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Department of Health Resources and Services Administration (HRSA)
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Re: Federal Register Docket No. HRSA-2020-0002 – Notice of Proposed Rule Change -
National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table.
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The National Vaccine Information Center (NVIC) submits this referenced, written public comment in response to the above referenced Notice of Proposed Rule Change (NPRM)¹ published in the *Federal Register*. NVIC opposes the proposed changes to remove shoulder injury related to vaccine administration (SIRVA) and syncope from the Vaccine Injury Table (VIT) in the national Vaccine Injury Compensation Program (VICP) for the reasons outlined below.

Background - NVIC's History with the National Childhood Vaccine Injury Act of 1986 (1986 Act)

NVIC co-founders Jeffrey Schwartz, Barbara Loe Fisher and Kathi Williams, whose children had suffered serious reactions to the DPT vaccine, founded the charitable non-profit educational organization, Dissatisfied Parents Together (DPT), in the spring of 1982. In 1989 the organization opened the National Vaccine Information Center (NVIC) and expanded its mission of “preventing vaccine injuries and deaths through public

education” to include defending the ethical principle of informed consent to medical risk-taking, including vaccine risk-taking. For more than 30 years, NVIC has publicly called for the institution of informed consent protections in U.S. medical and public health policies and laws to protect the human right of informed consent to vaccination.²

NVIC’s co-founders worked for four years with parents and Congress on the National Childhood Vaccine Injury Act of 1986 at the request of congressional legislative staff. Importantly, congressional intent was to create vaccine safety mechanisms in the childhood vaccination system while creating an expedited no-fault administrative federal vaccine injury compensation program (VICP) alternative to filing a civil court lawsuit against a pharmaceutical company or vaccine provider.

The Act’s legislative history demonstrates that Congress intended to make vaccine safety a priority by including vaccine safety informing, recording, reporting and research provisions in the law, and also to protect the national childhood vaccine supply by providing parents with a no-fault, less adversarial, less expensive and expedited administrative alternative to a vaccine injury lawsuit, which would help maintain parental trust in and support for the childhood vaccination program.

The VICP created in the 1986 Act was deliberately designed by Congress to give the benefit of doubt to plaintiffs and to avoid compelling the majority of petitioners to prove “causation in fact” for what are known today as off-table injuries. The spirit and intent of this design was for the government to err on the side of the plaintiff by awarding generous and expedited compensation in the absence of a more plausible biological explanation for the child’s injury or death following vaccination via recognized vaccine injuries listed on the federal vaccine injury table (VIT). Compensation also was to be awarded if there was evidence that a vaccination significantly aggravated a pre-existing health condition in the child and led to a substantial deterioration in the child’s health.³

Among the unique contributions that NVIC’s parent co-founders made to the 1986 Act was to secure the following requirements:

- All vaccine providers must give parents or guardians and individuals a CDC vaccine information statement (VIS), which contains vaccine benefit and risk information, for all routinely recommended childhood vaccines *prior* to being vaccinated;⁴
- All vaccine providers must record the vaccine manufacturer’s name and lot number and record serious health problems, including hospitalizations, injuries and deaths, following vaccination in the permanent medical record;⁵
- All vaccine providers must report adverse events following vaccination to the publicly accessible federal Vaccine Adverse Event Reporting System (VAERS);⁶
- The Secretary of the Department of Health and Human Services (DHHS) must establish a National Vaccine Program to “achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.”⁷

- The Secretary must “promote the development of childhood vaccines with fewer and less serious adverse reactions” and to “make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines,”⁸
- The Secretary of DHHS must “arrange for a broad study of the risks... to children associated with each vaccine set forth in the Vaccine Injury Table” and to “establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include the circumstances under which any such vaccine should not be administered; the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.” The Act stated that the Secretary “shall request the Institute of Medicine of the National Academy of Sciences to conduct the study” and do it “in consultation with the Advisory Commission on Childhood Vaccines.”⁹
- DHHS must secure the participation of “legal representatives of children who have suffered a vaccine-related injury or death” and “members of parent organizations concerned about immunization” and other members of the public on federal vaccine advisory committees, including ACCV and the National Vaccine Advisory Committee, to advise on vaccine “research priorities and other measures the Director [of the National Vaccine Program] could take to enhance the safety and efficacy of vaccines.”^{10 11}

