The Vaccine Monologues: Federal Vaccine Policy and SIRVA's Place in the Vaccine Injury Compensation Program

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INTRODUCTION

It's common parlance in these pandemic times: "I just got a covid shot, and my arm is a little sore!" Indeed, the Centers for Disease Control ("CDC") lists mild pain and soreness for several days at the injection site as a common side effect after receiving the Covid-19 vaccine or a booster shot.[1] However, there is a small minority of people for whom that shoulder pain does not go away after a few days.[2] For people without prior shoulder injuries who then suffer from shoulder pain within 48 hours of vaccination and who live with it for at least six months, their condition is known as "Shoulder Injury Related to Vaccine Administration" ("SIRVA"), a condition identified by the Department of Health and Human Services ("HHS") in 2010 and which often requires aggressive treatments like arthroscopic surgery or multiple cortisone injections to resolve.[3]

These past few years, vaccines have been front of mind for many. The Covid-19 pandemic upended our lives and institutions in every conceivable way, but nothing was affected more than the cultural debates around vaccinations. By the end of the second month of the pandemic, the federal government had promised hundreds of millions of dollars in support of Moderna's candidate vaccines.[4] The first Covid-19 vaccine was approved by the CDC less than eight months after trials started, faster than any vaccine previously developed, though this unprecedented speed of development meant it was neither unanimously lauded nor adopted.[5] Indeed, then-President Trump hosted daily press conferences in which he promoted treatments not approved by the FDA and proclaimed, "'[W]ith or without a vaccine, it's going to pass,'" both spurring and reflecting anti-vaccination sentiments around the country. [6]

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1. *Possible Side Effects After Getting a COVID-19 Vaccine*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Sept. 14, 2022) [https://perma.cc/2LLX-HQXZ].

2. Elisabeth Hesse (CDC) & Sarah Atanasoff (HHS), *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016*, 38 VACCINE 1076, 1088 (2020).

3. *Id.*

4. *Coronavirus Timeline*, DEPARTMENT OF DEFENSE, [https://perma.cc/GK7F-XW6D] (last updated Feb. 24, 2023).

5. *Id.*

6. *Timeline of Trump's Coronavirus Responses*, LLOYD DOGGETT U.S. REPRESENTATIVE (Mar. 2, 2022) [https://perma.cc/W6X3-LN3B].

The dominant political narrative casts doubt and hesitancy regarding the Covid-19 shots as a partisan issue, wherein Democrats are much more likely to get the vaccine than Republicans.[7] While this political divide does exist, simply labeling it as such obscures the way that misinformation and Republicans' ideas about freedom and liberty have led to a landscape of widespread vaccine hesitancy and stubborn rejection. 2021 reporting from rural America in the *New York Times* found that the most common reason for apprehension regarding the vaccine has to do with its speedy rollout, unknown long-term side-effects, and strong beliefs about bodily autonomy.[8] In that way, twenty-first century vaccine hesitancy is rooted in fear and trepidation—whether legitimate or not—of an adverse effect on the body.

In Part I, this Note provides an overview of the history of vaccines in the United States since their proliferation in the early nineteenth century, demonstrating that the states were the main engines of vaccine administration, while the federal government provided funds but was not involved in direct administration decisions. It was only in response to increasing reports of vaccine-related illness and injury as well as manufacturers' unwillingness to assume liability that the federal government established the National Vaccine Injury Compensation Program ("VICP"), a no-fault tort scheme to provide compensation for injuries caused by routine vaccinations.[9] In Part II, this Note argues that Congress empowered this specialized court, under the discretion of Special Masters, to adjudicate vaccine injury claims without any evidentiary standards to ensure scientifically legitimate outcomes. Indeed, without Federal Rule of Evidence 702 and analysis of the *Daubert* factors when considering expert medical testimony and evidence, inconsistent and illogical applications of science lead to unpredictable outcomes for Petitioners.

In Part III, this Note shows that the inconsistency and the evidentiary problems in the VICP, which escalated when HHS identified SIRVA as a condition caused by improper administration of vaccines. Once coined, SIRVA became the most popular claim filed in the VICP. To standardize its adjudication, HHS added it to the Vaccine Injury Table (the "Table") in 2017. The addition fundamentally changed the nature of the compensation program by undermining the funding and incentive structure aimed to ensure the proper manufacture of vaccines, not the proper administration of them. Indeed, both in practice—due to the number of claims—and in theory—as a condition not caused by the vaccine antigen itself—SIRVA poses serious problems to the integrity of the VICP and public confidence in vaccines.

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7. For COVID-19 vaccinations, party affiliation matters more than race and ethnicity. BROOKINGS INST. (Oct. 1, 2021) [https://perma.cc/Z9GZ-X5D3].

8. Sabrina Tavernise, *Vaccine Skepticism Was Viewed as a Knowledge Problem. It's Actually About Gut Beliefs*, NEW YORK TIMES, May 6, 2021 [https://perma.cc/8Q93-5FBW].

9. 42 U.S.C. § 300aa National Childhood Vaccine Injury Act, H.R. 5546, 99th Congress, 1308, 1321 (1986) (as amended 2016), *hereinafter* National Childhood Vaccine Injury Act.

Part IV details how, during an unprecedented global pandemic, HHS struggled to deal with the specter of SIRVA over the compensation program, resulting in flip-flopping policies that first eliminated SIRVA from the Table, then withdrew that elimination. This Note argues that these inconsistent policies, which lack any clear justification or reading of The National Childhood Vaccine Act demonstrate the ambiguity of the VICP's role as a site of government action. Not including SIRVA on the Table gives Petitioners evidentiary leeway and leads to unpredictable outcomes as they attempt to prove causation-in-fact; but including SIRVA on the Table strains the original intent and structure of the National Childhood Vaccine Act, pre-empting what most likely should be medical malpractice.

