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An Examination of a Proposed Rule: Removal of SIRVA from the Vaccine Injury Table

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AN EXAMINATION OF A PROPOSED RULE: REMOVAL OF SIRVA FROM THE VACCINE INJURY TABLE

by

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ABSTRACT

Vaccines are one of the greatest modern medical inventions. Even though vaccines have saved lives, however, no medical product is proven to be completely safe. Vaccines can have rare and sometimes deadly reactions. To address such occurrences, the U.S. Department of Health and Human Services (HHS) hosts a program that reviews petitions for compensation of injuries caused by vaccination. The program is called the National Vaccine Injury Compensation Program (VICP). The VICP was established in 1986 to reduce the number of product liability lawsuits against vaccine manufacturers that threatened to increase the cost of vaccines and lower life-saving vaccine administration to millions of people.

In 2020, through the Health Resources and Services Administration, the HHS proposed a revision to the VICP. Specifically, the HHS proposed removing an injury called Shoulder Injury Related to Vaccine Administration (SIRVA) from the VICP's no-fault compensation table.

The proposed revision of the removal of SIRVA has been the source for debate because it is clear through the establishment of the VICP's founding document that compensation for injuries caused by vaccine administration is required. The HHS is challenging the requirement of compensation for vaccine-related injuries through its proposed revision to the VICP's compensation table. By confronting the HHS's proposal for revision to the Vaccine Injury Table, this thesis demonstrates how existing policy prevents the HHS from making the revision. Using an analysis of precedent statutes and public health research, this thesis argues for the continued coverage of SIRVA with the current VICP.

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I. INTRODUCTION

Vaccines are one of the greatest developments of modern medicine. Since the first Smallpox vaccine in 1796, the use of vaccines has reduced mortality rates around the world, and in some cases eradicated diseases that were once considered deadly. Although vaccines have been effective in protecting against deadly diseases, no medical product is proven to be completely safe. Essential vaccines protecting against life-threatening diseases like pertussis, tetanus, measles, rubella, and polio carry risks such as anaphylaxis, encephalitis, neuritis, and in severe cases, death.[1]

Historically, people who experienced serious side effects to vaccines were forced to sue large vaccine manufacturers for product liability or medical malpractice. Generally, suing large vaccine manufacturers led to petitioners not being able to recover enough compensation because they had to prove a defective product which is hard to demonstrate in court when the issue is a negative reaction in the body. For vaccine manufacturers, in the cases where petitioners were able to demonstrate wrongdoing, these lawsuits also threatened to drive vaccine production down to counteract court costs. There was no cap for settlement. In addition, there was a massive increase in the number of lawsuits. Between 1978 and 1981, only nine liability lawsuits were recorded. In the mid-1980s, there were over 200 lawsuits.[2] It created a crisis situation for both parties.

[1] Schwartz, V. E., & Mahshigian, L. (1987, January 1). "National childhood vaccine injury act of 1986: An ad hoc remedy or a window for the future?." *Ohio State Law Journal*,*48*(2), 387-398 Retrieved September 21, 2021, from http://hdl.handle.net/1811/64373.

[2] *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011)

To satisfy petitioners and vaccine companies involved in this difficult trade off, Congress enacted the National Childhood Vaccine Injury Act of 1986 (the Act).[3] The Act established the National Vaccine Injury Program (VICP). The VICP emerged out of a national vaccination crisis related to vaccines taken in childhood such as Diphtheria, Pertussis (Whooping Cough), Tetanus, HPV, etc. The VICP emerged to solve the issue that both parties were facing: 1) it provided compensation for "vaccine-related injuries or death" and 2) it shielded vaccine manufacturers from liability.[4]

The threat of a reduced availability of vaccines could result in the avoidable death of millions of people.[5] The U.S. Congress acknowledged this crisis as a national public health problem and pushed to establish a no-fault alternative to tort lawsuits.[6]

The no-fault alternative is VICP, often referred to as, "vaccine court." Petitioners of the vaccine court file a petition to be compensated for a vaccine-related injury or death. In this petition, the petitioner must establish that they received a vaccine listed in the Vaccine Injury Table (Table) and that they sustained an illness, disability, or injury also listed in the Table.[7] The Act defines "vaccine-related injuries or death" as an "illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table."

