for over 30 years, as recently as two and a half years ago, and now seeing it from the "other side" for almost two years, **I can positively assure you that the sole reason HHS is pursuing this reversal of their own policy is due to the increased workload at HHS and DOJ.** Recent information released by HHS at the ACCV meeting on March 6, 2020, indicated that 54% of all claims filed in the VICP over the last three fiscal years are SIRVA cases. That means approximately 677 SIRVA cases per year have been added to the work required by the medical personnel at HHS and the lawyers at DOJ. While both offices have added staff to deal with this increased caseload, they are overwhelmed with the workload. I completely understand their stress, and frankly I lived in that frenzied work environment myself until my retirement in 2017. Nonetheless, a heavy workload is NO reason to deny citizens compensation for legitimate vaccine injuries as Congress intended.

HRSA's NPRM is flawed medically and legally, and it reverses decades of good vaccine policy.

Medical Considerations

The science underlying SIRVA is sound. HRSA itself, with its original Atanasoff article in 2010, did the initial study identifying SIRVA as a vaccine-related injury. Atanasoff et al. identified a reliable medical theory that antigenic material from the vaccine which is injected into synovial tissues results in an immune mediated inflammatory reaction causing severe and chronic pain. This peer-reviewed article, published in the prestigious medical journal "Vaccine," as well as several other peer reviewed articles, were carefully examined by the highly respected

National Academy of Medicine (“NAM”) and the NAM concluded that certain shoulder injuries were caused by the administration of a vaccine. From 2010 through 2017, HHS and the ACCV proudly proclaimed that the science was more than sufficient to add the SIRVA injury to the Vaccine Injury Table. Hesse (from CDC’s Immunization Safety Office) and Atanasoff did a second peer-reviewed article in 2019 affirming the original findings.

HRSA’s NPRM incorrectly states that “There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.” This assertion is belied by published vaccine studies performed by HRSA and the CDC. In 2019, Hesse (from CDC’s Epidemic Intelligence Service) and Atanasoff conducted a scientific review of the clinical characteristics of SIRVA in 476 VICP claims filed between 2010 and 2017. In all of these cases, the VICP issued a “concession” that the administration of the vaccine actually caused the claimant’s SIRVA. Of those 476 cases, only 36.1 percent revealed evidence that the vaccine site was responsible for SIRVA (that the vaccine was administered “too high” on the arm). This article was also published in the journal *Vaccine*.

Likewise, on January 29, 2020, *Vaccine* published a study by Hibbs et al. (from CDC’s Immunization Safety Office) that searched the Vaccine Adverse Event Reporting System (“VAERS”) database from July 2010 to June 2017 for reports of atypical shoulder pain and dysfunction within 48 hours of administration of an inactivated influenza vaccine. 1221 reports fit their criteria. Hibbs et al. concluded, “While specific etiology of cases is unknown, improperly administered vaccine, which is preventable, *might be a factor*” (emphasis added).

The 2019 study by Hesse and Atanasoff, and the most recent study published by CDC’s Hibbs et al. in January 2020 simply do not support the NPRM’s central thesis that uniform agreement exists in the scientific community that SIRVA is caused by improper vaccine administration rather than by the vaccine itself. Nor is the NPRM’s thesis supported by HRSA’s original study in 2010.

Finally, a highly respected orthopedic shoulder surgeon from Johns Hopkins, Dr. Uma Srikumaran, has written a scholarly open letter to the Secretary disagreeing with the NPRM’s central thesis. Dr. Srikumaran reviews the medical literature and evidence on SIRVA. See <https://www.sciencemag.org/sites/default/files/Srikumaran%20Open%20Letter%20to%20Health%20and%20Human%20Services%203.26.20%20FNL.SIRVA%20Insider.pdf> As quoted in *Science Magazine*, Dr. Srikumaran believes HRSA’s proposal “represents the scientific literature in a misleading way.” <https://www.sciencemag.org/news/2020/04/us-wants-end-most-payouts-leading-vaccination-related-injury>. Dr. Srikumaran’s letter argues against one of HRSA’s central assertions that the antigen from the vaccine has nothing to do with SIRVA. It indeed has everything to do with it, and Dr. Srikumaran’s conclusions are buttressed by the peer reviewed scientific studies discussed above as well as those cited in his letter. Please note that the *Science Magazine* article provides a quote from my spouse, Leah Durant, and describes her as an attorney and a SIRVA survivor.

Legal Considerations

There are many legal problems with HRSA's NPRM. I will discuss only two here.

HRSA cannot adopt an administrative rule that is contrary to Federal law. The Vaccine Act is an Act of Congress that was signed into law by President Ronald Reagan in 1986. The NPRM contravenes the express provisions of the Federal law. The NPRM wants to shift the liability for SIRVA and syncope injuries back to vaccine administrators and vaccine manufacturers in clear contradiction of the Act. The NPRM proposes to have Americans who suffer SIRVA bring a civil action against the administrators for negligence, so that "those who failed to properly administer the vaccine" would face liability. The Federal statute, however, was specifically designed to shield administrators from any liability.

HRSA's attempt to separate out the "administration of a vaccine" provisions from the protections of the Vaccine Act is legally incorrect. HRSA completely ignores several provisions of the Vaccine Act. 42 U.S.C. § 300aa-11, specifically provides protection for "administration" of a vaccine. Section 11(a)(2) of the Act explicitly states, "No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death **associated with the administration of a vaccine** after the effective date of this part..." Likewise, Section 11(3) clearly states, "No vaccine administrator or manufacturer may be made a party to a civil action . . . for damages for a vaccine-related injury or death **associated with the administration of a vaccine** after the effective date of this part." Further, Section 11(b)(2) plainly states "Only one petition may be filed **with respect to each administration of a vaccine.**"

In all, Congress used the term "administration of the vaccine" in 17 separate instances in the Vaccine Act. If HRSA wants "administration of a vaccine" to be excluded from the Act's coverage, HRSA's sole remedy is to lobby Congress to change the law, not to pass an administrative rule that disregards the express language of the Federal law passed by Congress. HRSA has no authority to override the actions of Congress and the President of the United States.