The Role of the Institute of Medicine (IOM), National Academy of Sciences

Because parents of vaccine injured children participating in the legislative process developing the 1986 Act had concerns about the influence of pharmaceutical corporations marketing vaccines in the U.S. and conflicts of interest within federal health agencies simultaneously responsible for developing, regulating, making policy for and promoting state mandated vaccine use, as well as monitoring vaccine safety, the IOM was the preferred entity named in the 1986 Act to review and analyze vaccine safety science. This was largely due to the IOM’s history of making an effort to assemble committees with broad representation and the utilization of a deliberative and transparent process and public engagement, unlike other government and industry funded organizations.¹²

The role intended for IOM report findings related to vaccine injury was to inform, update and expand the VIT with the addition of evidence-based injuries, which would in turn have the effect of expediting vaccine injury compensation and align with the overarching spirit and intent of the 1986 Act. The role of the ACCV in this context is to review IOM vaccine causality findings, which previously has been accomplished through IOM and

DHHS presentations to the ACCV.^{13 14 15 16 17} These presentations of evidence inform the Commission's recommendations to DHHS on the inclusion of IOM findings on the VIT and is part of the Commission's federal obligation under the 1986 Act.

Evidence Base for SIRVA and Syncope

As DHHS considers the proposed changes to the VIT, it is important to note that the number of federally recommended vaccinations have almost tripled between 1986 and 2016.^{18 19} Yet, as the number of recommended vaccines has expanded, there continue to be significant and growing gaps in the scientific understanding of vaccine risks.

In 2009, HRSA, an agency within DHHS, engaged the IOM to review the epidemiologic, clinical, and biological evidence of vaccine adverse health outcomes associated with "injected related events".²⁰ More specifically, syncope and deltoid bursitis, known as SIRVA, were part of a much larger HRSA list provided to the IOM for review. The list was based on petitioner claims to the VICP.^{21 22} DHHS also explicitly stated they had searched the VICP database and found 13 cases of SIRVA in which 12 were considered valid injuries and this fact was reported to the IOM for their review.^{23 24}

As has become a long-standing trend with regard to IOM vaccine causality statements, due to the continued lack of high quality scientific research and/or absence of research to inform vaccine injury,^{25 26} an IOM committee of scientific and medical experts was once again prevented from making vaccine causality statements for 135, or 85 percent,²⁷ of the 158 vaccine adverse events in their comprehensive 2012 report *Adverse Events Associated with Childhood Vaccines: Evidence and Causality*.²⁸

However, the 2012 IOM committee report did find strong biological mechanism evidence²⁹ to support a causal relationship between the injection of vaccines for the HRSA requested outcomes of syncope and SIRVA.³⁰ Additionally, the IOM did not rule out the ingredients in vaccines themselves as being involved in the biological mechanisms for these injuries, contrary to statements within the NPRM.^{31 32 33}

DHHS quickly presented the IOM findings to the ACCV, along with supporting evidence. Subsequently, and with the encouragement from DHHS, the ACCV unanimously recommended the addition of syncope and SIRVA injuries to the VIT at the March 8, 2012 ACCV meeting.³⁴ SIRVA and syncope were officially added to the VIT by DHHS in January of 2017.³⁵