One of the most prevalent injuries that occur to patients receiving vaccines by injection is Shoulder Injury Related to Vaccine Administration ("SIRVA"). SIRVA, as the name suggests, is a severe shoulder injury caused by faulty vaccine injection. When a vaccine is injected too

[3] National Childhood Vaccine Injury Act of 1986, 42 U.S.C § 300aa-10 et seq.
[4] 42 U.S. Code § 300aa–22 – Standards of responsibility: Paragraph (b)
[5] Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756.
[6] *"H.R. 5546 — 99th Congress: National Childhood Vaccine Injury Act of 1986."* Retrieved from: https://www.govtrack.us/congress/bills/99/hr5546
[7] 42 U.S. Code § 300aa–11

deeply into the shoulder, the needle releases the vaccine contents directly into the deltoid muscle. This can inflame the shoulder tendon and lead to excessive pain or a frozen shoulder.[8] This injury can severely impact a patient's ability to drive, cook, or go to work. SIRVA has been listed in the Vaccine Injury Table as an injury eligible for compensation in the vaccine court since 2017 because scientific literature and vaccine experts have concluded that a causal link exists between vaccine injection and the inflammation of the shoulder tendons.[9]

On July 20, 2020, the compensation for individuals suffering with SIRVA was put at risk. The U.S. Department of Health and Human Services (HHS), which hosts the VICP and conducts medical reviews of petitions, proposed a revision to the VICP to remove SIRVA from its list of compensational injuries. HHS contends that SIRVA is related to the negligent administration of the vaccine and not the contents of the vaccine itself.[10] In their argument, the HHS alleges that SIRVA is not "vaccine-related" because the injury is caused by improper injection. The HHS's attempt to exclude SIRVA because of the "administration of the vaccine" is incorrect and legally flawed. In excluding SIRVA and other injuries related to negligent administration, the HHS calls into question whether SIRVA should be removed from the Vaccine Injury Table.

This paper argues that SIRVA should not be removed from the Vaccine Injury Table because as a matter of policy, amending the Table with respect to SIRVA petitioners is inconsistent with the Act's original language that was written by Congress. Congress states in the Act that "No person may bring a civil action for damages in an amount greater than $1,000 or in

[8] Shahbaz, M., Blanc, P.D., Domeracki, S. J., Guntur, S..(2019) "Shoulder Injury Related to Vaccine Administration (SIRVA): an occupational case report." *Workplace Health Safety.67*(10):501-505. doi: 10.1177/2165079919875161.
[9]National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 FR 45132 (July 29, 2015)
[10] National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 85 FR 43794 (July 20, 2020)

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…".[11] Congress used the term "administration of a vaccine" multiple times within the Act. This thesis demonstrates how the HHS's express disregard of the law is flawed and should not be passed.

To support this argument this thesis first reviews the language of the legislation made by the Congress to demonstrate opposition of the revision. Additionally, this thesis shows through evaluation of applicable statutes, case law, and other research articles that the VICP has a duty to protect those adversely affected by life-saving vaccines, even if the adverse reaction is caused by negligent administration. This thesis stands with SIRVA patients to continue receiving compensation from the VICP.

[11] 42 U.S.C. § 300aa-11 (a)(2)

II. BACKGROUND

Early History of the Vaccine Crisis

In the 1980s, the number of lawsuits against Diphtheria, Tetanus, and Pertussis (DTP) vaccine manufacturers showed a dramatic increase. The DTP vaccine is lifesaving, protecting against three diseases: diphtheria, pertussis, and tetanus. People who had adverse reactions to the vaccination felt symptoms of fever, seizure, and encephalopathy.[12]

The total amount of money claimed from only half of the cases heard in 1986 was $2.5 billion.[13] The staggering amount of money paid to petitioners of product liability lawsuits against major vaccine manufacturers negatively affected the availability of life-saving vaccines on the market. In a 1986 article written by Dr. Alan Hinman, the crisis of this situation is illustrated as follows:

The total amount claimed in 1984 DTP vaccine suits ($1.3 billion) is more than 20 times the total value of 1984 sales of DTP vaccine at the 1984 market price of $2.80 per dose...If the current trend continues, suits will pose an increasing threat to the availability of DTP vaccine in the United States.[14]

Product liability lawsuits thus threatened to increase the costs of vaccines and drive down production. Fewer people had access to vaccines that could potentially save their lives as a result. It was obvious that a change needed to be made.

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[12] Blumberg DA, Lewis K, Mink CM, Christenson PD, Chatfield P, Cherry JD. (2019). "Severe reactions associated with diphtheria-tetanus-pertussis vaccine: detailed study of children with seizures, hypotonic-hyporesponsive episodes, high fevers, and persistent crying." *Pediatrics.91*(6):1158-65. PMID: 8502521.
[13] Hinman, A.R. DTP Vaccine Litigation. (June 1986) *Am J Dis Child*.;140(6):528–530. doi:10.1001/archpedi.1986.02140200038022
[14] Ibid., 529.