I. HISTORY OF FEDERAL VACCINE INTERVENTIONS PRE-1989

Vaccines were first developed as a means of inoculating the public against the smallpox epidemic that raged in the late 1700s.[10] Vaccination replaced the technique known as variolation, wherein active smallpox lesions were placed under the skin of an uninfected person.[11] Deriving its name from its source, the first vaccinations involved the transfer of cowpox lesions, which were not dangerous to humans, to the skin.[12]

Less than twenty years after English physician Edward Jenner first coined the technique, the United States Government stepped in to streamline the process, demonstrating the early use of federal oversight.[13] In 1813, U.S. Congress and President James Madison signed into law "An Act to Encourage Vaccination," which established the first National Vaccine Agency whose goal was to "'preserve the genuine vaccine matter, and to furnish the same to any citizen of the United States.'"[14] While the Act expedited the transfer of vaccines through the U.S. Postal Service, in the decades following, states took over as the main engines of spreading vaccines, many passing compulsory vaccination laws as the spread of disease increased with mandatory public schooling.[15] The landmark Supreme Court decision *Jacobson v. Massachusetts* clarified that vaccination, even compulsory vaccination, falls under the states' police power.[16] After the polio vaccine was developed, Congress authorized funds to give to states to buy vaccines, but did not prescribe the methods of distribution, kowtowing to the AMA's opposition to any vaccine distribution by the federal government other than to the poor.[17]

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10. Jennifer Reich, *The Public History of Vaccines*, *in* CALLING THE SHOTS: WHY PARENTS REJECT VACCINES 25 (2016).

11. *Id.* at 23.

12. *See id.* at 25.

13. *Id.* at 26.

14. *Id.*

15. *Id.* at 27.

16. Jacobson v. Massachusetts, 197 U.S. 11 (1905) (upholding a compulsory vaccination law that requires vaccination when the Board of Public Health says that it is necessary for public safety because it is within the state's police power).

17. Reich, *supra* note 10, at 45.

It wasn't long before reports of vaccine injury emerged in response to widespread use of the polio vaccine: the first major vaccine injury outbreak occurred in the early weeks of the polio vaccine rollout, with reports of paralytic polio in those who had received the vaccine; such reports led investigators to one specific company, which had not inactivated the vaccine during manufacture.[18] After the rollout of the easier-to-use oral polio vaccine, scientists discovered that the inactivated polio virus could revert to its active form, though this occurred in only one case per 2.6 million.[19] This problem, unlike the former, arose not from a manufacturing error, but from the design of the vaccine itself, which led to courts establishing a duty to warn consumers of risk or a duty to ensure that whoever gave the vaccine warned the consumer.[20] At the same time, the whole-cell-pertussis vaccine given to infants resulted in severe hospitalizations and deaths for at least thirty children, all of whom received the vaccines from different manufacturers.[21]

While the federal government continued to intervene, it did so solely to bolster state discretion and private authority over vaccine administration, only stepping in further when the companies refused to participate.[22] The next federal government action was the 1962 Vaccine Assistance Act, which created "a pool of federal funds that states and localities could use to buy and dispense vaccines against polio, diphtheria, pertussis, and tetanus."[23] Around that time, the CDC formed the Advisory Committee on Immunization Practices ("ACIP"), which recommended vaccines be delivered through private physician or well-child clinics in order to standardize the process and provide evidence of vaccination, which, by 1974, was a requirement for school attendance in forty states.[24]

With predictions of an especially bad flu season in 1976, the ACIP considered more direct federal intervention such as government manufacture of flu vaccine.[25] However, the ACIP decided instead to order the flu vaccine from private pharmaceutical companies and continue to facilitate distribution through the National Influenza Immunization Program ("NIIP"), thus facilitating federal intervention, but not enough to streamline or nationalize vaccine administration. [26] Companies were at first unwilling to accommodate the NIIP because they could not obtain insurance coverage against possible damages from the vaccine.[27] While the CDC supported proposed regulations that would provide a remedy for those harmed as

18. *Id.*
19. *Id.* at 47.
20. *Id.* at 48. *See generally* Anna Kirkland, *The Solution of the Vaccine Court*, *in* VACCINE COURT: THE LAW AND POLITICS OF INJURY 70 (2016) (explaining that lawsuits regarding "bad batches" of vaccines were first to be brought, paving the way for suits about properly manufactured vaccines).
21. Reich, *supra* note 10, at 57-58.
22. *Id.* at 48-49.
23. *Id.* at 50.
24. *Id.* at 51-2.
25. *Id.* at 53-54.
26. *Id.* at 54.
27. *Id.*

a result of vaccines licensed by the Food and Drug Administration and recommended by the ACIP, the Office of the Surgeon General rejected that proposal.[28]

In response, Congress passed legislation that authorized the federal government to assume liability for the manufacturing companies and required that the companies develop an informed consent form that would alert consumers to potential side effects.[29] In the 1976 flu season alone, the government received more than 4,000 injury claims that resulted in a twenty-million-dollar compensation payout.[30] The NIIP was limited to that flu outbreak, but it generated negative publicity about the flu vaccine in particular, leading people to distinguish it as less safe and less necessary than earlier vaccines for other infectious diseases.[31] Furthermore, the program resulted in a new CDC-developed informed consent form that required a patient signature to be included with all vaccines administered in clinics.[32] In the face of mandatory vaccine laws at the state level, increasing reports of vaccine-related injuries, distrust in vaccines from groups such as Dissatisfied Parents Together,[33] inadequate patchwork responses from state governments, and vaccine manufacturers refusing to produce vaccines,[34] a Congressional solution seemed like the only option.