Additionally, during ACCV meetings, numerous health care professionals have expressed support for retaining SIRVA on the VIT. One such professional was Dr. Srikumaran, MD, MBA, MPH, an Associate Professor of Orthopedic Surgery at Johns Hopkins Shoulder and Sports Medicine, who gave a professional opinion based on his clinical experience, that vaccine administration is solely responsible for all of the cases of SIRVA, pointing out that the injection of other medications or blood products into the bursa or joint do not cause SIRVA like injuries.³⁶ His written public comments also included research to support the causal role of vaccine products in the development of SIRVA. Dr Srikumaran also added that removing SIRVA and syncope from the VIT would significantly increase the cost of liability insurance for practitioners and vaccine manufacturers.³⁷

The Vaccine Injured Petitioners Bar Association also provided written comments on the NPRM noting that studies, which DHHS cites in the NPRM as supporting the removal of these injuries, in fact provide evidence that antigens in the vaccines may well be responsible for the development of SIRVA.^{38 39}

NVIC raised concerns about syncopal episodes specific to HPV vaccine in early 2007, and noted the higher incidence of syncopal episodes. NVIC called upon the FDA and CDC to warn parents and doctors that individuals receiving HPV vaccine should be monitored for 24 hours after vaccination for syncopal episodes, due to the fact that VAERS reports indicated that twice as many syncopal episodes occurred in children receiving GARDASIL vaccine.⁴⁰ NVIC followed up on these concerns with an analysis of VAERS reports relating to HPV vaccine adverse events in August 2007, and noted 239 syncopal episodes that resulted in many head injuries and fractures.⁴¹ This analysis also called upon the CDC to issue an advisory and to amend their guidance.

The Centers for Disease Control (CDC) currently states that with regard to syncope, the role of vaccines has not been ruled out:

“Fainting after getting a vaccine is most commonly reported after three vaccines given to adolescents: HPV, MCV4, and Tdap. Because the ingredients of these three vaccines are different, yet fainting is seen with all of them, scientists think that fainting is due to the vaccination process and not to the vaccines themselves. However, there is not yet a definite answer about whether an ingredient of the vaccines is responsible for the fainting or if adolescents are simply more likely than children or adults to experience fainting.”⁴²

The CDC also notes that a VAERS study on syncope due to vaccine administration can lead to serious injuries, and that syncope may be underreported and/or reported under seizures or convulsions in the VAERS database.⁴³ The CDC has also additionally stated:

“Fainting itself is generally not serious, but harm from related falls or other accidents can cause injury. The main concern is head injury. In a study of syncope-related VAERS reports, 7% of the fainting reports were coded as serious; 12% of these involved head injuries. Although fainting itself might or might not be preventable, it is important to prevent injuries when people do faint.”⁴⁴

NVIC notes that to date DHHS has failed to present any new evidence published since the 2012 IOM report to the Advisory Commission for Childhood Vaccines (ACCV). Deliberations for previous changes to the VIT were conducted in public meetings of the ACCV over a period of many months.⁴⁵ This departure from established process subsequently resulted in a unanimous vote by the ACCV to oppose DHHS’ proposed rule change to remove SIRVA and syncope from the VIT, due to lack of evidence presented by DHHS for their consideration.⁴⁶

Faulty Interpretation of the 1986 Act

The position that DHHS has taken in the NPRM to primarily exclude these recognized injuries from the VIT rests on their interpretation of 1986 Act relating to injury and definition, citing 42 U.S.C. §§ 300aa-33(5), 42 U.S.C. §§ 300aa-11(a)(1) and 42 U.S.C. §§ 300aa-11(a)(9).

However, DHHS has failed to provide context for the whole of the definition contained in the 1986 Act under 42 U.S.C. §§ 300aa-11(b)(1)(A), which states:

*“...any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died **as the result of the administration of a vaccine set forth in the Vaccine Injury Table** may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.”⁴⁷*

Currently, the 1986 Act does not preclude vaccine administration and related injuries⁴⁸ from meeting compensation requirements, and as originally passed by Congress in November of 1986⁴⁹ the definition of vaccine-related injury included injuries due to other components in vaccines. It is also clear from the addition of injection related injuries to the DHHS list of adverse events for IOM consideration,⁵⁰ and their subsequent searching of petitions for SIRVA that were additionally provided to the IOM for review, that administration of vaccines was already interpreted by DHHS to be embodied within the 1986 Act as compensable.