To effect change, Congress enacted the National Childhood Vaccine Injury Act of 1986. The Act established a no-fault claims court in which petitioners could receive compensation for vaccine-related injuries or death. The Act addressed two concerns: first, the number of lawsuits against vaccine manufacturers would be greatly reduced. The Act prohibited civil actions against vaccine administrators and manufacturers for injuries associated with the administration of a vaccine.[15] People who were injured or died due to vaccine administration could no longer sue the manufacturer or administrator and would have to file a petition with the National Vaccine Injury Compensation Program (VICP).

Second, the Act offered people injured by vaccines a source of repayment or compensation for their medical needs, including rehabilitation. Essentially, people suffering from vaccine-related injuries were mandated to petition for compensation under the VICP. They could not sue vaccine manufacturers for repayment of issues suffered from their vaccine-related injury and their only source for this repayment was the VICP. Therefore, the National Childhood Vaccine Injury Act of 1986 was a solution to a national public health crisis. It created an alternative to tort lawsuits in which plaintiffs could be overpowered by large corporations and never receive the compensation they needed.

The VICP Process

The process of the VICP begins with filing a petition with the United States Court of Federal Claims. Upon the initial filing, the petitioner must make clear to the Secretary of the Department of Health and Human Services whether their injury is “vaccine-related”.

The Act of 1986 states the following:

[15] 42 U.S. Code § 300aa–11 (a)(3)

A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the [Secretary of Health and Human Services] and the filing of a petition containing the matter prescribed by subsection (c) with the United States Court of Federal Claims.[16]

The key piece of requesting for compensation under the VICP is filing a petition which includes an affidavit and supporting documentation. The petition should demonstrate that the person who was injured or died had received a vaccine listed in the Vaccine Injury Table. The Vaccine Injury Table (Table) is a list of:[17]

...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 [VICP].[18]

Essentially, the Table is the first step that petitioners and the Secretary of the HHS take to discover whether the claim is eligible for compensation under the VICP. Vaccines that are listed in the Table for coverage by the VICP are: diphtheria, tetanus, pertussis (whooping cough), measles, mumps, rubella (German measles), polio, hepatitis A, hepatitis B, varicella (chickenpox), Hemophilus influenzae type b, rotavirus, pneumococcal conjugate, trivalent influenza (seasonal flu), meningococcal conjugate, and human papillomavirus.[19]

These vaccines in the Table also have injuries and onset time periods that are eligible for compensation. Various vaccine-related injuries, disorders, or disabilities can be applied as reactions to multiple vaccines.

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[16] 42 U.S. Code § 300aa–11 (a)
[17] See Appendix A
[18] 42 U.S.C. 300aa-14(c)
[19] Vaccine injury compensation program. The United States Department of Justice. (2018, September 24). Retrieved October 1, 2021, from https://www.justice.gov/civil/vicp.

Once a petitioner has identified the vaccine, injury, and onset time period in their petition, it must be approved as valid by the U.S. Department of Health and Human Services (HHS). Upon that approval, they are eligible for a hearing with the "special master" who makes the decision for whether they receive compensation under the VICP. The VICP is funded by a trust fund that gathers funds from an excise tax on each dose of vaccine that is purchased. The monies from this trust fund are what is distributed for compensation.[20]

SIRVA: A Rare Reaction

As previously stated, a number of vaccine-related injuries can occur as a result of the administration of various vaccines. One of these injuries, Shoulder Injury Related to Vaccine Administration (SIRVA),can occur with any vaccine administered by injection. SIRVA is described as a rapid occurrence of shoulder pain and dysfunction that persists as a result of complications in the deltoid muscle.[21] When most people are receiving vaccines through injection, they experience mild, transient pain in the shoulder area.[22] The pain usually does not persist or significantly impact quality of life. In cases of people suffering with SIRVA, the injury can be debilitating.

People who have SIRVA have ongoing work restrictions and the symptoms can last from 6 months to years. According to a case report from 2019, a total of 31% of SIRVA cases required

[20] National Vaccine Injury Compensation Program. Official web site of the U.S. Health Resources & Services Administration. (2021, September 29). Retrieved October 4, 2021, from https://www.hrsa.gov/vaccine-compensation/index.html.
[21] Szari, S., Belgard, A., Adams, K., & Freiler, J. (2019). "Shoulder Injury Related to Vaccine Administration: A Rare Reaction." *Federal practitioner : for the health care professionals of the VA, DoD, and PHS*, 36(8), 380–384.
[22] Cantarelli Rodrigues, Tatiane et al. "Subacromial-subdeltoid bursitis following COVID-19 vaccination: a case of shoulder injury related to vaccine administration (SIRVA)." *Skeletal Radiology* vol. 50,11 (2021): 2293-2297. doi:10.1007/s00256-021-03803-x

surgical intervention.[23] SIRVA is considered a "preventable injury". The injury occurs as a result of unintentional injection of vaccine or trauma from an inappropriate sized needle into the underlying fluid sac (bursa) of the shoulder.[24] SIRVA can be a severe injury to the musculoskeletal structures of the shoulder.