II. VACCINE INJURY COMPENSATION PROGRAM (VICP)

Congress's response to vaccine injuries established a new federalism with regard to vaccines. In response to guidelines issued by the American Medical Association ("AMA"), U.S. Representative Henry Waxman of California sponsored the National Childhood Vaccine Injury Act of 1986, which created the VICP, a no-fault alternative to tort litigation that covers injuries caused by vaccines recommended by the CDC for routine administration to children and pregnant women.[35] Claims for compensation filed with the VICP are litigated in the Court of Federal Claims and decided by Special Masters. The Department of Health and Human Services (HHS) is the named respondent and makes the initial determination as to whether a claim should be defended, settled, or conceded as

28. *Id.*
29. *Id.*
30. *Id.* at 55.
31. *Id.*
32. *Id.*
33. Now called National Vaccine Information Center, this group is the largest organization in the USA committed to eliminating vaccine mandates. *See id.* at 59.
34. *See* Kirkland, *supra* note 20, at 69 (stating that in 1984 one of the three manufacturers of DTP announced that it would stop producing because of the escalating costs of liability insurance).
35. Reich, *supra* note 10, at 60. The covered vaccines include many that are not only administered to children and pregnant women, like the flu vaccine. Anyone who receives a covered vaccine can apply for compensation within the thirty-six-month statute of limitations, which begins at the onset of the condition. Compensation is not limited to children and pregnant women; those categories just define the scope of vaccines covered by the program. In 2016, Congress passed the 21st Century Cures Act, which amended the VICP in two small ways with regard to vaccines recommended for use in pregnant women, neither of which is relevant to this paper. When describing the VICP, I am describing its current form, but that form has remained generally consistent since its establishment. *See About the National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERVICES ADMINISTRATION (Dec. 2022) [https://perma.cc/GHV3-MXA5].

to eligibility for compensation. For claims that HHS does not concede, attorneys at Department of Justice's Office of Vaccine Litigation first litigate eligibility for compensation and, if the Petitioner is found eligible, then the amount of money in damages.[36]

The structure of the VICP is meant to facilitate the manufacture of vaccines and provide a forum for injured petitioners to seek redress.[37] Manufacturers of vaccines pay a seventy-five-cent excise tax on each dose at the time of manufacture, which funds the Vaccine Injury Compensation Trust Fund.[38] Petitioners can apply for compensation for treatments, medical visits, death, and attorneys' fees. Pain and suffering damages are also available; however, they are capped.[39] Petitioners must exhaust the VICP remedies before filing a liability claim in federal or state court against the vaccine manufacturers.[40] In that way, the VICP reduces tort litigation against vaccine manufacturers thus incentivizing vaccine research and development and stabilizing prices by rendering costly liability insurance unnecessary as well as incentivizing people to get vaccinated by providing a standardized process through which to be compensated for any adverse effects.

By including detailed information about the covered vaccines and conditions in the program, as well as establishing the National Vaccine Advisory Committee, the Act foregrounds the importance of a program grounded in accurate scientific information.[41] The "Vaccine Injury Table" is a chart of vaccines, the injuries, disabilities, illness, conditions, and deaths that are known to be associated with the covered vaccines, and the time period in which the onset occurs or first symptom arises.[42] If the first symptom of the condition occurs within the specified time period on the Table and the condition meets the definition on the Table, it is presumed that the vaccine caused the condition unless another cause is proven.[43] In short, when a Petitioner files a "Table Claim," he must prove by a preponderance of the evidence that he suffers from the condition as defined in the Table and that condition's onset occurred within the stated time period.[44] When a Petitioner files a claim for compensation for a condition not on the Table or one that does not meet the Table requirements, the Petitioner must prove by a preponderance of evidence such as expert witness testimony, medical records, or

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36. *About the National Vaccine Injury Compensation Program,* HEALTH RESOURCES & SERVICES ADMINISTRATION (Dec. 2022), [https://perma.cc/SDA7-QYQC].

37. Laura Binski, *Balancing policy tensions of the vaccine in light of the omnibus autism proceeding: are petitioners getting a fair shot at compensation?,,* 39 HOFSTRA L. REV. 683, 693-94 (2011).

38. 26 USC § 4131 (2018)(b)(1). For example, the measles-mumps-rubella vaccine is taxed $2.25 because it prevents three diseases.

39. Currently, pain and suffering damages are capped at $250,000. *What You Need to Know About the National Vaccine Injury Compensation Program (VICP),* HEALTH RESOURCES & SERVICES ADMINISTRATION (Dec. 2022), [https://perma.cc/5JVT-A3JW].

40. *See Frequently Asked Questions,* HEALTH RESOURCES & SERVICES ADMINISTRATION (Dec. 2022).

41. National Childhood Vaccine Injury Act 300aa-5.

42. *Id.*

43. National Childhood Vaccine Injury Act 300aa-13.

44. National Childhood Vaccine Injury Act 300aa-13(b).

medical opinion that the vaccine caused the condition.[45] The vaccines initially chosen to be on the Table were ones in which an independent panel of experts formed by Congress reviewed existing scientific understanding to identify known side effects from vaccines.[46]

However, despite the supposed importance of science to the process, the use of scientific evidence under the VICP goes essentially unregulated, due to the Petitioner-friendly procedures which were intended to make it easier to bring claims. Claims in the VICP are adjudicated by a Special Master, who is appointed by the U.S. Court of Federal Claims and serves for four-year terms.[47] The Act stipulates that the court may not make a finding for compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion," thereby laying a floor of eligibility.[48] However, these guidelines do not make clear what exactly is necessary to prove a preponderance. Furthermore, Special Masters are not bound by the rules and standards in the Federal Rules of Civil Procedure or the Federal Rules of Evidence.[49] Indeed, the Act authorizes Special Masters to "include flexible and informal standards of admissibility of evidence."[50] The admissibility of evidence is particularly important in these vaccine cases, which depend entirely on medical records and scientific testimony and often involve novel scientific questions. These broad directives empower the Special Masters to employ liberal standards for admitting evidence and then make preponderance findings based on that evidence.