The NPRM also ignores 42 U.S.C. § 300aa-17. HRSA advocates for the position that monetary payment for negligence in the administration of a vaccine should be borne by the vaccine administrator, not the Vaccine Fund. That is contrary to law. Congress specifically envisioned instances where there might be negligence on the part of vaccine administrators and vaccine manufacturers, and they expressly provided a provision in the Act to deal with such circumstances. In Section 17 of the Act, the Vaccine Act's Subrogation provision, Congress places on the Secretary of HHS the responsibility to recoup Vaccine Trust Funds that were paid to a claimant for the negligence of a vaccine administrator or manufacturer. Rightfully so, Congress instructed HRSA, not John Q. Public who received a vaccine at his local doctor's office or pharmacy, to seek reimbursement from the administrator. Interestingly, in the thirty-two years since the effective date of the Vaccine Act, HRSA has never once availed itself of the Act's Subrogation provision. If the Secretary is sincerely interested in preserving Vaccine Trust

Funds, as the NPRM claims, Section 17 of the Vaccine Act provides the best mechanism for doing so.

Policy Considerations

The only reason that HRSA is completely reversing course now and seeking a change in the Vaccine Injury Table is because there were many, many more claims than they anticipated. They are now feeling overworked and thus regret adding SIRVA and syncope to the Vaccine Injury Table. But making national health policy based on government workload considerations is unwise and short-sighted.

Because of my “inside perspective” I know that that the primary goal of this reversal in policy is to alleviate the workload of overworked Federal employees at HHS and DOJ who are responsible for reviewing, evaluating and litigating all vaccine claims filed in the VICP. However, that is not the reason cited by the Secretary for eliminating SIRVA and syncope from the Vaccine Injury Table. The NPRM cites three different policy reasons for eliminating the two injuries. First, HRSA cites the fact that they want to preserve Vaccine Trust Funds thereby ensuring funds will be available for other more-meritorious cases. HRSA states that from Fiscal Year 2016 through Fiscal Year 2019, the Act paid \$119,154,985 to successful SIRVA petitioners. The average yearly payment then is \$39,718,328.30. That is nothing compared to the \$4,013,972,370 in the Vaccine Fund as of January 31, 2020. In fact, the Fund earned a whopping \$26,167,862 in interest on its investments in just the first three months of Fiscal Year 2020. And, of course, as noted above, by availing themselves of the Act’s Subrogation provision, HRSA could actually recoup every penny they paid out in SIRVA claims if in fact all instances of SIRVA are actually caused by administrator negligence as HRSA suggests.

The second policy consideration put forth by HRSA is that medical providers are sloppy, and there is no incentive for them to be careful when administering vaccines because they know they are protected by the VICP. This is an outrageous and insulting statement by HRSA and all medical professionals should be highly offended. According to HRSA’s logic, medical professionals such as doctors, nurses, and pharmacists will *only* be incentivized to do their jobs correctly if they can be sued for improperly administering a vaccine that results in SIRVA or syncope. HRSA’s logic is absurd. It is akin to proposing that we outlaw car insurance to incentivize drivers to be more careful.

Finally, as a justification for their reversal of policy, HRSA cites the fact that payouts from the VICP may convince some people that vaccines are not safe and that the Vaccine Program statistics will be used as justification by such people for not getting vaccinated at all. This argument is without merit. We cannot adopt standards for vaccine policy that cater to those who do not receive vaccinations. Our national vaccine policy must be geared to protect the 150,000,000 or more individuals who actually receive vaccines each year.

The timing of HRSA’s proposal could not be worse and quite frankly, is very suspicious. While Americans are distracted by the pandemic, HRSA is quietly working behind the scenes to reverse course and may ultimately cripple our nation’s vaccine provider infrastructure by exposing doctors, nurses and pharmacists to billions of dollars in lawsuits. If the proposed changes are

approved, it is highly likely the cost of malpractice insurance will skyrocket for these providers as well. Hopefully, our country is months away from a coronavirus vaccine. Now is not the time for HHS to put American lives at risk by reducing the pool of vaccine administrators and burdening the heroic medical care providers who are on the frontline of battling COVID-19. Now more than ever, our nation's doctors, nurses, and pharmacists need the protections provided by the Vaccine Act.

One final word, the NPRM refers to SIRVA and syncope cases as "frivolous" and "dubious" claims. They are not. Please bear in mind that HHS has been conceding SIRVA cases as being vaccine-related injuries since 2010. In fact, HRSA compensated syncope cases since the inception of the Program over 30 years ago. Ask anyone who has ever experienced SIRVA or syncope from a vaccine if their injury is frivolous. They are very painful injuries, often requiring one or more surgeries, and in some cases results in permanent damage. No one who has suffered one of these injuries would say it is frivolous or dubious.

I have spent my whole professional life in the VICP, and I am vested in seeing it succeed. Frankly, I am very scared that the proposed changes will cause the Program to unravel, a thought that makes me very worried having devoted my entire career to advancing the very noble goals of the Vaccine Act.

Secretary Azar and Administrator Engels, please stop this harmful proposal from moving forward.

I am happy to discuss this matter with you.

Thank you very much.

Respectfully yours,

/S/

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Health Resources & Services Administration



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Frequently Asked Questions

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About the VICP

What vaccine liability protection is afforded to vaccine administrators?

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The National Vaccine Injury Compensation Program (VICP) is an alternative to the tort system for resolving vaccine injury petitions. **Whether a vaccine administrator is afforded the liability protections of the National Childhood Vaccine Injury Act of 1986, as amended, (the Act) depends upon whether the vaccine is covered under the VICP.**

Under the Act, persons with petitions of vaccine-related injuries or deaths resulting from covered vaccines must first exhaust their remedies under the VICP before they can pursue legal actions against vaccine administrators.

To exhaust the remedies available under the VICP and pursue a legal action against a vaccine administrator outside of the VICP, a VICP petitioner must either withdraw his or her petition (if the special master of the U. S. Court of Federal Claims (Court) has failed to issue a decision or the Court has failed to enter judgment within the time provided by the Act) or reject the judgment under the VICP.

Although the Act provides liability protections to vaccine administrators who administer covered vaccines in many circumstances, these protections are not absolute.

There are instances when a vaccine administrator who gives a covered vaccine is not protected from liability by the Act, such as when an individual files a petition and is requesting damages of \$1,000 or less. In this case, a civil suit against an administrator may be permitted to be filed in state or federal court without first filing a petition in the VICP.

In addition, if the VICP has paid a petitioner for a vaccine-related injury, the VICP may be able to pursue its own action against a vaccine administrator using its subrogation rights.