An infographic[25] developed by the University of Waterloo in Ontario, details how various improper injection administration types can result in SIRVA. The infographic notes that an injection too high up on the shoulder can result in injecting the contents of the vaccine directly into the shoulder joint or bursa and that an injection too far to the side of the shoulder can result in injecting the vaccine contents into the auxiliary nerve. This misadministration of the vaccine can cause paralysis and/or neuropathy in the patient almost immediately.[26] SIRVA is dangerous, and while rare, it is a serious adverse effect to vaccine injection.

In 2017, following extensive scientific research and a report released from the Institute of Medicine, the HHS added SIRVA to the VICP Table to be eligible for compensation upon petition.[27] As one of the known adverse events from vaccination, petitioners had to demonstrate through medical records that: 1) they had no history of pain, inflammation, or dysfunction in the affected shoulder prior to the vaccine administration, 2) the pain they have experience occurs within 48 hours of the vaccine administration, 3) the pain and reduced motion only occur in the

[23] Shahbaz, M., Blanc, P. D., Domeracki, S. J., & Guntur, S. (2019). "Shoulder Injury Related to Vaccine Administration (SIRVA): An Occupational Case Report.". *Workplace Health & Safety*, *67*(10), 501–505. https://doi.org/10.1177/2165079919875161
[24] Ryan, T. (n.d.). "Updating the vaccine injury table". Retrieved October 5, 2021, from https://akastage-www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2012/March%208-9/20120308-iomreportupdate.pdf.
[25] See Appendix B
[26] Bancsi, A., et al. (2019) "Shoulder injury related to vaccine administration and other injection site events." *Canadian Family Physician* vol. 65,1, 40-42.
[27] 85 FR 43794

shoulder that the vaccine was injected in, and 4) the petitioner has no other condition that would explain the symptoms they experienced.[28]

It is significant to report that 93% of VICP petitioners reported showing symptoms within 48 hours of vaccination. These petitioners also reported having persistent symptoms that lasted longer than a few weeks.[29] When people petition a case to the VICP to report that they have SIRVA, they are reporting because they are aware that their persistent shoulder pain and dysfunction can have a severe impact on their ability to work, exercise, and participate fully in their daily life.

[28] Ibid. 17
[29] Clinic, C. (2021, September 24). "SIRVA Reprise, COVID Vaccine Injury Fund." Retrieved October 5, 2021, from https://www.carilionclinic.org/news/417---sirva-reprise-covid-vaccine-injury-fund/.

III. DISCUSSION

SIRVA can have a serious effect on the livelihood of people. The injury can be so serious that the costs of medicine and rehabilitation overwhelms patients. Prior to being added to the VICP, the compensation received by SIRVA patients from 2011 to 2016 was $29,087,666.[30] The compensation awarded by the Special Master is capped at $250,000 and pays for a large sum of medical and rehabilitative bills from their vaccine-related injury. The Act was created for the purpose of providing an easier and cheaper alternative to civil litigation for individuals who suffered injuries caused by the administration of vaccines.

When petitioners claim SIRVA as a result of the administration of a vaccine they are able to receive compensation for their medical and rehabilitative bills. They are only able to receive compensation because SIRVA and the vaccine they received is listed on the Vaccine Injury Table (Table). Even though people who suffer from SIRVA can be out of work for months and are reliant on compensation from the VICP, the Department of Health and Human Services (HHS) petitioned on July 20th, 2020 to remove SIRVA from the Vaccine Injury Table.[31] The HHS is the administrative body of the VICP and proposes changes to the Vaccine Injury Table when they receive new scientific knowledge about vaccines, injuries, disorders, etc. The Health Resources and Service Administration regulates discussion of these petitions by the public.

Should the HHS remove SIRVA from coverage under the VICP? Upon majority disagreement with the HHS's petition to remove SIRVA from the VICP's Vaccine Injury Table, the HHS rescinded their proposal in April of 2021. This thesis demonstrates why the HHS should

[30] Update on SIRVA, HHS.gov. (n.d.). Retrieved November 8, 2021, from https://www.hhs.gov/sites/default/files/Nair_Special%20Highlight_SIRVA%20remediated.pdf.
[31] 42 CFR Part 100, Federal Register / Vol. 85, No. 139 / Monday, July 20, 2020

not resuscitate the proposal by reviewing prior case law and interpreting the language of established regulations, penal code, and opinions of the courts.