Indeed, in these questions of paramount importance, Special Masters do not use the *Daubert* standard to evaluate scientific claims, which poses both practical and ethical concerns to the program.[51] Under Federal Rule of Evidence 702 and the *Daubert* line of cases that interpreted it, reliability is a precondition for the admissibility of evidence.[52] When evaluating an expert witness, judges should consider tested falsity of claims, peer reviewed publications, error rates, standards of control, and general acceptance of the methodology or conclusion.[53] While critics of *Daubert* argue that it gives the judge overboard discretion to gatekeep evidence from consideration, that discretion pales in comparison to that in the VICP, where there are no guidelines at all. Indeed, the seminal three-prong *Althen* test, used in the program to prove causation, only requires plaintiffs "to prove only that they have a logical theory—a proposed explanation—of

45. *Id.*

46. Reich, *supra* note 10, at 61.

47. Binski, *supra* note 37, at 695.

48. National Childhood Vaccine Injury Act 300aa-13(a)(1).

49. Binski, *supra* note 37, at 696.

50. National Childhood Vaccine Injury Act 300aa-12(d)(2)(b).

51. Brandon Boxler, *What to do with Daubert: How to Bring Standards of Reliable Scientific Evidence to the National Vaccine Injury Compensation Program*, 52 WM & MARY L. REV 1319, 1348-50 (2011) (explaining that the Federal Circuit has never adopted *Daubert* as the VICP standard and has stated that while *Daubert* was helpful, it was neither necessary nor dispositive).

52. *See* Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579, 585 (1993).

53. General Electric Co. v. Joiner, 522 U.S. 136 (1997) (rejecting notion from *Daubert* that courts cannot look at conclusions because methodology and conclusions cannot be separated in practice).

causation," not that it is based on reliable science.[54] In short, epidemiological studies or any other empirical medical basis are not required to prove causation.[55]

Another example of evidentiary inconsistency is varied amounts and types of evidence required to prove a claim. For example, Petitioners rely on molecular mimicry as a theory of causation linking a vaccine to an autoimmune condition, but different Special Masters give differing levels of credence to molecular mimicry.[56] Scientists agree that molecular mimicry can occur when a foreign molecule (such as a component of a vaccine) and a natural molecule in the body have either a similar sequence or structure, such that the body's immune antibodies generated to fight the foreign molecule mistake the similar natural molecule as foreign (an autoimmune reaction).[57] However, proving that molecular mimicry occurred in a specific instance is tricky, and the closest "proof" one can get is identifying sequence homologies—similar molecular sequences— between the foreign and the natural molecule.[58] Sequence homologies can lead to structural homologies—molecules that look the same once they are coded and folded into proteins—but not always.[59] In the same way, non-homologous sequences can also create structural homologies.[60] A review of cases from the Office of Special Masters reveals that some Special Masters require Petitioner to identify specific sequence homologies as an indicia of reliability that a molecular mimicry reaction took place, whereas other Special Masters rule based on the content that particularized biological proof is not necessary to prove causation.[61] The lack of adequate evidentiary guidelines mean that "idiosyncratic differences among judges and litigators continue to influence the outcome of cases."[62]

It is well documented that not only is there inconsistency between cases adjudicated by the different Special Masters, but also inconsistency between cases before individual Special Masters.[63] For example, a Special Master found that an Institute of Medicine report was more persuasive than the conflicting testimony of Dr. Mark Geir; and a less than a year later the same special master reached the "exact opposite conclusion," finding that Dr. Geier's testimony was more persuasive than the IOM report.[64] Both of these decisions were affirmed on appeal because the standard for overturning a Special Master's decision is "arbitrary and capricious," a deferential review standard under which such opposite conclusions

54. Boxler, *supra* note 51, at 1352.

55. Boxler, *supra* note 51, at 1352.

56. Megan Robertson, *Molecular Mimicry: Exemplifying the Procedural Insufficiencies of the Vaccine Injury Compensation Program*, 26 FEDERAL CIRCUIT BAR JOURNAL 513, 519 (2017).

57. *Id*. at 514.

58. *Id*. at 518.

59. *Id*.

60. *Id*.

61. *Id*. at 522-23.

62. Nora Freeman Engstrom, *A dose of reality for specialized courts: lessons from the VICP*, 163 UNIV. OF PENNSYLVANIA L. REV. 1631, 1677-78 (2015).

63. *See* Boxler, *supra* note 51, at 1342.

64. *Id*.

can coexist.[65] Under an arbitrary and capricious review, the Federal Circuit has not promulgated evidentiary guidance that applies to vaccine cases; therefore, outcomes under the program are unpredictable and inconsistent.[66]

This inconsistency regarding the scientific basis of claims in the program poses significant ethical challenges for the lawyers that practice in Vaccine Court. The Act only establishes one ethical obligation for attorneys in the program: "It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death."[67] Of course, letting individuals know about the program is important, but the Congressional intent of the Act was to compensate individuals who suffered from a legitimate vaccine-related injury. Fulfilling that intent requires establishing an evidentiary bar on petitioners who have no medical or epidemiological evidence to prove their claims. Without such evidentiary standards, petitioners are able, and perhaps even encouraged, to bring claims without regard for the accuracy and authenticity of those claims, making the VICP a locale without the ethical norms of practice meant to safeguard the legal system from false and frivolous suits. As the next two sections of this essay will show, SIRVA has only complicated the scientific and ethical landscape of the VICP, as the program has moved further away from the science it is supposedly meant to stand for.

III. SIRVA AND THE CHANGING LANDSCAPE OF THE VICP

This section argues that SIRVA changed the nature of the VICP, shifted the focus of the Program away from its original legislative intent, and warped the incentive structure that The Act established in 1989.

In 2010, HHS published an article in the journal *Vaccine* entitled "Shoulder injury related to vaccine administration (SIRVA)," coining the acronym SIRVA to describe a condition characterized by shoulder pain presenting less than twenty-four hours after a vaccination and lasting for at least six months.[68] The study's methodology was a case review of the claims submitted to the VICP between 2006-2010, and out of those claims, HHS identified thirteen instances of SIRVA.[69] The article presents a medical overview of the symptoms, severity, and treatments of SIRVA in the thirteen identified cases, analyzing the changes to the deltoid and bursa that caused the pain.[70]

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65. *Id*. at 1341-42.