Are there legal requirements for vaccine companies to distribute and administer vaccines not licensed in the U.S.?

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Covered Vaccines

What is the Vaccine Injury Table?

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How are changes made to the Vaccine Injury Table?

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National Vaccine Injury Compensation Program

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[Infographic](#) (PDF - 1.1 MB)

[Covered Vaccines](#)

[Vaccine Injury Table \(Revised and Effective March 21, 2017\)](#) (PDF - 119 KB)

[Vaccine Injury Table \(Effective between July 23, 2015 and March 20, 2017\)](#) (PDF - 139 KB)

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National Vaccine Injury Compensation Program (VICP) Fact Sheet (PDF - 200 KB)

H.R. Rep. No. 908, 99TH Cong., 2ND Sess. 1986, 1986
U.S.C.C.A.N. 6344, 1986 WL 31971, H.R. REP. 99-908 (Leg.Hist.)

****6344 P.L. 99-660, HEALTH PROGRAMS**

DATES OF CONSIDERATION AND PASSAGE

Senate August 12, October 18, 1986

House October 17, 1986

Senate Report (Labor and Human Resources Committee) No. 99-380,

Aug. 6, 1986 [To accompany S. 1744]

Cong. Record Vol. 132 (1986)

Related Reports:

Senate Report (Labor and Human Resources Committee) No. 99-225,

Dec. 18, 1985 [To accompany S. 1848]

Senate Report (Governmental Affairs Committee) No. 99-506,

Sept. 30, 1986 [To accompany S. 1209]

House Report (Energy and Commerce Committee) No. 99-908,

Sept. 26, 1986 [To accompany H.R. 5546]

House Report (Energy and Commerce Committee) No. 99-903,

Sept. 26, 1986 [To accompany H.R. 5540]

House Report (Energy and Commerce Committee) No. 99-154,

June 3, 1986 [To accompany H.R. 2417]

Senate Report (Labor and Human Resources Committee) No. 99-229,

Jan. 22, 1986 [To accompany S. 1762]

Much of Title III of this Public Law was derived from H.R. 5546. House Report (Energy and Commerce Committee) No. 99-908, Sept. 26, 1986 [to accompany H.R. 5546] is set out:

HOUSE REPORT NO. 99-908

September 26, 1986

***1** The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5546) to amend the Public Health Service Act to establish a National Vaccine Program for the development of new vaccines and the improvement of existing vaccines and a program to compensate the victims of vaccine-related injuries and deaths, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

* * * * *

***3 PURPOSE AND SUMMARY**

H.R. 5546, the 'National Childhood Vaccine Injury Act of 1986', creates a new system for compensating individuals who have been injured by vaccines routinely administered to children. The system consists of two separate, but related parts and concerns only the actions of those injured by specified childhood vaccines and the manufacturers of such vaccines.

Part A of the system amends the Public Health Service Act to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity. All individuals injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program. Judgments and awards entered under the compensation program must be expressly rejected before other remedies may be pursued. Funding for the program is provided through a tax to be placed on designated childhood vaccines.

Part B of the system deals with the additional remedies that are available to vaccine-injured persons should they elect to reject a judgment and award made under the compensation program and to take action directly against a vaccine manufacturer. Under

Subsection (c)—State Limitations of Actions.—If a petition is filed under the Program, the State statute of limitations is to be stayed with respect to a civil action for a vaccine-related injury or death. If, for example, a State law provides that a civil action must be brought within three years of the onset of an injury and if a petition is filed two and a half years after the onset of a vaccine-related injury and if—following the compensation proceedings—a petitioner then elects to initiate a civil action, the State limitation of actions is to be stayed for the duration of the compensation proceedings and the petitioner, in this example, would have six months after the judgment on compensation in which to initiate a civil action under the State law. If, however, the State statute of limitations makes special provisions for minors such that actions need not be brought before the age of 18 and if the petitioner files for compensation at age three and, at age four, elects to reject the compensation judgment and initiate a civil action, then the State statute of limitations is unaffected and the civil action may be brought until the age of 18.

Section 2117—Subrogation

Subsection (a)—Generally Rule.—The Vaccine Injury Compensation Trust Fund (described below in Title II) is to be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation is paid. This right of subrogation does not, however, allow the Fund to recover an amount greater than the compensation paid. The court may refer the record of a compensation proceeding to the Secretary and to the Attorney General with recommendations as to subrogation.

While the Committee recognizes that other similar authorities of subrogation of rights of recovery are often unexercised, the Committee anticipates that the Secretary, in an effort to ensure the solvency of the Fund and to lower the surcharge necessary to continue the Fund, will vigorously pursue the rights of the government in this instance.

****6365 *24** *Subsection (b)—Disposition of Amounts Recovered.*—Amounts recovered under this authority are to be deposited in the Fund.

Section 2118—Increase for Inflation

The compensation set for death benefits and for maximum awards for pain and suffering under Section 2115 (described above) are to be increased to account for inflation. The civil penalty authorized under Section 2128 (described below) is to be similarly increased. This provision is adopted in an attempt to maintain these provisions at meaningful levels, rather than allowing them to become token amounts.

Section 2119—Advisory Commission on Childhood Vaccines

Subsection (a)—Establishment.—The Advisory Commission on Childhood Vaccines is to be established and is to be composed of nine members appointed by the Secretary. These members are to be health professionals, members of the general public, and attorneys. The Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control, the Commissioner of Food and Drugs are to be ex officio members.

Subsection (b)—Term of Office.—Members are to be appointed for three year terms, although initial members are to be appointed to staggered terms.

Subsection (c)—Meetings.—The Commission is to meet four times a year and at the call of the chair.

Subsection (d)—Compensation.—Standard compensation provisions are made for Commission members.

Subsection (e)—Staff.—The Secretary is to provide appropriate staff to the Commission.

Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

(e) The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

■ 14. Section 73.16 is amended by revising paragraph (l)(1) to read as follows:

§ 73.16 Transfers.

* * * * *
(l) * * *

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (e.g., prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited to, the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

* * * * *

■ 15. Section 73.17 is amended as follows:

- a. In paragraphs (a)(1)(iii) and (a)(3)(v) by adding "or other storage container" after "freezer".
- b. By revising paragraph (a)(1)(v).

- c. By adding paragraph (a)(8).
- d. By revising paragraph (b).
- e. By revising paragraph (c).

The revision and additions read as follows:

§ 73.17 Records.