Defeated Purpose Of The Act

The purpose of the National Childhood Vaccine Injury Act was to significantly reduce the amount of people who file strict liability lawsuits against vaccine manufacturers in civil court and compensate those who took on the risk of vaccination and suffered a vaccine-related injury or death as a result. The risk of adverse reaction to vaccination is taking on by the majority of people because vaccines are necessary to keep us safe from life-threatening diseases. SIRVA is one of these adverse risks.

By removing SIRVA from the Vaccine Injury Table, the HHS is defeating the original purpose of the Act. As explained in the original language of the Act:

The Secretary shall establish in the Department of Health and Human Services, a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.[32]

The Act's core purpose is to prevent spread of infectious diseases through encouraged immunization and prevent adverse reactions to vaccines. Needless to say, adverse reactions to vaccines are, for the most part, unavoidable. SIRVA is preventable through proper education and training of healthcare personnel; however, injuries still happen and the people that suffer from SIRVA should be compensated. The Act encourages immunization by offering the VICP.

The government's responsibility is to ensure that systems are in place to encourage vaccination or prevent the spread of human infectious diseases. The most common method for

[32] 100 STAT. 3756 PUBLIC LAW. SEC. 2101.

governments to protect those who are "damaged" by compulsory or recommended vaccines. By offering this method of compensation, vaccine hesitancy declines, and the spread of disease is reduced.[33]Governments weigh the costs of spending billions to compensate those who bore the risk of being adversely affected by a recommended vaccine alongside the cost of increased percentages of vaccine hesitancy, reduced rates of vaccination, and increased spread of preventable infectious diseases.

With removal of SIRVA from the Vaccine Injury Table, the HHS runs the risk of decreasing public confidence in vaccines that prevent preventable diseases. According to Parmet (2010), a leading expert on public health law, in her article "Pandemic Vaccines-The Legal Landscape", highly publicized lawsuits against vaccine manufacturers run the risk of undermining confidence in vaccines.[34] If the HHS removes SIRVA from the VICP, petitioners may attempt to sue vaccine manufacturers in traditional court. In addition to running the risk of decreasing confidence in vaccines, the HHS can lose valuable information about SIRVA patients that may be useful in the future. The VICP allows for the United States to identify and research the causes of the vaccine-related injuries that may go otherwise unnoticed (due to its rare nature). For SIRVA especially, claims within the VICP has allowed for research to explore vaccine delivery technologies that avoid improper injections.[35] The research being done can eradicate SIRVA completely by educating vaccine administrators and healthcare providers on the proper

[33] D'Errico, S.; Zanon, M.; Concato, M.; Peruch, M.; Scopetti, M.; Frati, P.; Fineschi, V.(2021). ""First Do No Harm". No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy." *Vaccines*, 9, 1116. https://doi.org/10.3390/vaccines9101116
[34] Parmet, W. E., (1970, November 11). "Pandemic vaccines - the legal landscape." *New England Journal of Medicine*. Retrieved November 12, 2021, from https://www.nejm.org/doi/full/10.1056/NEJMp1000938.
[35] Ibid. 1242.

vaccine injection practices. However, if SIRVA is removed from the VICP then the resources and attention necessary to eradicate SIRVA may never be provided.

The removal of SIRVA from the Table would cause people who suffer from SIRVA to sue vaccine administrators for negligence and liability. Without compensation from the VICP, SIRVA patients are forced to find other resources to pay for medical and rehabilitative costs. An increase in the number of lawsuits against vaccine administrators could be a disincentive to vaccine administration and has potential to lead to a vaccine crisis where vaccine administrators are overwhelmed by lawsuits. The proposal to remove SIRVA completely disregards the purposes of the Act.

The HHS' Proposed Rule

The HHS' primary argument for the removal of SIRVA was that the injury is preventable and caused by negligent injection of vaccines. Their basis for this argument is that SIRVA is often caused by an inappropriate sized needle or poor injection technique; it is not caused by the antigens of the vaccine. [36]

Stephen Sugarman, a professor of torts at UC Berkeley School of Law, explores the results that can occur when an injury is not listed on the Table. In his article, Sugarman shares that a committee of advisors works to amend the Table to add new injuries as "the consensus view changes with the availability of new studies."[37] SIRVA has been part of the Table since 2017 and it has been proven that there is a scientific causal link between vaccine injection and the injury. HHS's proposed revision is not based on new studies demonstrating a lack of

[36] 85 FR 43794

[37] Sugarman, S. (2007). "Cases in vaccine court — legal battles over vaccines and autism". *The New England Journal of Medicine*, 357, 1275-1277. DOI: 10.1056/NEJMp078168

connection between vaccine injection and the shoulder injury instead, the revision is based on a misreading of the legislation and misrepresentation of the existing statutes.

