U.S. Department of Justice

Civil Division

Assistant Attorney General *Washington, D.C. 20530*

May 15, 2020

Robert P. Charrow, Esquire
General Counsel
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Charrow:

I write in support of the draft Notice of Proposed Rulemaking (NPRM) that includes a provision to remove shoulder injury related to vaccine administration (SIRVA) from the Vaccine Injury Table of the National Childhood Vaccine Injury Act. As a result of SIRVA's inclusion on the Table, the Vaccine Injury Compensation Program (VICP), which was designed to compensate children for the rare unavoidable injuries arising from routine childhood immunization, has been inundated by SIRVA claims filed almost exclusively by adults. According to data presented at the March 2020 meeting of the Advisory Commission on Childhood Vaccines, in the last 2 fiscal years since SIRVA was added to the Table, over 54% of the more than 2,400 petitions filed in the VICP have alleged SIRVA.

There is no reason to believe that these numbers are a temporary phenomenon, given that SIRVA claims are both lucrative for claimants to pursue and simple for attorneys to prosecute compared to claims based on childhood vaccine injuries. More than 2,000 SIRVA cases have been filed since FY 2015, while almost no shoulder injury cases were filed in the previous decades of the VICP. The amounts paid out of the Vaccine Injury Trust Fund to compensate SIRVA petitioners are considerable. To illustrate, from FY 2015 through FY 2018, more than $100 million has been paid out of the Vaccine Injury Trust Fund to compensate SIRVA petitioners. The median award of compensation in SIRVA cases is $100,000, which is significantly higher than awards in the civil tort system for comparable injuries. At least twenty cases have been identified in which petitioners have submitted altered medical records, some of which changed the site of vaccination, raising concerns about the integrity of the VICP. One consequence of this significant influx of SIRVA cases is that there is now nearly a ten-month delay in the review of VICP petitions by HRSA medical professionals, which is a necessary prerequisite for all VICP cases to reach resolution. Another consequence of the inclusion of SIRVA is that VICP cases are taking longer to resolve than in past years. In the year following the addition of SIRVA to the Table, 156 fewer cases were adjudicated than in the previous year; the average amount of time for a case to finally resolve has increased significantly since 2017 (from 575 days to 751 days). Data presented at the last ACCV meeting showed that 924 petitions awaited initial review, including 530 of which had been filed in FY 2019. Another

consequence is that non-SIRVA cases, including those filed on behalf of children, are adversely affected as resources are stretched or diverted to litigate SIRVA cases.

There is also significant doubt on whether there is a proper legal basis for shoulder injuries to be compensated through the VICP because SIRVA is not a typical "vaccine-related injury" under the Vaccine Act. The Act contains what are known as "gatekeeping" provisions. *See* 42 U.S.C. § 300aa-11. One such provision states that the Act "applies only to a person who has suffered *a vaccine-related injury or death* and who is qualified to file a petition for compensation under the Program." 42 U.S.C. § 300aa-11(a)(9) (emphasis added). The Act provides that the "term 'vaccine-related injury or death' means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. § 300aa-33(5).

Although the term "vaccine" is itself not defined by statute, courts have focused on the ingredients (the "substance") of a vaccine, and the reaction of the human body elicited by the vaccine's formula, not impurities or devices used to administer the vaccine. For example, in *Dean v. HHS*, No. 16-1245V, 2018 WL 3104388 (Fed. Cl. Spec. Mstr. May 29, 2018), the special master defined "vaccine" as "'any substance designed to be administered to a human being for the prevention of 1 or more diseases.'" *Id.* at *9 (quoting 26 U.S.C. § 4132(a)(2)). In reaching this conclusion, the special master drew from a medical dictionary that defined "vaccine" as "'a suspension of attenuated or killed microorganisms . . . or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases.'" *Id.* (quoting DORLAND'S ILLUSTRATED MEDICAL DICTIONARY at 412). This finding was thus consistent with the statutory definition of a "vaccine-related injury," which explicitly excludes injuries caused by non-pure vaccines, i.e., vaccines with an "adulterant or contaminant" added. *See* 42 U.S.C. § 300aa-33(5).

Accordingly, a distinction exists between an injury caused by the vaccine components, and an injury caused by the instrument used to administer a vaccine, i.e., a needle. A needle is not a "substance designed to be administered to a human being for the prevention of 1 or more diseases," nor is it "a suspension of attenuated or killed microorganisms . . . or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases." *Dean*, 2018 WL 3104388, at *9.

SIRVA is believed to be caused by negligent administration of a needle or the physical act of injecting the needle into the bursa, and not the effects of the substance of the vaccine on the human body. *See* 42 C.F.R. § 100.3(b)(10). Because SIRVA is properly understood as an injury caused by a needle and the administration of the needle rather than a vaccine, serious doubt exists as to whether SIRVA satisfies the "gatekeeping" provisions of the Vaccine Act. If SIRVA is a needle-related negligence injury and not a vaccine-related injury, then it is not a cognizable claim under the Act. *See* 42 U.S.C. § 300aa-11(a)(9).

Compensating for SIRVA is also inconsistent with the intent of the Vaccine Act to provide compensation in rare cases of unavoidable injury. The Vaccine Act should be construed

"in a way [that] is consistent with the intent of Congress." *Hellebrand v. HHS*, 999 F.2d 1565, 1570-71 (Fed. Cir. 1993). The VICP was created to increase the safety of vaccines. *See* 42 U.S.C. § 300aa-1; *Terran v. HHS*, 195 F.3d 1302, 1307 (Fed. Cir. 1999). But by immunizing tortfeasors in typical negligence claims such as SIRVA, the VICP creates a disincentive for administrators to learn proper technique. Indeed, the administrators themselves may have no idea that they are using an improper technique, as claims of injury are filed in the Court of Federal Claims, not against the vaccine administrator. SIRVA "cases allege the shots were administered incorrectly—usually too high on the arm—but . . . the program has no mechanism [due to privacy laws] to notify the shot-giver of the injury he or she likely caused," and "[t]hus, they would have no reason to seek additional training." Jodie Fleischer et al., *Half of All New Federal Vaccine Cases Allege Injury from Shots Given Incorrectly*, NBC Washington, https://www.nbcwashington.com/investigations/Half-of-All-New-Federal-Vaccine-Injury-Cases-Allege-Shots-Given-Incorrectly-481441201.html. Keeping SIRVA on the Table may discourage people from receiving vaccines out of fear that vaccine administrators may cause them injury. In addition, large payouts from the VICP for SIRVA cases, disseminated through social media, amplify fears about vaccine safety and further the false impression that vaccines are dangerous. One of the potential threats to public health is "vaccine hesitancy," as resurgence of preventable diseases usually occurs in unvaccinated populations.

For these reasons, the Department supports the draft proposal to remove SIRVA from the Vaccine Injury Table.

Sincerely,

JOSEPH HUNT

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Joseph H. Hunt
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