(a) * * *
(1) * * *

(v) The select agent used, purpose of use, and, when applicable, final disposition,

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

- (i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;
- (ii) A written description of the viability testing protocol used;
- (iii) A written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken;
- (iv) The name of each individual performing the validated inactivation or viable select agent removal method;
- (v) The date(s) the validated inactivation or viable select agent removal method was completed;
- (vi) The location where the validated inactivation or viable select agent removal method was performed; and
- (vii) A certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

* * * * *

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications,

laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Dated: January 9, 2017.

Sylvia M. Burwell,
Secretary.

[FR Doc. 2017-00726 Filed 1-18-17; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906-AB01

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: On July 29, 2015, the Secretary of Health and Human Services (the Secretary) published in the Federal Register a Notice of Proposed Rulemaking (NPRM) to amend the regulations governing the National Vaccine Injury Compensation Program (VICP or program) by proposing revisions to the Vaccine Injury Table (Table). The Secretary based the Table revisions primarily on the 2012 Institute of Medicine (IOM) report, "Adverse Effects of Vaccines: Evidence and Causality," the work of nine HHS workgroups who reviewed the IOM findings, and consideration of the Advisory Commission on Childhood Vaccines' (ACCV) recommendations. The Secretary amends the Table through the changes in this final rule. These changes will apply only to petitions for compensation under the VICP filed after this final rule becomes effective.

DATE: This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Narayan Nair, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8N146B, Rockville, MD 20857, or by telephone (855) 266-2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660 (42 U.S.C. 300aa-10 et seq.), established the VICP, a Federal

compensation program for persons thought to be injured by vaccines. The statute governing the VICP has been amended several times since 1986 and is hereinafter referred to as “the Act.” Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is designated as the “Respondent.” The Court, acting through judicial officers called Special Masters, makes decisions as to eligibility for, and the amount of, compensation.

To gain entitlement to compensation under this program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what is referred to as a “Table Injury.” That is, a petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the “Vaccine Injury Table”—corresponding to the vaccination in question and that the onset of such injury took place within a time period also specified in the Table. If so, the injury is presumed to have been caused by the vaccination and the petitioner is entitled to compensation (assuming that other requirements are satisfied) unless the Respondent affirmatively shows that the injury was caused by some factor other than the vaccination (*see* 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B)), and 300aa–14(a)).

In prior Table revisions, the Secretary determined that the appropriate framework for making changes to the Table is to make specific findings as to the illnesses or conditions that can reasonably be determined, in some circumstances, to be caused or significantly aggravated by the vaccines under review and the circumstances under which such causation or aggravation can reasonably be determined to occur. The Secretary continues this approach through the use of the 2012 IOM report, the work of the nine workgroups who reviewed the IOM findings, and consideration of the ACCV’s recommendations. After consultation with the ACCV, the Secretary may modify the Table by promulgating regulations, with notice and opportunity for a public hearing and at least 180 days of public comment. *See* 42 U.S.C. 300aa–14(c) and (d).

II. Summary of the Final Rule

After the IOM released its 2012 report, 9 HHS workgroups comprising HRSA and Centers for Disease Control and

Prevention (CDC) medical staff reviewed IOM’s conclusions for 158 vaccine-adverse events, as well as any newly published scientific literature not contained in the report, and developed a set of proposed changes to the Table and its definitional counterpart, the Qualifications and Aids to Interpretation (QAI). For the vast majority of the vaccine-adverse event pairs reviewed (135), the IOM determined that the evidence was inadequate to accept or reject a causal relationship. Considering the remaining IOM conclusions and the ACCV Guiding Principles, the Secretary in this final rule is adopting certain additions or changes to the Table where the scientific evidence either convincingly supports or favors acceptance of a causal relationship between certain conditions and covered vaccines, which are unchanged from the proposed rule. As required by the Act, the changes in the proposed rule were presented to the ACCV, which reviewed and concurred with the Table changes set forth in this final rule.

Additionally, the Secretary, following the recommendation of the ACCV, is finalizing the Table change, as proposed, to add the injury of Guillain-Barré Syndrome (GBS) for seasonal influenza vaccinations, which is consistent with the approach taken in the Countermeasures Injury Compensation Program (CICP). Studies have demonstrated a causal association between the monovalent 2009 H1N1 vaccine and the 1976 swine flu vaccine and GBS. These causal associations were the basis of the 2015 decision by the Secretary in the CICP Pandemic Influenza A Countermeasures Injury Table Final Rule (80 FR 47411) to include GBS as an injury associated with the 2009 H1N1 influenza. With respect to that vaccine, the Secretary found that there was compelling, reliable, and valid medical and scientific evidence of an association between the 2009 H1N1 vaccine and GBS, which is required to add an injury to the CICP’s Injury Table. To date, the H1N1 antigen has been included in all seasonal influenza vaccines beginning with the 2010–2011 flu season. HHS notes that seasonal influenza vaccine formulations, unlike other vaccines, include multiple antigens that change from year-to-year, and enhanced surveillance activities to detect the incidence of GBS that occurred during the 2009 H1N1 pandemic may not occur with each virus strain change. In light of this information and other information as discussed in the proposed rule, the ACCV recommended

that the Secretary add GBS consistent with one of its Guiding Principles: That where there is credible evidence to both support and reject a change to the Table, the change should, whenever possible, be made to the benefit of petitioners.

In addition, in the final rule, the Secretary adopts the proposed rule’s new paragraph (b), *Provision that applies to all vaccines listed*. To streamline the Table, this paragraph includes any acute complication or sequela, including death, of the illness, disability, injury, or condition listed, as a Table injury (absent an exclusion as set forth under the QAI) rather than adding the provision to every line of the Table. To further streamline the Table, the Secretary deleted redundant wording in the various definitions, particularly with regard to any references to the presumption of causation, and the importance of the entire medical record. These elements have been included in paragraph (b) and are unchanged from the proposed rule. Finally, in this final rule, the Secretary adopts changes in the proposed rule that simplify and expand applicability of a provision that previously applied only to an encephalopathy. This provision, which indicates that idiopathic conditions do not rebut the Table presumption, now applies (through inclusion in paragraph (b)), to all injuries, while continuing to apply to an encephalopathy.