Notably, the VIT definition of SIRVA states that vaccine antigens may have a role in the development of SIRVA.^{51 52 53}

Trust Fund Remains Fiscally Sound and Exceeds Current Needs

DHHS also has taken the position in the NPRM that continuing to award compensation for SIRVA and syncope vaccine injuries threatens to deplete the VICP’s trust fund.

However, data presented by DHHS demonstrates that for the past two fiscal years the majority of petitions (54 percent) filed with the VICP were for SIRVA injuries,^{54 55 56} data also demonstrates that the trust fund is fiscally sound. Reported income from the VICP is over \$380 million for fiscal year ending 2020, which exceeds the total annual compensation awarded by VICP since the addition of these injuries to the VIT.⁵⁷

This healthy state of the trust fund was also echoed in a March 2000 report to Congress from the U.S. General Accounting Office, which stated:

“The \$1.46 billion trust fund balance appears to provide a more than adequate reserve, given experience to date for claims payments and related administrative costs.”⁵⁸

Notably, the current balance in the trust fund, which was reported to the ACCV for the fiscal year ending 2020, demonstrates that it is even healthier now, with a balance at

almost \$4.1 billion.⁵⁹ In point of fact, the trust fund continues to grow despite a continued narrowing of the VIT by DHHS for the purpose of reducing federal compensation to assist the vaccine injured.

SIRVA, Syncope Removal from VIT Will Increase Workloads and VICP Program Costs

While the NPRM also states concern about “dubious” SIRVA petitions, we note that the vast majority of non-SIRVA vaccine injury claims are rejected and not compensated by the VICP. As of Dec. 1, 2020, DHHS reported that only 34 percent (7,705 out of 22,685) of all vaccine injury petitions filed with the VICP have been compensated.⁶⁰ The VICP routinely dismisses cases that do not meet well-established criteria and SIRVA and syncope are not exceptions to the VICP’s history of rejecting nearly two out of three vaccine injury compensation claims.

With regard to the 1986 Act’s intent, when the VICP was first implemented, 74 percent of injury claims were for children with acknowledged vaccine injuries listed on the VIT. By 2015, that number had dwindled to two percent, while the number of off-table claims had skyrocketed to 98 percent.⁶¹

This massive reduction in petitions qualifying for on-table injuries in an expedited, less adversarial no-fault administrative compensation process means that petitioners are forced to hire an attorney to prove vaccine injury in the U.S. Court of Federal Claims in contested proceedings similar to a court trial.⁶² As noted earlier in this public comment, the design of the VICP was intended to avoid off table vaccine injury claims, in favor of expeditious, less expensive, less traumatic and more just federal compensation via acknowledgement by DHHS that, in the absence of a more biologically plausible explanation, plaintiffs should be awarded compensation if their injuries appear on the VIT.

VICP data provided to the ACCV by DHHS indicates a decrease in the number of SIRVA settlements as a result of its inclusion on the VIT, which demonstrates adherence to the spirit and intent of the 1986 Act. Removal of SIRVA (and syncope) from the VIT would most certainly reverse that accomplishment and reduce the number of claims that can be resolved quickly rather than being contested in the Court of Federal Claims, which will only increase VICP administrative costs and provide no relief to caseloads that current special masters are struggling to handle.^{63 64}

NVIC is not alone in questioning the impact that the removal of SIRVA and syncope will have on the VICP’s ability to deliver as Congress intended. Mike Milmo, a vaccine injury attorney and former DOJ attorney for the VICP, was critical of DHHS’ caseload concerns and noted that by removing SIRVA and syncope from the VIT, DOJ staff would actually face increased workloads by having to spend more time trying to negotiate settlements rather than expediting compensation by conceding cases for injuries that appear on the VIT.⁶⁵

