National Vaccine Information Center

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U.S. Department of Health & Human Services (DHHS) &
Department of Health Resources and Services Administration (HRSA)
c/o Ms. Tamara Overby, Acting Director
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Official Comment Submission: Regulations.gov

Re: Federal Register Docket No. HRSA-2021-0001 – National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Notice of Proposed Rulemaking; Public Comment Period; Delay of Effective Date. Document Citation 86 FR 9308.

The National Vaccine Information Center (NVIC) submits this additional written public comment in response to the above referenced Delay of Effective Date.[1] published in the *Federal Register.* NVIC continues its opposition to the proposed changes of removing shoulder injury related to vaccine administration (SIRVA) and syncope from the federal Vaccine Injury Table (VIT) in the national Vaccine Injury Compensation Program (VICP) for the reasons outlined below.

Additionally, NVIC appreciates this review of the final rule and additional opportunity to provide comment. We encourage HRSA and DHHS to again review our initial public comment on the NPRM submitted on January 12, 2021, as well as our comments contained herein, and seriously consider striking down this rule.

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

As noted in our initial public comment on Jan. 12, 2021,[2] NVIC has unique standing to provide comments on the VICP due to the work of NVIC's cofounders with Congress to draft and pass the National Childhood Vaccine Injury Act of 1986, which created the VICP and the VIT.

As previously stated, 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.

DHHS Final Rule Comments and Interpretation of the 1986 Act Remains Faulty

While DHHS has the legal ability to remove SIRVA and syncope from the VIT, doing so violates the spirit and intent of the law, which was 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.

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.[3]

Data presented by DHHS to the Advisory Commission on Childhood Vaccines (ACCV) demonstrates that since the inclusion of SIRVA and syncope in 2017 on the VIT, the majority of petitions (54 percent) filed with the VICP have been for SIRVA injuries.[4] [5] [6]

The removal of these injuries from the Table will reverse the course of the Act's legal intent of expanding the VIT to expedite compensation, which in essence implements avoidance of "causation in fact" cases.

As noted in our previous comment,[7] the Act does not preclude injuries resulting from vaccine administration,[8] [9] a point that DHHS agreed with in 2009 with their addition of injection related injuries to the list of adverse events for review by the Institute of Medicine (IOM).[10] The list was based on petitioner claims to the VICP,[11] [12] and DHHS explicitly stated they had searched the VICP database and found 13 cases of SIRVA, of which 12 were considered valid injuries.[13] [14]

Respectfully, the response by DHHS in the final rule regarding these facts is inconsistent, revisionist, and lacks scientific justification for proceeding with this rule.[15]

Evidence Base for SIRVA and Syncope

Though there has been a long-standing trend of a continued lack of high quality scientific research and/or absence of research to inform vaccine injury,[16] [17] in their 2012 report, *Adverse Events Associated with Childhood Vaccines: Evidence and Causality,* the IOM found strong biological mechanism evidence[18] to support a causal relationship between the injection of vaccines for the requested outcomes of syncope and SIRVA.[19] 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. [20] [21] [22]

These findings were presented to the ACCV by DHHS and the IOM with encouragement for their inclusion within the VIT multiple times between the issuing of the IOM report up to the formal rule issued by DHHS in January 2017. [23] [24]

As NVIC noted previously, during 2020 and the NPRM process, numerous health care professionals also expressed support for retaining SIRVA on the VIT based on their clinical experience[25] [26] with some noting that the injection of other medications or blood products into the bursa or joint do not cause SIRVA like injuries and provided the evidence base for consideration.[27]

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 provided evidence that antigens in the vaccines may well be responsible for the development of SIRVA.[28] [29]

NVIC also provided additional information relating to syncopal episodes post vaccination[30] [31] and noted that the Centers for Disease Control (CDC) currently states that with regard to syncope, the role of vaccines has not been ruled out.[32] Notably, the VIT definition of SIRVA states that vaccine antigens may have a role in the development of SIRVA.[33]

Regarding DHHS's general process of basing changes to the VIT on scientific evidence, DHHS has failed to follow its previous process of presenting evidence to the ACCV,[34] [35] [36] [37] [38] [39] [40] as well as failing to request a review of evidence[41] that has occurred since 2009 when the IOM was first requested by DHHS to consider injection-related injuries. It is clear that DHHS has not only switched its position, but has done so in a manner that lacks integrity and fails to provide transparency.

To all appearances, this rule-making process has deliberately skirted the intent of the Act and abused the authority given to DHHS, due to the failure to transparently engage, consider, explore and present the scientific evidence base, particularly given DHHS's history in advocating for integration of these injuries into the Table. DHHS's characterization of the ACCV's fact-based objection to the removal of these injuries as being "not adequately persuasive"[42] rings hollow, given the lack of effort on DHHS' part to provide scientific evidence to justify their actions.

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

The intent of the Act, as noted earlier, was a less adversarial no-fault administrative compensation process that avoided petitioners being forced to hire an attorney to prove vaccine injury in the U.S. Court of Federal Claims.[43]

Reports from the General Accounting Office in 1999 and 2014 note that narrowing of the VIT creates an adversarial process and shifts the burden to the petitioner, making it harder to be compensated for vaccine injuries.[44] [45]

While government and public health officials are concerned about "vaccine hesitancy" with regard to both federal routinely recommended vaccines [46] and COVID-19 vaccines,[47] implementation of this rule will not only increase hesitancy, but continue to take the VICP further away from the spirit and intent of the 1986 Act. It is clear that the enactment of this rule will fail to adequately inform the VIT or special masters adjudicating VICP claims, will fail to provide expeditious vaccine injury compensation to

plaintiffs with SIRVA and syncope injuries, and will provide no relief to VICP caseloads.[48] [49]

NVIC strongly encourages DHHS to reverse this rule, which was aggressively pursued and implemented in the last days of the previous Administration, and take steps to restore the VICP to the original intent of the 1986 Act.

Sincerely,

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Theresa K. Wrangham
Executive Director

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