In this final rule, in addition to the changes described in the proposed rule, the Secretary has made the following non-substantive changes to the proposed rule for purposes of clarity:

- a. Added headings to (c)(2)(ii) and (c)(3)(ii).
- b. Moved text from the end of paragraph (c)(3)(ii)(C) to create a new (c)(3)(ii)(D).
- c. Changed paragraphs (c)(11) and (12) by revising the sentence regarding organs other than the skin by adding “the” before “disease”, inserting “and” after “organ”, and moving “, not just mildly abnormal laboratory values” to the end of the sentence.
- d. Revised paragraph (c)(15)(i) by changing “nine weeks” to “9 weeks”.
- e. Changed paragraph (e)(1) (“Coverage Provisions”) for purpose of clarity and consistency with 42 U.S.C. 300aa–14(c)(4) by adding “only” before “to petitions for compensation.”

The modified Table applies only to petitions filed under the VICP after the effective date of this final rule. Also, petitions must be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed under the VICP, set forth in 42 U.S.C. 300aa–16(a),

With regard to the MMR vaccine, because natural infection of measles, mumps and/or rubella virus is thought to lead to neurologic illness by damaging neurons through direct viral infection and/or reactivation, it is theorized that the same mechanisms may be responsible for vaccine-associated encephalopathy and encephalitis. However, of the studies examined and described by the IOM in its 2012 report, none identified causality between the MMR vaccine and encephalopathy or encephalitis. Similarly, the IOM concluded that the mechanistic evidence for an association is weak, based on knowledge about natural infection and only a few case reports. Accordingly, the Secretary does not agree that brain inflammation or acute and chronic encephalopathy have been acknowledged as a serious complication of either the DTaP or MMR vaccines. However, for the reasons discussed in the NPRM, the Secretary chose to retain these conditions in the revisions to the Table and QAI.

Comment: One commenter, when conveying views on acute encephalopathy as “one of the most serious complications of vaccination . . .” also referenced both encephalitis and encephalomyelitis in the discussion.

Response: The Secretary would like to clarify that encephalitis and encephalomyelitis (which is referred to as acute disseminated encephalomyelitis or ADEM) are distinct conditions. While they share some clinical characteristics, ADEM is a demyelinating condition with distinct differences from other types of encephalitis, as demonstrated on brain magnetic resonance imaging (MRI). The type of encephalitis that was initially attributed to DTwP was not described as demyelinating. Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on an MRI are distinct, with only ADEM displaying evidence of acute demyelination. For scientific accuracy, we have excluded ADEM from the Table definition of encephalitis.

Comment: One commenter, while applauding the expansion of the Vaccine Injury Table and agreeing with the IOM’s recommendations, stated that the Table remains wholly inadequate to properly address “the widespread epidemic of vaccine adverse events.” The commenter stated that the reason for this is that science has been corrupted by commercial interests, by financial ties between industry, regulators, and academic institutions

and that health care delivery has been compromised by financial ties between industry, physicians, and their trade publications.

Response: The Secretary believes that the revisions to the Table and QAI increase clarity and scientific accuracy regarding those injuries that will be afforded the Table’s presumption of vaccine causation. As previously indicated, the revisions to the Table and QAI were based primarily on the 2012 IOM report which was developed after the IOM committee conducted a comprehensive review of the scientific literature on vaccines and adverse events. The committee charged with undertaking this review consisted of 16 members with expertise in the following fields: pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. The members of the review committee were subject to stringent conflict of interest criteria by the IOM. In addition, the proposed Table changes were developed by HHS workgroups and reviewed by the ACCV, the membership of which, by statute, reflects a variety of stakeholders with different perspectives.

Comment: One commenter stated that the Secretary should not make changes to the Vaccine Injury Table that would make it more difficult for “victims” to be compensated.

Response: The Secretary believes that the revisions to the Table and QAI set forth in this final rule, such as the addition of injuries, will make it easier for petitioners alleging injuries that meet the criteria in the Table and QAI to receive the Table’s presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated the injury). This will make it easier for such petitioners to receive compensation under the VICP.

Comment: One commenter asked that additional consideration be given to the human papillomavirus (HPV) vaccination as a cause of postural orthostatic tachycardia syndrome (POTS), a condition where individuals can experience fainting and lightheadedness. The commenter also stated that the “review period” should be indefinite for the HPV vaccine.

Response: Like all vaccines used in the United States, HPV vaccines are required to go through years of safety testing before they are approved by the FDA. After they are approved and made available to the public, CDC and FDA continue to evaluate vaccines to ensure their safety. To date, there is no medical or scientific evidence that the HPV

vaccine causes POTS and safety monitoring has not shown any other problems. Extending the review period for alleged injuries due to the HPV vaccine would require a statutory amendment to the Act’s statute of limitations which is not within the scope of the final rule.

Comment: A commenter requested that food allergies be added to the Table asserting that food proteins that are present in vaccines cause the development of food allergies. The commenter also requested removal of the time limit that compensation is not provided for injuries or death that occurred more than “8 years before the effective date of the revision of the Table” because the commenter believes that “food proteins in vaccines have been causing injury for decades.”

Response: The Secretary does not agree that food allergies should be added to the Table as injuries. HHS conducted a literature search of the major medical databases for any articles linking the development of food allergies to vaccinations (81 FR 17423, March 29, 2016). Despite an extensive search, HHS found no published research addressing any linkages or potential causality between vaccinations covered by VICP and the development of food allergies in any population. In addition, revision of the Act’s statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: One commenter suggested that autism spectrum disorders be added to the Vaccine Injury Table. The commenter also requested removal of the time limit that compensation not be provided for injuries or death that occurred more than “8 years before the effective date of the revision of the Table” because the commenter believes that “bovine milk contaminated vaccines have been causing injury for decades.”