66. *Id*. at 1343 ("Vaccine Act jurisprudence lacks a clear statement regarding what amount, type, or quality of evidence plaintiffs must provide to satisfy the preponderance standard. This voice has produced unpredictable—and even contradictory—case law").

67. The National Childhood Vaccine Act 300aa-10(b).

68. S. Atansasoff, T Ryan, R Lightfoot, & R Johann-Liang, *Shoulder injury related to vaccine administration (SIRVA),* 28 VACCINE 8049, 8049 (2010).

69. *Id*. at 8049-50 (describing the survey that identified 11 women and 2 men with a mean age of 50. 62% of cases occurred after the influenza shot).

70. *Id*. at 1849.

The conclusions in this initial SIRVA overview suggest that SIRVA's cause is incorrect administration of the vaccine in the patient's arm.[71] Specifically, the conclusion section states that medical literature supports the potential for a prolonged "immune-mediated inflammatory reaction" if the vaccine is "unintentionally injected into the structures underlying the deltoid muscle due to inappropriate needle length and/or injection technique."[72] SIRVA can lead to bursitis, bone erosion, and damage to the rotator cuff and bicipital tendons.[73] In 46% of the cases studied, the patients reported that the vaccine administration was "too high."[74] The end of the article lists ways to mitigate SIRVA by taking into account gender and body mass index when choosing a needle, by an awareness of proper injection technique on the part of the administrator, and seated positions on the part of both the patient and administrator.[75]

In the years following the initial case report, SIRVA claims skyrocketed, thereby changing the nature of the VICP by shifting its focus from injuries sustained due to the vaccine itself to injuries sustained due to incorrect administration of the vaccine. In 2011, there were 7 SIRVA claims filed with the VICP (1.8% of total Petitioner claims), and by 2016, there were 446 (40.7% of total Petitioner claims).[76] This 38% increase is a dramatic shift in the types of cases before Special Masters. Importantly, SIRVA was not yet on the Vaccine Injury Table in 2016, and so these Petitioners were required to prove that they both suffered from SIRVA and that the vaccine was the cause-in-fact for it.[77] In the majority of these SIRVA claims in each year between 2012 and 2016, HHS conceded more SIRVA cases than it defended, meaning in most cases Petitioners did not have to offer any evidence whatsoever.[78] Out of the 227 conceded SIRVA claims between 2011 and 2016, 47.7% included patient documentation of an administration error.[79]

In 2017, HHS issued a final rule adding SIRVA to the Vaccine Injury Table.[80] Adding a condition to the Table makes it easier for a Petitioner to obtain compensation because a Petitioner only has to prove by a preponderance of evidence that he suffered from SIRVA after receiving a covered vaccine, not that the vaccine was a cause-in-fact of that condition. Specifically, a Petitioner has to prove that he suffered "[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain" his

71. *Id*. at 8052. Although this is a small sample-size, this conclusion is bolstered with the same findings in a much larger survey of SIRVA claims between 2010 and 2016. Out of the 227 conceded SIRVA claims in that five-year window, 47.7% included patient documentation of an administration error. 75% of those reported errors was that the injection was "too high." *See* Hesse, *supra* note 2, at 1081.

72. Atanasoff, *supra* note 68, at 8052.

73. *Id*. at 8051. See also SIRVA Claims to VICP 2010-2016 at 3.

74. Atanasoff, *supra* note 68, at 8052.

75. *Id*.

76. Hesse, *supra* note 2, at 1087.

77. *Id*. at 1081.

78. *Id*. at 1088.

79. *Id*. at 1080.

80. 82 Fed. Reg. 12, 6294, 6294 (Jan. 19, 2017) (to be codified at 42 CFR Part 100).

symptoms, "pain occurs within [48 hours of vaccination], "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and "[n]o other condition or abnormality is present that would explain the patient's symptoms."[81]

SIRVA is different from the other injuries and conditions on the Vaccine Injury Table because, prior to HHS's 2010 report, it was not a pre-existing medical condition recognized by doctors, as are the other conditions on the Table. The initial 1989 table included the following conditions: anaphylaxis, encephalitis, hypotonic-hyporesponsive collapse, residual seizure disorder, and paralytic polio, all of which were established medical conditions treated regularly by doctors that existed prior to the creation of the VICP.[82] In its 2017 proposed rule, HHS added several new conditions to the Table "where the scientific evidence either convincingly supports or favors acceptance of a causal relationship between certain conditions and covered vaccines" based on reports from the IOM and the Advisory Commission on Childhood Vaccines ("ACCV").[83] Other conditions added to the Table in 2017 for various covered vaccines include vasovagal syncope,[84] chronic arthritis,[85] and thrombocytopenic purpura,[86] all of which were also established medical conditions prior to their connection to the VICP.

The evidentiary problems that the lack of consideration of the *Daubert* factors poses, as discussed above, is particularly salient with regards to SIRVA because it is not an established medical condition.[87] I do not mean to suggest that it is impossible for a new, not previously understood condition to arise out of claims filed with the VICP, but rather that by adding SIRVA to the Table without mentioning its novelty sub silentio makes Vaccine Court into an unregulated site of medical research.[88] In that way, adding SIRVA to the Table and therefore not requiring Petitioners to prove causation-in-fact eliminates the unpredictability and the evidentiary problems faced by the VICP with regard to SIRVA cases.[89]

However, adding SIRVA to the Table fundamentally shifts the patient population receiving compensation away from the original population—children—that the Act meant to protect. Over 99.2% of SIRVA cases filed between 2010 and 2019 were filed by adults, and between 2016 and 2019, $119,154,985 has been

81. *Id.* at 6296.

82. *Id.*

83. 82 Fed. Reg. 12 at 6295.

84. *Id.* at 6304 ("Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine.").

85. *Id.* at 6302 ("Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.").

86. *Id.* at 6303 ("This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm3 with normal red and white blood cell indices.").

87. *See* Hesse, *supra* note 2, at 1079 (explaining that SIRVA is a condition established by HHS researchers).

