Chicago-Kent College of Law
C-K Law Group | Law Offices of Chicago-Kent

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SUBMITTED VIA FEDERAL E-RULEMAKING PORTAL

Re: Proposed rulemaking to remove SIRVA and syncope from the Vaccine Table

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To Whom It May Concern:

I am writing to express my opposition to Health Resources & Service Administration (HRSA)'s proposed rulemaking that would revise the Vaccine Table by removing "shoulder injury related to vaccine administration" (SIRVA) and vasovagal syncope, which is loss of consciousness (e.g., fainting) as covered injuries. I am a Clinical Professor of Law at IIT Chicago-Kent College of Law where I supervise a legal clinic focused on representing individuals injured by vaccines. The vast majority of my legal work for well over the past decade has involved litigating VICP cases within the U.S. Court of Federal Claims. In addition, I was appointed to the Advisory Commission on Childhood Vaccines (ACCV) by the Secretary of Health Services in late 2011 and served as a commissioner until January 2017. During my service on the ACCV, I was present for meetings (spanning several years) during which multiple presentations and discussions occurred involving HHS's proposal to add SIRVA and syncope to the Vaccine Table. In 2015, the ACCV on which I served voted unanimously in favor of the changes that resulted in the current version of the Vaccine Table which HHS now seeks to change.

I have read HHS's justification for the proposed rulemaking which would undo the carefully considered changes implemented in March 2017 and find the arguments in support of removing SIRVA and syncope to be lacking legally, scientifically, and from a public health policy perspective. I would point out further that the hasty and secretive manner in which HHS has pursued this rulemaking is in stark contrast to the comprehensive, inclusive, and thoughtful approach taken by HHS with respect to the 2015 table revisions in which I participated as a member of the ACCV.

To begin with, from a legal perspective, the plain language of the Vaccine Act allows for compensation when a "vaccine-related injury or death has occurred." 85 Fed. Reg. at 43795. It is undisputed that SIRVA and syncope are both injuries that occur in the setting of a vaccination. HRSA's legal argument that because SIRVA and syncope are injuries that can, or even frequently do, involve negligence by the vaccine administrator somehow transforms these injuries into uncovered injuries has no credible support from the text of the statute. HHS also provides no caselaw to support their novel interpretation of the Vaccine Act that an exception exists for "vaccine-related injuries" for injuries which potentially involve negligence. In fact, the Vaccine Act is predicated on the idea that any and all vaccine injuries, regardless of potential fault by manufacturers or administrators, should be pursued through the VICP. Not only is this clear from the plain language and the legislative scheme of the Act, but it is also fully supported by the congressional intent of the Act to "stabilize the vaccine market and facilitate compensation" by establishing a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." *Bruesewitz v. Wyeth*, 562 U.S. 223, *3 (2010) quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995).

In support of its strained and unprecedented interpretation of the Vaccine Act that any potential negligence by the vaccine administrator creates an exception to what historically has been deemed by HHS as a vaccine-injury, HRSA claims that "SIRVA and vasovagal syncope result from the use of improper—that is, negligent—administration technique." (85 Fed. Reg. at 43796). From a medical and scientific perspective, this assertion is simply incorrect. As explained in a letter to HHS written by one of the foremost medical experts on the topic:

> The evidence supports that both vaccine antigen and injection into or near the bursa or synovium are required to cause SIRVA. This is in contradistinction to vasovagal syncope that is a response to the needle or the injection itself and has nothing to do with vaccine antigen. Vasovagal syncope can and does occur routinely with various injections that do not contain any vaccine antigen (they also occur with aspirations-removal of fluid, or blood draws). SIRVA does not result from the 'trauma' of the needle being close to or within the bursa or synovium; rather, bursitis and synovitis are directly caused by the vaccine antigen delivered by the needle. I do not agree with the IOM report suggesting "the injection, and not the contents of the vaccine, contributed to the development of deltoid bursitis" (this is causal fallacy). While it is true the scientific community believes the risk of SIRVA is greatest with inappropriate deep and 'high' administration, the fact remains that antigenic material is required to elicit a typical SIRVA injury. In other words, the mechanism of causation is an immune-mediated inflammatory reaction to antigenic material injected into or near the synovium or bursa. While needle injection is necessary to deliver the antigen into these structures, it is not sufficient to cause bursitis or synovitis alone. Also, antigen within the skin or muscle does not cause SIRVA; rather, both the needle injection into the synovium or bursa and the antigen are required to cause SIRVA. If there was a way to get antigen into the bursa or synovium without the needle this would likely cause SIRVA. (Open Letter to Sec. Alex Azar, from Dr. Srikumaran dated March 26, 2020).