Response: The Secretary does not agree that autism spectrum disorders should be added as an injury to the Table. The 2012 IOM report found that the epidemiologic and mechanistic evidence favored rejection of a causal relationship between the MMR vaccine and autism. Moreover, in opinions that were upheld on appeal to the U.S. Court of Appeals for the Federal Circuit, special masters of the U.S. Court of Federal Claims held that the MMR, whether administered alone or in conjunction with thimerosal-containing vaccines, is not a causal factor in the development of autism or autism spectrum disorders. In addition, revision of the Act’s statute of limitations would require a statutory

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

**Advisory Committee on
Immunization Practices (ACIP)**



**Summary Report
October 25-26, 2017
Atlanta, Georgia**

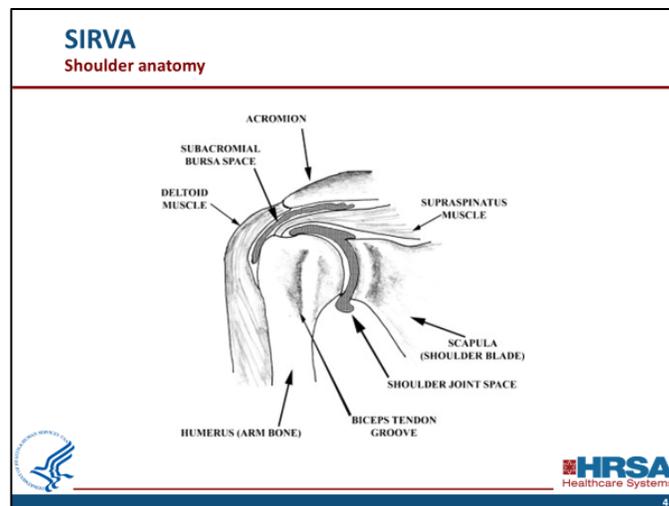
Data from HRSA VICP Claims

Narayan Nair, MD
Division Director/Chief Medical Officer
Division of Injury Compensation Programs
Healthcare Systems Bureau
Health Resources and Services Administration

Dr. Nair provided some background on shoulder injury related to vaccine administration (SIRVA) and shared some compensation data from the VICP. SIRVA is thought to result from the unintentional injection of a vaccine into the tissues and structures that lie underneath the deltoid muscle of the shoulder. The IOM reviewed the scientific and medical literature, and found that the evidence convincingly supported a causal relationship between vaccine administration and what they referred to as “deltoid bursitis.” One of the pieces of evidence that they considered was a paper by Dr. Atanasoff et al., who is a Medical Team Leader with the Division of Injury Compensation Programs (DICP), who published a case series reporting the experience of the VICP with regard to shoulder injuries following vaccination. The IOM reviewed this article and commented that the cases were consistent with deltoid bursitis.

This was a small case series of 13 claims, all of whom were from adults. They all had shoulder pain, with 93% reporting that the pain started within 24 hours after vaccination. Over half said that they had significant pain immediately after vaccination, and nearly half of them had concern at the time of administration that the vaccine was given too high in the shoulder compared to previous vaccinations. The most common findings in this case series were pain and limited range of motion (ROM). It was very uncommon for these individuals to report any type of neurologic symptoms, 31% required some type of surgical intervention, and over half required a corticosteroid injection for their shoulder pain.

To review the shoulder anatomy, this is an anterior view of the right shoulder:



Underlying the acromion and deltoid muscle, is the subacromial bursa space. There are additional reports of shoulder injury related to vaccine administration. Most notably, a paper was published by Marko Bodor in *Vaccine* in 2006 that reported on 2 cases of shoulder pain after vaccination that occurred within 2 days of vaccination. They used ultrasound on both

patients and on 21 controls, and they found that the bursa can extend 3 to 6 centimeters beyond the acromion and can lie anywhere between 0.8 centimeters to 1.6 centimeters below the surface of the skin. That is roughly about a third to .67 inch. Given that a standard adult needle is an inch, they proposed a theory that the vaccine was given high in the shoulder and the contents of the vaccine were injected into the subacromial bursa space, which triggered a robust local inflammatory response that led to bursitis, tendonitis, and inflammation of the shoulder capsule. In this paper, the authors proposed that injections should not be performed in the upper third of the deltoid muscle to avoid these types of injuries Marko Bodor, Enoch Montalvo; *Vaccination-related shoulder dysfunction; Vaccine 25 (2007) 585–587*].

In terms of compensation data, Dr. Atanasoff's paper was published in 2010 and the IOM published its findings in 2011. From 2011-2014, there were 59 claims alleging shoulder injuries. Those individuals received approximately \$9.7 million. In 2015, those numbers had increased to 98 cases and approximately \$12.4 million. In 2016, there were 202 claims alleging SIRVA and compensation was approximately \$29 million. In 2017, there were 163 claims and compensation was approximately \$19.9 million. That does not include attorneys' fees or legal costs.

SIRVA was added to the Vaccine Injury Table earlier this year. While many injuries are compensated that are not found on the Vaccine Injury Table, the benefit of being on the table is that it does streamline the process and allows for a lookback period wherein individuals have a longer period of time to file, in this case, a SIRVA claim. A significant number of claims are anticipated in the future.

Data from the Vaccine Adverse Event Reporting System (VAERS)

Tom Shimabukuro, MD, MPH, MBA
Immunization Safety Office
Centers for Disease Control and Prevention

Dr. Shimabukuro presented reports of shoulder dysfunction following IIV in the VAERS system. Looking at this anterior view of the right shoulder, he asked everyone to imagine that the arrows are injection sites and that they were tracking up the arm away from the thickest most centrally located portion of the deltoid muscle where the injection should be given:



Image by Alissa Eckert, CDC Division of Communication Services

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AAP News

Shoulder injury related to vaccine administration reported more frequently

H. Cody Meissner, M.D., FAAP

September 01, 2017

ID Snapshot

Shoulder injury related to vaccine administration (SIRVA) is believed to be caused by an immune response following inadvertent, direct injection of a vaccine into the deltoid bursa or joint space.

The presentation of SIRVA typically includes rapid onset of severe, long-lasting shoulder pain following vaccination in the deltoid muscle, resultant limited range of motion and absence of infection. Data from the Vaccine Adverse Event Reporting System suggest SIRVA is being reported with increasing frequency.

Which of the following statements regarding vaccine administration are correct?

- a) The suggested route of administration for each vaccine is recommended by the manufacturer and is based on studies showing maximum safety and immunogenicity.
- b) The presence or absence of an adjuvant is not a factor when considering vaccine administration.
- c) For most infants younger than 12 months of age, the anterolateral thigh muscle is the preferred site because it has more muscle mass than the deltoid muscle.
- d) The buttock generally should not be used for active immunization because of limited absorption from gluteal fat.

Answer: a, c and d are correct

Vaccines should be administered in an anatomic area where neural, vascular or tissue injury is unlikely to occur. For intramuscular injections, the needle length should be long enough to ensure injection occurs in the muscle mass. Too long a needle length increases the risk that injection may involve nerves, blood vessels or skeletal structures. Suggested needle lengths are presented in the 2015 *Red Book* (Table 1.7, page 28, <http://bit.ly/2tgo990>). Most intramuscular injections are performed with a 22- to 25-gauge needle.

