The National Vaccine Information Center (NVIC) submits this additional written public comment in support of the proposal to withdraw the above noted final rule, which removed syncope and shoulder injury related to vaccine administration (SIRVA) from the federal vaccine injury table (VIT).

As previously noted in our public comments relating to this rule, NVIC co-founders are parents of DPT vaccine injured children who went on to establish the charitable non-profit educational organization, Dissatisfied Parents Together (DPT) in 1982, now known as NVIC. NVIC’s co-founders worked with Congress to secure vaccine safety informing, recording, reporting and research provisions in the Act, as well as had input into development of the VIT for the federal Vaccine Injury Compensation Program (VICP) included in the Act, which gives our organization unique standing to provide comment.

The retaining of these injuries on the VIT is consistent with the Act’s intent of expanding the VIT based on scientific evidence through the engagement of the National Academy of Medicine, formerly the Institute of Medicine (IOM) and the previously robust process initiated by the U.S. Department of Health and Human Services (DHHS) to add these injuries to the VIT.

NVIC additionally notes that, the federal compensation mechanism of the Act was specifically created to provide support to children who were injured or died after receiving federally recommended childhood vaccines. The majority of VICP claims were supposed to be administratively awarded without contest by DHHS and the Department of Justice, which is why a VIT providing guidelines for awarding compensation was included in the Act.

At the inception of the VICP, 74 percent of injury claims were for children with acknowledged vaccine injuries listed on the VIT. However, by 2015 these “on-table” vaccine injury claims had drastically decreased to just two percent of total claims with a corresponding increase in the number of off-table vaccine injury claims being 98 percent. These
increases in lengthy, off-table vaccine injury claims contested by DHHS, which require adjudication in the U.S. Court of Federal Claims, is largely due to systematic narrowing of the VIT by DHHS through rule-making authority and the continuing lack of federal funding of high quality bench science to inform the VIT.

Reports by the General Accounting Office (GAO) have noted that the impact of narrowing the VIT creates a more adversarial process by shifting the burden to the petitioner. This defeats congressional intent of providing families with a less adversarial, less traumatic, expedited administrative alternative to a vaccine injury lawsuit and makes it much harder for petitioners to be justly compensated for vaccine injuries. DHHS should responsibly address the legitimate high caseload concerns in more appropriate ways than punishing plaintiffs by further narrowing the VIT.

The impact of long standing, significant gaps in knowledge about vaccine safety, especially inadequate understanding of the biological mechanisms of vaccine injury and death, is a big reason why “off-table” claims continue to increase. Since the claims in the VICP began to be processed three decades ago, multiple reports authored by IOM committees between 1991 and 2013 noted the lack of high quality vaccine safety science research and published studies designed to explain the biological mechanisms of and genetic, epigenetic and environmental risk factors for vaccine injury and death. This lack of scientific knowledge about individual susceptibility to adverse responses to vaccination has consistently compromised the operation of the VICP and the integrity of the VIT, which serves as a guide for the awarding of federal compensation.

NVIC makes the following additional recommendations:

- Review previous changes to the VIT that have had the effect of narrowing the table and have made the VICP highly adversarial and inconsistent with IOM findings, with consideration for similar withdrawals of previous rules;
- Address inherent conflicts of interest at DHHS that inhibit the funding of methodologically sound vaccine safety research and contributes to the erosion of public trust in federally recommended vaccines.

Recently, the government has prioritized the addressing of “vaccine hesitancy.” The withdrawal of this rule, which makes it much harder for those who have suffered syncope and brachial neuritis after receiving federally recommended vaccines to be compensated, is a step toward restoring public trust in a federal program that was supposed to instill trust in the vaccine system.

Sincerely,

Barbara Loe Fisher
Co-founder & President

Theresa Wrangham
Executive Director

References

4. HRSA. (10) Shoulder injury related to vaccine administration (SIRVA). In: Vaccine Injury Table. Mar. 21, 2017; Pg. 8.