In a 1993 federal claims case, the Court found that when the patient's injury was a result of negligent administration of the vaccine, they had no difficulty in concluding that any resulting injury from the vaccine is vaccine-related.[38] Since an injury that occurs as a result of negligent administration is still considered vaccine-related, the HHS cannot remove SIRVA from the Table.

SIRVA is a vaccine-related injury and therefore, should continue to be compensated for through the VICP. Recent cases of SIRVA petitioners have shown that the Courts agree. A case heard in 2021, a petitioner alleged that they had developed SIRVA after a recent vaccine administration.[39] The plaintiff proved that the vaccine caused them to suffer from SIRVA for more than 6 months after the initial vaccination. The Courts established that:

the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown by the government that the injury was caused by some other factor other than the vaccination.[40]

The "but-for" clause prevents the HHS from removing SIRVA from the Table because petitioners are already required to meet the prongs of SIRVA to demonstrate that "but-for" the administration of the vaccine they would not have sustained their injuries.[41] If the government cannot demonstrate that the injury sustained had no causal relationship with the vaccine then the VICP must compensate the petitioner.

[38] *Amendola v. Sec'y, HHS*, 989 F.2d 1180, 1181 (Fed. Cir. 1993)
[39] *Yost v. Sec'y of HHS*, , at *9, Fed. Cl. May 6, 2021
[40] *Yost v. Sec'y of HHS*, Fed. Cl., May 6, 2021
[41] 86 FR 21209

While acknowledging the definition of SIRVA and reasoning provided by the HHS, the HHS's proposed rule must be rescinded because no medical evidence or statutory evidence has been found that SIRVA is not causally related to vaccination. Moreover, removal of SIRVA poses serious risk to public health. The removal of SIRVA from the VICP's Vaccine Injury Table may cause a decline in vaccine administration, an increase in vaccine hesitancy, and a spread of preventable infectious diseases.

IV. CONCLUSION

The purpose of the Act of 1986 was to "ensure the production and procurement of safe and effective vaccines" and "direct the distribution and use of vaccines." By creating the NVICP, Congress effectively met those prongs by allowing those injured by vaccine injection to use an alternative remedy to receive compensation for their injuries. This compensation program increases the likelihood of people taking on the risk of vaccination. Yet, despite this central purpose of the Act, the HHS is proposing to remove SIRVA from the Vaccine Injury Table.

SIRVA should not be removed from the Table because the principle of the Act is to protect community members by offering a no-fault remedy to compensate them. By recognizing the history of the Act of 1986 and the purpose of the vaccine court, this thesis has shown that the HHS must keep SIRVA on the Table. Although the HHS has defined coverage on the Table, removal of SIRVA is ill-advised. SIRVA is one of the potential adverse effects of vaccine injection. Similar to other vaccine-related injuries, such as arthritis or brachial neuritis, SIRVA can be debilitating for patients, and they may never fully recover.

SIRVA's removal from the Table may have harmful effects on the vaccine administration process. In a climate where anti-vaccination sentiments have increased, removing one of the most prevalent injuries from the compensation table seems counterproductive and inappropriate. People that suffer SIRVA symptoms have reported that a loss of feeling in their shoulder, have to endure extensive surgery, rehabilitative sessions, and are unable to work. Previously, the compensation offered by the VICP made people more comfortable with undertaking the risk of injury with vaccine injection.

The no-fault coverage of victims who suffer from SIRVA should continue. They should remain on the list of those who receive compensation for taking on adverse risks. Facing adverse risk by receiving vaccines is part of community members' responsibility to keep the entire community safe. Getting vaccinated is part of community duty and people take on that risk so that they can protect those in the community who are physically incapable of vaccination.

SIRVA, as one of the most prevalent cases filed in vaccine court, should remain on the Injury Table because our government's duty is to protect the interests of society.[42] Part of that duty is to award compensation to those affected negatively by vaccine administration to encourage vaccination amongst the wider population further. The risk of reduced vaccination rates far outweighs the HHS's call to follow the technicality of definition.

At this time, COVID-19 vaccines are not covered in the Vaccine Injury Table and therefore won't be impacted by the proposed rule to remove SIRVA. However, COVID-19 vaccines may be added to the Vaccine Injury Table in the future and as we learn more about the effects of the vaccine, we may see SIRVA as an adverse reaction. The proposal to remove SIRVA from the VICP is untimely when anti-vaccination sentiments are rising across the country. With the potential of compensation, SIRVA remaining on the Vaccine Injury Table can give people the confidence to vaccinate themselves.