However, to the extent that negligence may well be a component of some SIRVA injuries, categorically excluding these as vaccine-related injuries on that basis would make sense only if one could determine/show that negligence **alone** was the cause of the injury. In other words, if the SIRVA injury would not have occurred absent the interaction of the vaccine ingredients and the immune system, then the vaccine would still be a substantial factor and but-for cause of the injury. See *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1351-52 (Fed. Cir. 1999).[1] Contrary to HRSA's unsupported assertions, the medical literature is clear that regardless of whether negligent

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[1] In *Shyface*, the petitioners alleged that encephalopathy leading to the death of their son occurred as a result of the combination of an underling sepsis infection and a DPT vaccination. After an examination of the statutory language of the Vaccine Act and its legislative history, the Court endorsed the Restatement rule for purposes of determining vaccine injury. 165 F.3d at 1352. The Court concluded that an action is the "legal cause" of harm if that action is a "substantial factor" in bringing about the harm, and that the harm would not have occurred but for the action." 165 F.3d at 1352.

administration occurs, all SIRVA injuries necessarily involve an inflammatory, immune reaction in the deltoid/bursa region. See *Vaccination-related Shoulder Discomfort*, M. Bodor & E. Montalvo; *Shoulder injury related to vaccine administration (SIRVA)*, S. Atanasoff, et. al.

Even if one could reasonably construe the language of the Vaccine Act as carving out injuries when negligent administration is involved, which in my view it cannot, it is a disastrous idea from a public health policy perspective. The Vaccine Act is by no means perfect and a robust, good-faith assessment of how to balance the competing desires of fairly compensating those injured by vaccines with ensuring a safe, reliable, and stable vaccine market is warranted. However, the VICP has clearly been successful in terms of directing almost all vaccine injury litigation into a federal no-fault system and thereby nearly eliminating completely civil litigation against both vaccine manufacturers and vaccine administrators.

As HRSA knows, if the rulemaking is finalized and SIRVA claims are removed from the Vaccine Table, SIRVA claims will continue to be filed and pursued as causation-in-fact cases.[2] Presumably, HHS will argue for dismissal in all of these cases based on their newly formulated interpretation of the Vaccine Act that is contrary to how the Act has been interpreted by the Court and HHS since the Act went into effect over 30 years ago. Unless the U.S. Court of Appeals for the Federal Circuit hears an appeal and agrees with HHS' legal analysis, these cases will remain in the program and all that this rulemaking effort will have accomplished is additional delays in the processing of SIRVA claims, confusion as to the legal status of SIRVA injuries pending a lengthy litigation and appeal process, and an **erosion of trust in the federal government's role vis-à-vis vaccines**, vaccine injuries, and fairly compensating the rare cases involving people who are injured from their participation in our nation's immunization policies.

Obviously, if SIRVA and syncope claims are excluded from the VICP, the injuries and potential claims would not suddenly disappear. Rather, vaccine administrators – meaning nurses, doctors, pharmacies, employer-sponsored health services, etc. – will likely be sued by these same vaccine-injured individuals and these entities would be required to defend these claims in state court. At a minimum, defending these claims would increase the overall costs associated with our vaccine policy and almost certainly reduce the availability of vaccination in light of the increased risk of liability on administrators. Furthermore, while civil litigation may provide some level of compensation for certain individuals, others would be discouraged or unable to pursue vaccine injury claims because of the increased costs associated with civil litigation and direct payment of attorney fees. Over time, there's little doubt that this latter consequence would reduce the number

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[2] The Vaccine Act provides a petitioner with two ways to establish causation, by alleging a Table injury or arguing causation in fact. *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *De Bazan v. Sec'y of HHS,* 539 F.3d 1347, 1351-52 (Fed. Cir. 2008). If SIRVA is no longer considered a Table injury, petitioners can still stablish causation in fact by showing through a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen,* 418 F.3d at 1278.

of individuals who are willing to get vaccinated.

In closing, I strongly urge that HHS abandon the current proposed rulemaking effort because it is contrary to law and an ill-considered public health policy, particularly in light of the current Covid-19 pandemic.

Sincerely,

Ed Kraus