



May 18, 2020

Advisory Commission on Childhood Vaccines
Division of Injury Compensation Programs
Health Resources & Services Administration
5600 Fishers Lane
Rockville, MD 20857

Advisory Commission on Childhood Vaccination (ACCV) Members:

The Biotechnology Innovation Organization ("BIO") is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. Its member organizations have an interest in vaccines and related public policy considerations such as appropriate resolution of claims of injuries attributed to vaccination.

BIO respectfully submits that the Advisory Commission on Childhood Vaccines (the "ACCV") should recommend that the Secretary not proceed with the draft Notice of Proposed Rulemaking (the "draft NPRM") concerning the removal of Shoulder Injury Related to Vaccine Administration ("SIRVA") and vasovagal syncope from the Vaccine Injury Table ("Table") of the National Childhood Vaccine Injury Act (the "Vaccine Act" or "Act"). BIO's position is supported by four principal considerations.

First, it was barely three years ago that the Secretary added SIRVA and syncope to the Table. As noted in the draft NPRM, that science-driven decision was informed by ACCV recommendations and followed review by nine HHS work groups of a 2012 report on vaccines by the Institute of Medicine ("IOM") -- the opinion of which is entitled to great weight in the Vaccine Injury Compensation Program (the "Program").¹ The several subsequent publications cited in the draft NPRM do not call into question the IOM's analysis or otherwise materially change the scientific record that was before HHS and its work groups at the time of the 2017 rule.

¹ See, e.g., Hooker v. Sec'y of Health & Human Servs., No. 02-472V, 2016 WL 3456435, at *31 n.25 (Fed. Cl. Spec. Mstr. May 19, 2016).



Second, the draft NPRM implies that injuries like SIRVA and syncope should not be on the Table because the Program only covers injuries attributable to the contents of a vaccine.² HHS took the opposite position, however, when it proposed the addition of SIRVA and syncope to the Table in 2015 and issued the final rule effecting those additions in 2017. The draft NPRM does not point to any change in the law or in anything else that would justify a different interpretation of the scope of the Program now, just three years later. In addition, even before SIRVA and syncope were added to the Table, claims for those injuries were routinely compensated in the Program.³ HHS has even stated in legal papers filed in the Program that “the Vaccine Act has broad scope over claims related to vaccinations[,] ... related not only to the vaccine itself, but also to those related to misadventures from the act of administering the vaccine.”⁴ As the United States Supreme Court put it, the Act established the Program to compensate

² At times, the draft NPRM says that the Program should cover only injuries attributable to vaccine “contents,” in order to draw a distinction from SIRVA and syncope, which the draft NPRM says are the result of administrator error. At other times, the draft NPRM says that the Program should cover only injuries attributable to the vaccine “antigen.” As evidenced by the experience with claims related to the thimerosal preservative in vaccines, precedent from numerous courts unmistakably establishes that injuries attributable to vaccine contents are covered by the Program. That was also the finding of the Office of Special Masters in Leroy v. Secretary of Department of Health & Human Services, 2002 WL 31730680, at *16 (Fed. Cl. Spec. Mstr. Oct. 11, 2002). In papers filed in the Leroy case, HHS itself stated that Program “compensation ha[d] been granted to vaccinees for injuries sustained from a vaccine preservative” and the legislative history of the Act demonstrated that “injuries allegedly related to thimerosal [must] be brought under the Program.” Id. at *1. Although we believe that the draft NPRM should not be supported, we add that if it is to go forward, it should consistently speak in terms of a distinction between administrator error and vaccine “contents.”

³ See, e.g., Loeding v. Sec’y of Health & Human Servs., No. 15-740V, 2015 WL 7253760, at *1 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) (setting forth HHS Secretary’s concession “that petitioner is entitled to compensation” for SIRVA and brachial neuritis claim); Guyer v. Sec’y of Health & Human Servs., No. 15-0448V, 2015 WL 5168357, at *1 (Fed. Cl. Spec. Mstr. Aug. 13, 2015) (same, SIRVA claim); Anderson v. Sec’y of Health & Human Servs., No. 15-187V, 2015 WL 5168257, at *1 (Fed. Cl. Spec. Mstr. July 29, 2015) (conceding on syncope and post-concussion syndrome claim); Xanthopoulos v. Sec’y of Health & Human Servs., No. 14-1101V, 2015 WL 3407542, at *1 (Fed. Cl. Spec. Mstr. May 4, 2015) (same, claim for “vasovagal syncope, and subsequent traumatic brain injuries secondary to the vaccination”).

⁴ Leroy, 2002 WL 31730680, at *12 (quoting HHS’s Brief at 4 (citing Pociask v. Secretary of HHS, No. 96-569V, 1999 WL 199053 (Fed. Cl. Spec. Mstr. Mar. 24, 1999) (compensating petitioner for her arm abscess after tetanus vaccination); Amorella Moore v. Secretary of HHS, No. 91-1558V, 1992 WL 182194 (Fed. Cl. Spec. Mstr. July 13, 1992) (awarding damages for sterile arm abscess resulting from the DPT vaccine)).