The HHS's proposal for revision to the Vaccine Injury Table has been challenged and evidence has shown a lack of statutory support for removing SIRVA from the Table. Scientific research has shown that SIRVA originates from negligent vaccine administration. And yet, the

[42] Seiler, N., Taylor, H., Faden, R., (2004) "Legal and Ethical Considerations in Government Compensation Plans: A Case Study of Smallpox Immunization", *1 Ind. Health L. Rev. 1*. Retrieved from https://mckinneylaw.iu.edu/ihlr/pdf/vol1p1.pdf

definition of SIRVA does not exclude the injury from coverage under the VICP. Compensation under the VICP is important to our vaccination system in the United States. The HHS should not be allowed to remove a prominent injury from the VICP without providing scientific evidence or statutory support for its proposal.

APPENDIX A

Vaccine Injury Table

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 B. Brachial Neuritis	≤4 hours. 2-28 days (not less than 2 days and not more than 28 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.*, DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
III. Vaccines containing measles, mumps, and rubella virus or any of its components (*e.g.*, MMR, MM, MMRV)	A. Anaphylaxis B. Encephalopathy or encephalitis	≤4 hours. 5-15 days (not less than 5 days and not more than 15 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
IV. Vaccines containing rubella virus (*e.g.*, MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (*e.g.*, MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	≤12 months.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
VII. Vaccines containing polio inactivated virus (*e.g.*, IPV)	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
IX. Haemophilus influenzae type b (Hib) vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
X. Varicella vaccines	A. Anaphylaxis	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	7-42 days (not less than 7 days and not more than 42 days).
	C. Varicella vaccine-strain viral reactivation	Not applicable.
	D. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	E. Vasovagal syncope	≤1 hour.
XI. Rotavirus vaccines	A. Intussusception	1-21 days (not less than 1 day and not more than 21 days).
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIV. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
	D. Guillain-Barré Syndrome	3-42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1hour.

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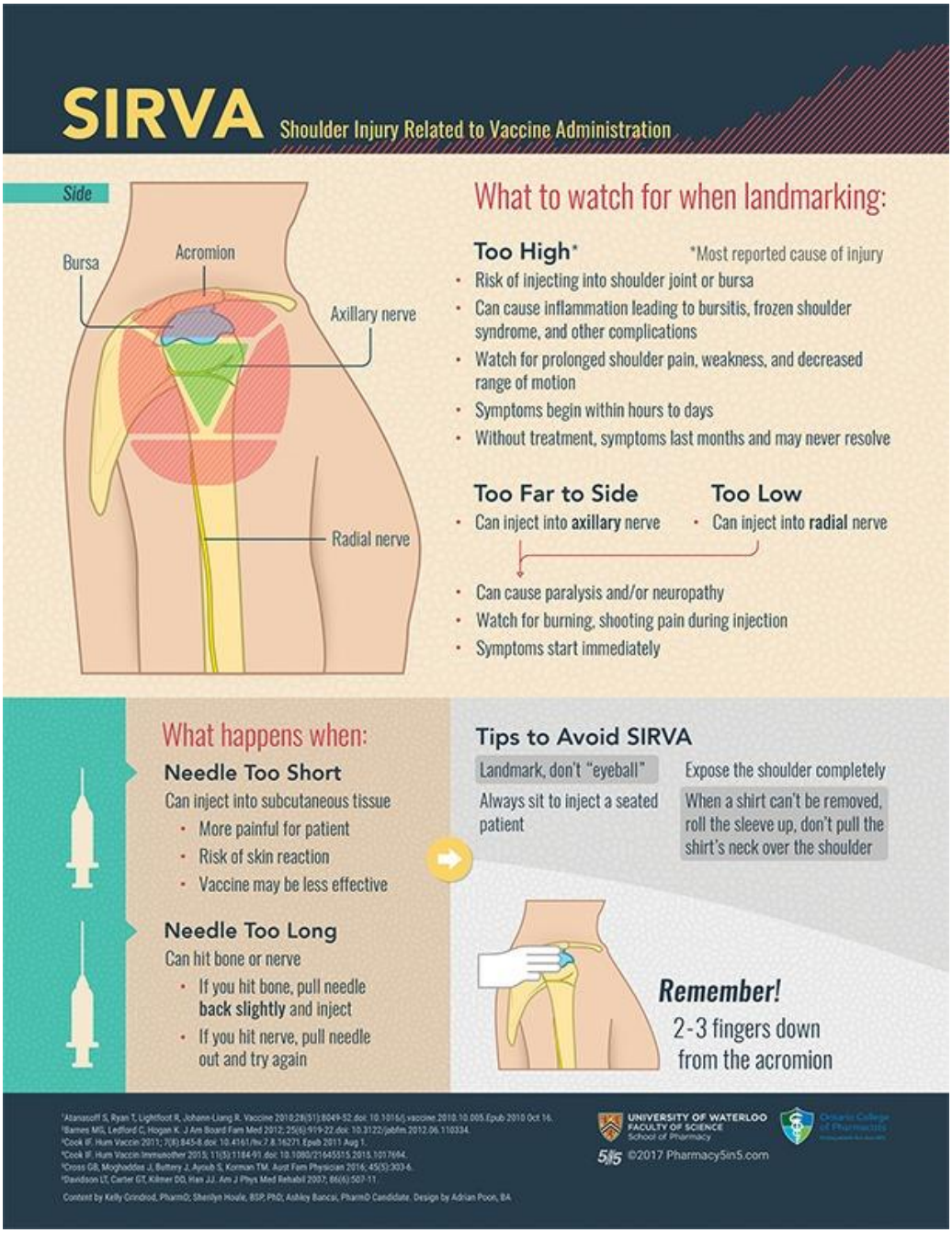
APPENDIX B