Injectable vaccines are administered by the intramuscular, subcutaneous or intradermal routes except for the smallpox vaccine, which is administered by the percutaneous route using a bifurcated needle (scarification).

Selection of the proper injection site and needle length depends on the amount of muscle and adipose tissue at the selected site, the child's age and the volume to be injected. Inactivated vaccines containing an adjuvant should be injected into muscle to avoid the risk of local irritation, skin discoloration and granuloma formation that may be associated with subcutaneous injection.

For infants less than 1 month of age, a 5/8-inch needle is suggested for injection in the anterolateral thigh. For term infants 1 through 12 months of age, a 1-inch needle is suggested. For toddlers and children, either the anterolateral thigh or deltoid muscles are suggested. If two vaccines are administered in the same limb at the same visit, they should be spaced 1-inch apart.

Transient, mild shoulder discomfort following immunization in the deltoid muscle is a common side effect of vaccination. Severe, persistent shoulder pain in association with prolonged limitation of function is rare.

SIRVA identifies a specific condition that is associated with vaccine inadvertently administered into the deltoid bursa or joint space. Patients with SIRVA experience shoulder injury that is more severe than would be expected from just needle trauma. One theory suggests that an immune reaction to one or more components of the vaccine may be responsible for signs and symptoms of SIRVA.

In a series of 13 cases among adult patients published by the Vaccine Injury Compensation Program (Atanasoff S, et al. *Vaccine*. 2010;28:8049-8052), shoulder pain was noted immediately after vaccination in 50% of cases, and pain developed in 90% within 24 hours. The most common findings on physical examination were painful and limited range of motion. Arm weakness and sensory changes were uncommon. Deep tendon reflexes were normal. Symptoms persisted six months to several years, and 30% of patients required surgery.

Several theories have been proposed to explain why SIRVA is reported less frequently in children, despite the number of vaccines administered. Administration in the anterolateral thigh avoids the risk of joint involvement; bunching of the subcutaneous and deltoid tissue prior to vaccination may increase the distance to the shoulder; and the developing subacromial bursa may be less developed (smaller) in children.

Most cases in adults occur after administration of a vaccine to which some immunity already exists because of previous immunization such as influenza or tetanus-containing vaccines. This may result in a greater inflammatory response following inadvertent injection into the skeletal structures of the shoulder.

The number of people for whom compensation for SIRVA was awarded by the Vaccine Injury Compensation Program in 2016 was 202 cases. Many instances of SIRVA may be avoided by proper vaccination technique and positioning.

Dr. Meissner is professor of pediatrics at Floating Hospital for Children, Tufts Medical Center. He also is an ex officio member of the AAP Committee on Infectious Diseases and associate editor of the AAP Visual Red Book.

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M M Ipp et al., *Pediatrics*, 1989

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José Groswasser et al., *Pediatrics*, 1997

This chapter reviews liability for vaccine injuries historically; the rationale, development, and implementation of the National Vaccine Injury Compensation Program (VICP); and the program's current status. The first part of the chapter discusses the development of the law in the United States until 1986, the year of the passage of the National Childhood Vaccine Injury Act of 1986 (NCVIA). Later sections discuss the administration of the VICP, reported decisions relating to liability for the production and administration of vaccines after 1986, and current developments in the area of vaccine injury liability and compensation.

VACCINE LIABILITY BEFORE 1986

To understand the decisions that were rendered in cases filed against vaccine manufacturers and administrators before 1986, it is important to understand the nature of products liability law as it was evolving in that era. Before the early 1980s, manufacturers were not held liable for the harm associated with a product unless it failed to comply with the standards of manufacturing or care implemented by similarly situated manufacturers. Usually, vaccine manufacturers sued by consumers would prevail because they used customary practices and complied with statutes and regulations and because of the doctrine of the *learned intermediary*, discussed later.

This standard began to change when, in 1965, the American Law Institute introduced the concept of "strict liability" in its *Restatement (Second) of Torts*. Although the principles embodied in this *Restatement* were not applied uniformly to lawsuits against vaccine manufacturers and administrators, they served as guiding principles in the field and were viewed by many as significant emerging legal doctrines.

Under the *Restatement's* doctrine of strict liability, a manufacturer who sold a product in a defective condition that made the product unreasonably dangerous was subject to liability for harm caused to the user or consumer even if the manufacturer exercised all possible care in the preparation and sale of the product.¹ A product was deemed defective if it was in a condition not contemplated by the ultimate consumer, which made it unreasonably dangerous to the consumer.² Although the doctrine of strict liability lowered the burden required to find manufacturers liable for the harm caused by their products, the authors of the *Restatement* recognized that some products were, by their nature, "unavoidably unsafe," and determined that such products should not be deemed unreasonably dangerous under the doctrine of strict liability.³ Thus, products such as vaccines, which necessarily entail some risks (risks considered reasonable given their benefits to the community), were not deemed defective or unreasonably dangerous so long as they were properly prepared and accompanied by adequate warnings.⁴ Consequently, vaccine manufacturers and administrators were generally not held liable for harm caused by their products before 1986, so long as these requirements of proper preparation and adequate warnings were satisfied.

The risk of liability created by the requirements to properly prepare vaccines and provide adequate warnings is important. If, for instance, a lot of vaccine was defective and caused disease in recipients because the disease-causing agent was not

sufficiently inactivated or because of contaminants, the manufacturer could be liable, whether or not the defect could be shown to be the manufacturer's fault. This happened with early lots of Salk poliovirus vaccine, and there were numerous and substantial recoveries by persons who acquired polio from the vaccine.⁵ As another example, if a physician administered a vaccine when it was contraindicated (e.g., administered Sabin oral poliovirus vaccine [OPV] to a child known to be immunodeficient or administered a second dose of diphtheria and tetanus toxoids and whole-cell pertussis [DTP] vaccine after a child had a severe adverse reaction to the first), the physician could be liable if the adverse consequence risked by violating the contraindication occurred. Furthermore, if a physician administered a vaccine without warning the patient of the risks, the physician could be liable if the risks occurred.