88. *See* Boxler, *supra* note 51, at 1352.

89. *Id.*

paid out of the Fund to SIRVA Petitioners, the vast majority of whom are adults.[90] Compensating adults in this way runs contrary to the original intent of the Act, which, after all, is named The National Childhood Vaccine Injury Act. Indeed, the mandatory vaccination laws that spurred a desire for a means of compensation for adverse events were ones aimed at children, specifically, who needed these vaccinations to enroll in Public Schools.[91] The Act establishes children as a priority in other ways, too, namely via the creation of the Advisory Commission on Childhood Vaccines and the implementation of measures for "Assuring a 'Safer Childhood Vaccination Program in the United States.'"[92] Thus, making it easier for SIRVA Petitioners to receive compensation means that children, who were the initial main targets of the legislation, are receiving less compensation.

Adding SIRVA to the Table also shifts the incentive structure of The Act because the excise tax paid per dose by vaccine manufacturers can now more easily go to petitioners who suffered an injury due to incorrect *administration* of the vaccine rather than due to a manufacturing error. Indeed, the Act insulates both "administrator[s]" and "manufacturer[s]" from a vaccine-related injury or death law suits, however the content of The Act focuses primarily on the conduct of manufacturers.[93] Firstly, it is the vaccine manufacturers, producers, and importers who pay into the Vaccine Injury Compensation Fund through a seventy-five-cent excise tax on each dose.[94] This funding structure implies that the tax replaces the role of liability insurance for these manufacturers, who, by paying the tax to the government are shielded from tort law suits. In 2021, members of Congress introduced the Vaccine Access Improvement Act, which, if passed, would even more strongly intertwine the manufacture's tax with the Vaccine Table.[95] This proposed legislation would automatically impose the excise tax on vaccines that HHS adds to the Table. In practice, this would mean that the manufacturers of the vaccines against which Petitioners are filing claims would be funding the damages for those Petitioners, thereby strengthening the analogy that the VICP works as an incentive for manufacturers to produce safer vaccines.[96]

Secondly, the recording and reporting of information section prioritizes information about the vaccine itself rather than the procedure for administering it: The Act requires recordkeeping of "the vaccine manufacturer and lot number of the vaccine," and the "name and address, and if appropriate, the title of the health care provider administering the vaccine."[97] While information about the administrator is taken down, only the person's contact information remains, [98] which will

90. 85 Fed. Reg. 139, 43795, 43798 (July 20, 2020) (to be codified at 42 CFR Part 100).
91. *See* Reich, *supra* note 10, at 56.
92. *See* The National Childhood Vaccine Injury Act 300aa-5, 300aa-25.
93. *Id*. at 1334.
94. 26 USC § 4131 (2018)(b)(1).
95. *See* Lloyd Doggett, H.R. 3656 (117th Congress), *Vaccine Access Improvement Act of 2021*.
96. *See id*.
97. The National Childhood Vaccine Injury Act 300aa-25(a)(2).
98. *Id*.

not meaningfully aid in assessing whether the vaccine was injected correctly. Indeed, meaningful inquiry into the actual administration of the vaccine would require information about the injection process, which arm was injected, and where on the arm the needle was inserted. The drafters of The Act in 1989 had no way of knowing that SIRVA claims would come to make up half of the claims in the program. This development perverts the Act's current funding structure and does nothing to prevent cases of SIRVA.

During the notice and comment period for its proposed modifications to the Table, HHS demonstrated its unwillingness to consider modifications to the program in light of the challenges that SIRVA presents. Indeed, one commentor "indicated a belief that SIRVA is due to lack of education on proper injection technique. The commenter further stated that the CDC should make SIRVA, which the commenter believes is 100 percent preventable, a priority."[99] This comment speaks to the real root of the issue: the VICP is not set up to reduce the number of SIRVA cases because taxing the manufacturers per dose is not incentive for that issue. HHS's lackluster and generic reply was unresponsive to this commenter's point: "This final rule will add SIRVA as an injury associated with certain vaccines on the Table. In the VICP claims are adjudicated by special master in the Court. SIRVA prevention activities are not within the scope of this final rule."[100]

IV. SIRVA DURING THE PANDEMIC

Since 2016, SIRVA claims have continued to increase—likely because adding it as a cognizable condition to the Vaccine Injury Table provides Petitioners with a much easier route to compensation than if SIRVA was not on the Table[101] – however HHS's policies have not followed any sort of predictable trajectory. Instead, it has leveraged confidence in the Covid-19 vaccine as a reason to keep SIRVA on the Table demonstrating that the absence of evidentiary standards to guide the VICP leaves no scientifically-backed ethical standard guiding HHS's policy conclusions.

In July of 2020, HHS issued a notice of proposed rulemaking indicating the Department's plan to remove SIRVA from the Table under a narrower reading of the Vaccine Act requiring the injury be casually related to the vaccine itself, not its administration.[102] In January of 2021, HHS published this rule in final form

99. 82 Fed. Reg. 12 at 6295, 6296 (Jan. 19, 2017) (to be codified at 42 CFR Part 100).

100. *Id*.

101. 85 Fed. Reg. 139 at 43798 (stating that in 2017, Petitioners filed 605 SIRVA claims; in 2018, 671 SIRVA claims, and in 2019, SIRVA 711 claims. Between 2017 and 2019, SIRVA claims made up 52% of all claims filed in the VICP.).