SIRVA and other injection site events.



Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. Can Fam Physician. 2019 Jan;65(1):40-42.

REFERENCES

417 - SIRVA Reprise, COVID Vaccine Injury Fund. (2021, September 24). Retrieved from Carilion Clinic: https://www.carilionclinic.org/news/417---sirva-reprise-covid-vaccine-injury-fund/

Amendola v. Sec'y, HHS, 989 F.2d 1180, 1181 (Fed. Cir. 1993)

Bancsi, A., Houle, S. K., & Grindrod, K. A. (2019). Shoulder injury related to vaccine adminsitration and other injection site events. *Canadian Family Physician* , 40-42.

Blumberg , D. A., Lewis, K., Mink , C. M., Christenson, P. D., Chatfield, P., & Cherry, J. D. (2019). Severe reactions associated with diphtheria-tetanus-pertussis vaccine: detailed study of children with seizures, hypotonic-hyporesponsive episodes, high fevers, and persistent crying. *Pediatrics*, 1158-1165.

Bruesewitz v. Wyeth, 562 U.S. 223 (2011)

Cantarelli, T., Hidalgo, P., Skaf, A., & Serfaty, A. (2021). Subacromial-subdeltoid bursitis following COVID-19 vaccination: a case of shoulder injury related to vaccine administration (SIRVA). *Skeletal Radiology*, 2293-2297.

D'Errico, S., Zanon, M., Concato, M., Peruch, M., Scopetti, M., Frati, P., & Fineschi, V. (2021). "First Do No Harm". No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy. *Vaccines*, 1116- 1130.

Hinman, A. R. (1986). DTP Vaccine Litigation. *American Journal of Diseases of Children*, 528-530.

H.R. 5546 — 99th Congress: National Childhood Vaccine Injury Act of 1986. Retrieved from: https://www.govtrack.us/congress/bills/99/hr5546

National Childhood Vaccine Injury Act, 42 U.S.C § 300aa-10 et seq.(1986)

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 FR 45132 (July 29, 2015)

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 85 FR 43794 (July 20, 2020)

National Vaccine Injury Compensation Program: Rescission of Revisions to the Vaccine Injury Table, 86 FR 21209 (April 22, 2021)

Parmet, W. (2010). Pandemic vaccines - the legal landscape. *The New England Journal of Medicine* , 1949-1952.

Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756.

Ryan, T. (n.d.). Updating the vaccine injury table. Retrieved October 5, 2021, from https://akastage-www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2012/March%208-9/20120308-iomreportupdate.pdf.

Schwartz, V. E., & Mashigian, L. (1987). National childhood vaccine injury act of 1986: An ad hoc remedy or a window for the future? *Ohio State Law Journal*, 387-398.

Seiler, N., Taylor, H., & Faden, R. (2004). Legal and ethical considerations in government compensation plans: A case study of smallpox immunization. *Indiana Health Law Review*.

Shahbaz, M., Blanc, P. D., Domeracki, S. J., & Guntur, S. (2019). Shoulder Injury Related to Vaccine Administration (SIRVA): An occupational case report. *Workplace Health Safety* , 501-505.

Sugarman, S. D. (2007). Cases in vaccine court — legal battles over vaccines and autism. *The New England Journal of Medicine*, 1275-1277.

Szari, S., Belgard, A., Adams, K., & Freiler, J. (2019). Shoulder Injury Related to Vaccine Administration: A Rare Reaction. *Federal practitioner : for the health care professionals of the VA, DoD, and PHS*, 380-384.

Update on SIRVA, HHS.gov. (n.d.). Retrieved November 8, 2021, from https://www.hhs.gov/sites/default/files/Nair_Special%20Highlight_SIRVA%20remediated.pdf.

Vaccine injury compensation program. (2018, September 24). The United States Department of Justice. Retrieved October 1, 2021, from https://www.justice.gov/civil/vicp.

Yost v. Sec'y of HHS, Fed. Cl., May 6, 2021