These themes were also echoed in a 1999 report from the U.S. General Accounting Office on the operation of the VICP, which stated:

“HHS’ recent changes to the vaccine injury table will make the process easier for some people to obtain compensation, but will make it more difficult for a larger number to do so. This is because far more claims have historically been associated with injuries HHS removed from the table than with injuries HHS added to it. For example, about half of the awards made since the program’s inception have been for neurological injuries that HHS later removed from the table in 1995 and 1997. Removing these injuries shifts the burden of proof to the petitioner, making it more difficult to qualify for compensation under VICP.”⁶⁶

In 2014, in congressionally requested report on the operational status of the VICP,⁶⁷ the GAO again noted the adversarial nature of the program and stated:

“Since fiscal year 1999, HHS has added six vaccines to the vaccine injury table (but has not added covered injuries associated with these vaccines to the table). This means that while individuals may file VICP claims for those vaccines, each petitioner must demonstrate that the vaccine that was administered caused the alleged injury. In general, each of the six vaccines was added within 2 years of the Centers for Disease Control and Prevention’s recommending it for routine administration to children and having an excise tax imposed. Since 1999, two vaccines, both of which had covered injuries associated with them, were removed from the vaccine injury table. See appendix II for the vaccines and injuries added and removed from the vaccine injury table since 1999. At the end of the fiscal year 2014, 16 vaccines were covered by the program, 8 of which did not have associated covered injuries on the table.”⁶⁸

Long Standing Significant Vaccine Safety Knowledge Gaps

The above statements by the GAO underscore the long standing significant vaccine safety knowledge gaps that existed at the time the National Childhood Vaccine Injury Act was passed in 1986 and still persist more than three decades later. These scientific knowledge gaps continue to exist, despite the findings by multiple National Academy of Sciences committees between 1991 and 2013 confirming that vaccines can and do carry known and unknown health risks that can be greater for some people than others, and despite repeated requests by parents of vaccine injured children and concerned health care professionals that biological mechanism and methodologically sound epidemiological studies must be done to prevent vaccine injuries and deaths and better inform federal agencies making decisions about who should receive vaccine injury compensation.

The long standing refusal by DHHS to make vaccine safety science a priority and fund research into the causes for and prevalence of vaccine injuries and deaths in the U.S., particularly investigation into the genetic, epigenetic, environmental and other individual risk factors that make some people more vulnerable to suffering adverse responses to vaccination,⁶⁹ combine to prevent evidence-based causality statements from informing the VIT. Therefore, lack of scientific knowledge about vaccine risks inhibits the awarding of less adversarial, less expensive, expedited federal vaccine injury compensation to vaccine injured plaintiffs, which ends up not only magnifying the suffering of vaccine injured plaintiffs but contributes to increased program costs.

The continued reluctance by DHHS to make vaccine safety research into the causes and risk factors for adverse responses to vaccination a priority is representative of DHHS' historic opposition to the passage of the 1986 National Childhood Injury Act that continues to be manifested by the agency's failure to uphold the 1986 Act's scientific research mandate, which requires ongoing research to reduce the risks of vaccine adverse reactions.^{70 71} This failure results in greatly contributing to the lengthy off-table settlement process that requires petitioners to prove "causation in fact", something that Congress intended to avoid when the VIT was created.

It is for the above reasons that NVIC opposes removal of syncope and SIRVA from the VIT. These injuries occur as a direct result of individuals being given CDC recommended vaccines and should be retained as on-table injuries in the VICP. NVIC requests that DHHS' withdraw this NPRM and instead seek to uphold the spirit and intent of the 1986 Act, particularly as it pertains to adding injuries to the VIT in recognition of Congress's intention to offer the vaccine injured less expensive, less traumatic, expedited, just and generous compensation as an alternative to filing a lawsuit against pharmaceutical corporations or vaccine providers.

Sincerely,



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