"injuries and deaths traceable to vaccinations."⁵ Injuries resulting from improper technique certainly fit within this scope, as HHS correctly recognized three years ago and throughout the Program's history.

Third, coverage for SIRVA and syncope is entirely consistent with the Program's twin purposes of creating a simplified means of recovery for those injured by the administration of vaccines and providing liability protection to vaccine administrators and manufacturers. According to the legislative history of the Act, Congress intended to provide, among other things, "a complete system of vaccine compensation" "which will provide compensation to those persons who are inadvertently injured by routine immunizations while allowing those persons who believe that they have a claim for remedies in court to pursue it."⁶ The policy objective is triggered by the immunization and does not vary with whether the claimed injury is a consequence of the contents versus the administration process.

Fourth, the draft NPRM is not supported by the cited financial considerations. We acknowledge that some vaccine opponents cite the total amount paid out of the Program as evidence that vaccines are not safe.⁷ We question, however, whether removal of SIRVA and syncope from the Table would thwart this misuse of compensation data. According to the NPRM, the Program has paid an average of approximately \$30 million per year for SIRVA claims in the three fiscal years during which SIRVA has been on the Table.⁸ This constitutes less than 1.0% of the \$4 billion life-to-date total that the Program has paid for claims for all injuries. Those who want to make misleading use of payouts in Program awards will be able to do so with equal force even if there are no future successful claims for SIRVA or syncope.

We also question whether SIRVA and syncope claims pose a risk of "reducing the funding available for children and others who are injured by vaccine antigens."⁹ The fund balance as of January 31, 2020 is greater than \$4 billion.¹⁰ It has continued to grow even after SIRVA and syncope were added to the Table. It

⁵ Shalala v. Whitecotton, 514 U.S. 268, 269-70 (1995) (emphasis added) (citing H.R. Rep. No. 99-908, at 3-7, reprinted in 1986 U.S.C.C.A.N. at 6344-45 (1986)).

⁶ H.R. Rep. No. 100-391(I), 100th Cong., 1st Sess. at 691 (1987), reprinted in 1987 U.S.C.C.A.N. 2313-365 (emphasis added).

⁷ See NRPM, at 8-9.

⁸ The amounts paid for syncope claims have been far less, roughly \$125,000 per year according to the draft NPRM.

⁹ NPRM at 9.

¹⁰ Nat'l Vaccine Injury Compensation Update 19 available at: <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/03062020-dicp-update.pdf>.



therefore does not appear that inclusion of SIRVA on the Table, to say nothing of syncope, is putting the fund at risk.

Although the draft NPRM does not mention the financial cost of HRSA's administration of SIRVA and syncope claims, BIO submits that these burdens are not a proper basis for reversing HHS's position. BIO believes that it would be more appropriate for HHS to take steps to secure increased appropriations to support HRSA's administration of the Program, and BIO applauds and supports ACCV's prior efforts in this regard.¹¹

Finally, we close by noting Secretary Azar's remarks last fall about flu vaccine:

A recent national study indicated that the main reasons for not getting a flu vaccine are the following: People think flu isn't serious or they are unlikely to get very sick from influenza. People have concerns about the safety and side effects of flu vaccines. People think flu vaccines don't work.

I'm here today to tell you: Flu can be serious, and it kills tens of thousands every year.

But flu vaccines are safe and effective. Hundreds of millions of doses of flu vaccine have been safely given to Americans for more than 50 years. The FDA, in close coordination with CDC and NIH, works year-round to fight the flu, helping to ensure that all flu vaccines are safe and effective.¹²

The vast majority of SIRVA claims arise in the context of the flu vaccine. BIO submits that the proposed draft NPRM would run counter to the important public

¹¹ BIO supports HRSA's "FY 2021 Budget Request for VACP Administration of \$16.2," which "is \$6.0 million above the FY 2020 Enacted level;" will support "administrative expenses to process approximately 1,280 claims filed in FY 2021, including costs associated with medical expert reviews and expert testimony in" Vaccine Court; and "will allow HRSA to begin a multi-year effort to eliminate the claims backlog." Health Resources & Servs. Admin., Justification of Estimates for Appropriations Committees 415, available at: <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>. Increased funding—not reduced coverage by the Vaccine Act—would best address that backlog and expedite claim resolution.

¹² Alex M. Azar, Remarks on Annual Flu Vaccination Campaign (Sept. 26, 2019), available at: <https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-annual-flu-vaccination-campaign.html>.



health objective of maximizing flu vaccination by (a) undermining vaccine confidence with unexplained reversals of interpretation of science and Program scope made just three years ago and throughout the Program's history, and (b) tinkering with the extraordinarily successful Program formula of providing a forum for recovery while also providing liability protections for manufacturers and administrators.

BIO thanks the ACCV for its consideration of these views.

Sincerely,

/s/

John Murphy
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Biotechnology Innovation Organization