102. 85 Fed. Reg. 139 at 43798. This proposed rule also included removing vasovagal syncope from the Table because it is an injury due to the incorrect administration of the vaccine rather than the vaccine antigens themselves. Vasovagal syncope is the loss of consciousness caused by a transient decrease in blood to the brain. Like SIRVA, vasovagal syncope was added to the Table in 2017. Unlike SIRVA, vasovagal syncope is an established medical condition dating back to the early 1900s and it is not related exclusively to vaccines, but rather can occur when the body overreacts to any startling trigger including the site of blood or extreme

using the same narrower reading of the Act.[103] HHS cited six main reasons to support its position that the Act should be read narrowly. First, the Federal Court has explained that enabling the Act to apply to negligence that is not related to the vaccine's effects could include situations like an administrator dropping a baby while administering a vaccine.[104] Second, because the definition of vaccine-related injury in the Act carves out an exception for "an adulterant or contaminant intentionally added to the vaccine" it suggests Congress's intent was to allow suit only when the injury was not caused by individual fault.[105] Third, negligent administration can occur for any vaccine, not just the vaccines covered under the Act; it would be seemingly arbitrary to provide compensation for negligent administration of some vaccines but not others.[106] Fourth, Congress protected manufactures from liability from "unavoidable" side effects that occur even when the vaccine was properly prepared, which indicates Congress's intent to preserve state tort remedies for avoidable injuries.[107] Fifth, the reporting requirements are inadequate if the VICP was designed to compensate for negligence by the administrator.[108] Sixth, Congress empowered the Secretary of HHS to make improvements in the administration of vaccines, thereby implying that the compensation program does not cover that issue.[109]

HHS also suggested taking SIRVA off of the Table on public policy grounds. Indeed, leaving SIRVA on the Table does not incentivize administrators to improve or get training in vaccination technique, and because VICP proceedings are generally not available to the public, vaccine administrators may not even be aware that they used incorrect technique.[110] Furthermore, the proliferation of SIRVA cases in the VICP leaves less funding available for people who sustained unavoidable injury that did not result from improper administration.[111] Relatedly, one comment noted, "Some commenters believe that SIRVA and vasovagal syncope cases submitted to the VICP has also contributed to delayed process in awarding monies to those with valid claims related to the vaccine itself," to which the HHS responded, "The Department agrees."[112] Simply agreeing with a statement about backlog framed by "some commenters believe" does not provide any new information, nor does it confirm that delays exist because of SIRVA

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emotional distress. *See Vasovagal Syncope,* MAYO CLINIC [https://perma.cc/X7YF-85DW]. Furthermore, vasovagal syncope has not dominated the VICP like SIRVA has. *See* Hesse, *supra* note 2. Thus, while the reasons to remove SIRVA from the Table may also apply to vasovagal syncope, this note's focus is exclusively SIRVA.

103. 86 Fed. Reg. 12, 6249, 6252 (Jan. 21, 2021) (to be codified at 42 CFR Part 100).

104. 85 Fed. Reg. 139 at 43796 (citing Amendola v. Sec., Dept. of Health & Human Servs., 989 F.2d 1180, 1187 (Fed. Cir. 1993)).

105. 85 Fed. Reg. 139 at 43796.

106. *Id*. at 43796-97.

107. *Id*. at 43797.

108. *Id*.

109. *Id*.

110. *Id*.

111. *Id*. at 43798.

112. 86 Fed. Reg. 12 at 6252.

applications. But it is reasonable to believe that awards might be meted out faster with fewer cases in the program.

HHS's narrow reading of the Act makes it ultimately unclear as to whether its actions would bar all future SIRVA petitions, or simply eliminate the presumption of cause-in-fact.[113] Indeed, petitioners successfully brought SIRVA claims through the VICP before it was added to the Table in 2017 by using medical experts to prove that the vaccine was a cause-in-fact of their individual cases of SIRVA, and removing it from the Table should allow SIRVA claims to proceed as they did pre-2017. However, HHS's response to one of the comments on its rule casts doubt on whether that would be the case. One comment reads, "Not all SIRVA is related to improper injection technique, and some or all cases of SIRVA result from the antigen itself, not just the needle placement."[114] HHS's response was a reiteration of the agreement within the scientific community that SIRVA is caused by improper vaccine administration, however this response suggests that it is impossible that a case that meets the criteria for SIRVA (pain in the shoulder, onset within 48 hours, lasting for more than six months) to be a result from the vaccine itself.[115] HHS cites two case studies of SIRVA to back up its statement,[116] unpersuasive evidence for such a sweeping claim. Indeed, one of the core tenets of science is that no theory can be disproven; rather, hypothesis can only be supported and again and again. Thus, it is scientifically impossible to proclaim that a legitimate vaccine antigen-induced case of SIRVA could not occur, and petitioners should be allowed to file such a claim with the VICP and seek to prove causation-in-fact.

Also in its rule, HHS contends that removing SIRVA from the Table will result in increased confidence in vaccines and science among the general public.[117] The last paragraph of the long justification for this new rule argues that the dramatic increase in overall VICP claims due to SIRVA's place on the Table "erroneously suggests that vaccines are less safe than they in fact are… Thus reductions in VICP petitions, particularly those claiming SIRVA, will support the overwhelming scientific understanding that vaccines are both safe and effective."[118] Here, HHS makes the claim that a high number of claims filed in the VICP—whether ultimately compensation or not—would attract negative attention to vaccines because of more reports of injuries.[119] Whether HHS was aware of it or not in July of 2020, four months into the Covid-19 pandemic, this line of reasoning was a harbinger of the debates to come over Covid vaccines.

When President Biden assumed the Office of the President, HHS's policy priorities changed, resulting in another reversal: HHS withdrew the rule removing

113. *Id*. at 6254.
114. *Id*.
115. *Id*.
116. *Id*.
117. 85 Fed. Reg. 139 at 43798.
118. *Id*.
119. *Id*.