Despite the limits on liability imposed by general doctrines of products liability law in cases concerning adverse reactions from vaccines, certain judicial decisions in the pre-1986 era imposed liability even when the vaccines were properly made and administered. These cases, which were a significant impetus to the enactment of the NCVIA, can be divided into three categories: the *Reyes* decision, the swine flu litigation against the government, and the 1980s decisions.

Reyes v Wyeth Laboratories,⁶ decided in 1974 by the United States Court of Appeals for the Fifth Circuit, held a manufacturer of OPV liable to a child who contracted paralytic poliomyelitis after being administered the vaccine. The decision broadened the potential liability faced by manufacturers in the context of mass vaccination efforts.

This case articulated an exception to the learned intermediary doctrine. Under the general rule, a manufacturer of prescription medicines, including vaccines, is obliged to provide warnings concerning the product to the healthcare provider (the learned intermediary), but has no duty to directly warn the user of the product of its associated risks. This doctrine is based on the assumption that the medical professional makes an individualized medical judgment with respect to the risks and benefits of a particular drug or vaccine and a particular patient. The *Reyes* decision narrowed this general rule, holding that, when a manufacturer can reasonably be said to be aware that the product (i.e., the vaccine) will be administered in such a way that no personalized medical advice will be provided (e.g., in the context of a public health department's immunization effort in which the patient had no direct contact with a physician), the manufacturer is responsible for providing warnings directly to patients or ensuring that such warnings will be given.

In *Reyes*, the manufacturer shipped the vaccines to the Texas Department of Public Health, accompanied by the Food and Drug Administration (FDA)-required package inserts containing warnings concerning the possible consequences of the vaccine. The Texas Department of Public Health sent the vaccine to the county health department without ensuring that the warnings would actually be given to vaccine recipients (or their parents). The nurse who administered the vaccine to the child in this case did not warn the parents of the minute risk that a recipient or contact could contract the disease. Although the *Reyes* Court determined that OPV was not unreasonably dangerous per se, it concluded that the vaccines were

persons injured by childhood vaccines should receive fair compensation and determined that the tort system used at the time to provide such compensation was inadequate.²¹

Congress addressed these issues by creating the VICP, a federal “no-fault” system under which awards can be made to vaccine-injured persons quickly, easily, and generously. Persons injured through the receipt of a vaccine after the effective date of the legislation generally are required to file claims with the VICP before they are allowed to bring a civil suit against vaccine manufacturers or administrators. Although the statute is entitled the “National Childhood Vaccine Injury Act,” eligibility for compensation extends to children and adults. Rules of evidence, discovery, and other legal procedures are relaxed to accelerate the compensation process. Petitioners in VICP proceedings need not demonstrate negligence on the part of a vaccine manufacturer or administrator, thus the no-fault designation. Petitioners with eligible claims must exhaust their remedies within the VICP before filing lawsuits against vaccine manufacturers or administrators. To do so, a petitioner must withdraw his or her petition from the VICP (if the Court of Federal Claims fails to issue a decision or enter judgment within the time periods provided for in the NCVIA) or reject the judgment entered (whether or not compensation was awarded).

In addition to the establishment of the VICP and the imposition of liability protections, the NCVIA established sweeping vaccine safety provisions and created a more prominent vaccine safety role for the federal government. The NCVIA included a mandate for the reporting of certain adverse events. Healthcare providers and vaccine manufacturers are required to report the occurrence of any event set forth in the Vaccine Injury Table (VIT) (Table 83.1) and any contraindicating reaction to a vaccine that is specified in the manufacturer’s package insert.²² The report must state the symptoms and manifestations of the illness or injury, how long after administration of the vaccine such symptoms occurred, and the manufacturer and lot number of the vaccine administered. These reports are to be made to the Vaccine Adverse Event Reporting System. Other vaccine safety mandates include record keeping by vaccine administrators (documenting the date of vaccine administration, the manufacturer and lot number, and the name and address of the administrator) and development and dissemination of risk-to-benefit information materials (known as Vaccine Information Statements) by the Secretary of Health and Human Services (HHS). The NCVIA also required certain

studies, conducted by the Institute of Medicine (IOM), of vaccine adverse events.

The NCVIA also established two advisory panels, the Advisory Commission on Childhood Vaccines (ACCV)²³ and the National Vaccine Advisory Committee (NVAC).²⁴ The NCVIA mandates that the ACCV include as members equal numbers of health professionals, members of the public (including legal guardians of children injured by vaccines), and attorneys (including a representative of persons injured by vaccines and a representative of vaccine manufacturers). The ACCV makes recommendations to the Secretary of HHS on changes to the VIT and other issues related to the administration of the VICP. The NVAC has much broader responsibilities, including the authority to recommend ways to achieve optimal prevention of disease through changes related to vaccine research, development, delivery, safety, and efficacy. The NVAC makes recommendations to the HHS Assistant Secretary for Health.

Although the NCVIA was landmark in design and scope, numerous amendments to the initial legislation were enacted. Funding of the VICP, not provided for in the original legislation, was authorized by Congress in early 1987.²⁵ Additional protections for manufacturers defending claims filed by persons after exhausting their remedies under the VICP also were written into the law at this time. These included the statutory bars to actions based on plaintiff allegations of vaccine misdesign or inadequate warning of risk, two common tort theories pursued in the 1980s, and the elimination of punitive damages unless gross negligence in vaccine production was proven.²⁶ At the same time, the provision requiring claimants to pursue their claim through the VICP before filing a tort claim against manufacturers was expanded to include healthcare providers, a protection that was not offered by the original act. Subsequent legislation in 1993 permanently reauthorized the VICP and provided a mechanism for adding new vaccines and for the Secretary of HHS to modify the VIT.²⁷ Vaccines recommended by the CDC (usually on recommendation by the Advisory Committee on Immunization Practices) for routine administration to children would be added to the VICP. As described below, a statutory amendment passed in 2016 expanded the VICP’s coverage to include vaccines recommended by the CDC for routine administration to pregnant women. Congress also would have to enact an excise tax as a necessary step before coverage could begin.

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TABLE 83.1 Vaccine Injury Table^a

In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

Vaccine	Illness, Disability, Injury or Condition Covered	Time Period for First Symptom or Manifestation of Onset or of Significant Aggravation After Vaccine Administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis	≤4 hours
	B. Brachial neuritis	2-28 days (not less than 2 days and not more than 28 days)
	C. Shoulder injury related to vaccine administration ^b	≤48 hours
	D. Vasovagal syncope ^b	≤1 hour

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