SIRVA from the Table. SIRVA's removal was scheduled to go into effect on February 22, 2021, but it was delayed by the Biden Administration via the "Regulatory Freeze Pending Review" memorandum issued on the second day of his presidency, which postponed the effective date sixty days for rules published in the Federal Register but not yet in effect.[120] After issuing a proposed withdrawal of the rule in March of 2021, HHS published a final withdrawal in the Federal Register on April 22, 2021.[121]

HHS's policy justification for keeping SIRVA[122] on the Table was the same justification for removing it from the Table that HHS used several months prior: namely, that keeping SIRVA on the Table would increase public confidence in vaccines amidst the Covid-19 vaccine emergency.[123] While the Final Rule stated that decreased claims filed in the VICP will make vaccines appear safer to the public, in withdrawing the rule, HHS states that continuing to cover SIRVA will give the appearance of a stronger safety net and a government willing to take responsibility.[124] The Final Withdrawal of the rule states, "it is not appropriate to remove categories of vaccines and types of injuries from the Table in the midst of the pandemic, especially in light of the Federal Government's unprecedented vaccination effort and data showing lower rates of routine immunizations."[125] Here, the logic is that should SIRVA no longer be covered by the Table, it might disincentivize the public from receiving the Covid-19 vaccine; even though the COVID-19 vaccine is not covered under the VICP, meaning petitioners could not be compensated for *any* adverse effect it causes, the importance of general vaccine confidence during a pandemic is of the utmost importance.[126] However, in light of reporting about vaccine hesitancy that suggests it is one's core beliefs that determine whether one receives the vaccine, it is unclear if HHS decision had any effect.[127]

HHS is also concerned about the people administering the COVID-19 vaccine. More specifically, HHS cites an amendment to the Public Readiness and Emergency Preparedness Act to expand the groups of people qualified to administer Covid-19 vaccines in order to get as much of the public vaccinated as

120. Ronald A. Klain, Regulatory Freeze Pending Review, WHITEHOUSE.GOV (Jan. 20, 2021) [https://perma.cc/3XKN-L42Q].

121. 86 Fed. Reg. 76, 21209 (Apr. 22, 2021) (to be codified at 42 CFR Part 100).

122. And vasovagal syncope.

123. Revision to the Vaccine Injury Table: Notice of Proposed Withdrawal, HHS, 7-8 (Mar. 17, 2021).

124. *See* 86 Fed. Reg. 76 at 21213 ("HHS agrees that removing compensable table injuries, like SIRVA and vasovagal syncope, might run counter to public health goals and increase vaccine hesitancy because doing so could remove the possibility of an accessible and efficient forum for compensation for these injuries.").

125. *Id*.

126. *See* Notice of Proposed Withdrawal at 8. ("Although the COVID-19 vaccine is not part of the VICP, HHS is cognizant of the fact that any action taken that concerns administration of other vaccine could impact the National Strategy's goals and affect the federal government's effort to combat COVID-19").

127. *See* Tavernise, *supra* note 8 ("'At the root are these moral intuitions—these gut feelings—and they are very strong . . .'").

possible.[128] In light of that reality, HHS is

> concerned that [removing SIRVA from the Table] could have a negative impact on vaccine administrators, which would be at odds with the federal government's efforts to increase vaccinations in the United States to respond to the Coronavirus Disease 2019 pandemic, as well as to make up for observed delays in routine vaccinations that have occurred during the pandemic.[129]

Implied in this sentence is that potential vaccine administrators might be worried about potential liability for SIRVA and decide not to administer the much-needed COVID-19 vaccine. While the removal of SIRVA from the Table took place mid-pandemic, it is true that the first Covid-19 vaccines were just being distributed at that time, and so there was less passion and impetus to instill vaccine confidence in the public. But it is nonetheless noteworthy that nothing in HHS's withdrawal of the final rule disputes any of the textual, historical, or structural reasons for removing SIRVA from Table.

Indeed, the other reasons cited for keeping SIRVA on the Table are procedural ones: HHS states that the promulgation of the January 21, 2021 Final Rule was "irregular in its haste" and that HHS did not fully engage with the ACCV or the public.[130] Specifically, the draft of the Notice of Proposed Rulemaking was not officially provided to the ACCV, the draft was not discussed publicly by the ACCV nor was a representative of HHS made available to answer questions about it, and for those reasons the ACCV unanimously voted to oppose the rule.[131] In response to a comment on the proposed withdrawal, HHS further explained that the agency requires "sufficient time to carefully and methodically consider the state of the science regarding SIRVA"[132] Thus, the rule removing SIRVA from the Vaccine Injury Table was withdrawn before it ever went into effect, and, at least for now, SIRVA remains a cognizable injury for which petitioners can receive compensation without going through the onerous and unpredictable process of proving causation-in-fact, thereby insulating vaccine administrators from liability for preventable mistakes.

V. CONCLUSION: THE FUTURE OF SIRVA

The VICP was a significant federal response to vaccine development in the United States, but its structure and rules, which lack an ethical core underlying all claims, leave the court vulnerable to exploitation. Specifically, not including

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128. 86 Fed. Reg. 76 at 21211 (including dentists, EMTs midwives, optometrists, paramedics, physician assistants, podiatrists, respiratory therapists, and veterinarians).

129. Notice of Proposed Withdrawal, *supra* note 126, at 8.

130. 86 Fed. Reg. 76 at 21210.

131. *Id*. (explaining that opposition vote was on the grounds that 1. no representative from HHS provided evidence or reasoning behind the rule, 2. SIRVA is caused by vaccines, 3. exposing liability to administrators could be disincentivizing, and 4. the draft of the rule did not adhere to ACCV's guiding principles for changing the Table).

132. 86 Fed. Reg. 76 at 21212 (stating that the last time HHS completed a comprehensive review of the literature was before adding SIRVA to the Table in 2017).

SIRVA on the Table gives petitioners evidentiary leeway and leads to unpredictable outcomes as they attempt to prove causation-in-fact. But including SIRVA on the Table strains the original intent and structure of the National Childhood Vaccine Act, pre-empting what most likely should be a medical malpractice state court case. One possibility is to keep SIRVA on the Table, but put a cap on damages such that SIRVA is not eating an entire year's worth of funding. Another possibility is to amend The Act to clarify what types of injuries should be within the jurisdiction of the VICP.

Ultimately, though, debates about how to treat SIRVA within the VICP obscure what should be the most important question: since SIRVA is preventable with proper vaccine administration technique, how can we train vaccine administrators such that there are fewer cases of SIRVA in the future? A national certification program for all vaccine administrators, for example, could make progress towards a goal of eliminating SIRVA entirely.