

**Health Resources and Services Administration Responses to
Questions from Jodie Fleischer (NBC Universal) about
National Vaccine Injury Compensation Program**

***Note: This question/answer exchange occurred between January 23rd and April 24th 2018.**

- 1) Per data provided by your agency, in 2017, 50% of all of the new petitions filed in the Vaccine Injury Compensation Program were SIRVA cases: 602 out of 1243 total petitions filed.
- (a) Is that a concern for HHS/HRSA officials?
 - (b) How would HHS/HRSA characterize the urgency of that situation?
 - (c) Given that SIRVA is defined as an injury caused by improper administration of the vaccine, what is HHS/HRSA doing to combat the rise of SIRVA occurrences?
 - (d) Does HHS/HRSA maintain any data regarding the type of location where the SIRVA related injections were given ie: doctor's office, grocery/convenience store, workplace etc.
 - (e) To what does HHS/HRSA attribute the increase in SIRVA cases?

HRSA Response: All vaccine injuries are a concern, which is why the Vaccine Injury Compensation Program (VICP) exists. As to what is being done to "combat" the issue, we suggest you contact the Centers for Disease Control and Prevention (CDC) for further information, as they are tasked with providing vaccine administration education and training to health care practitioners. CDC is also responsible for monitoring vaccine adverse events.

HHS, specifically HRSA, administers the VICP, which provides compensation to individuals injured by certain vaccines. However, over 80 percent of all compensation awarded by the VICP comes as a result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury. And as stated in the January 26, 2018 response to you, "As for the geographic location of the claimant and place of the vaccine administration, HRSA does not track or monitor this data."

Follow-up questions:

- a) Aside from the concern over ALL vaccine injuries, is there any additional concern regarding the rise in SIRVA cases given that they now account for half of the new claims being filed in VICP?
- e) To what does HHS/HRSA attribute the increase in SIRVA cases?

Follow-up answers:

Since SIRVA was identified as a vaccine-related injury by VICP medical staff working on claims several years back, awareness of these injuries has grown both among the public and among health professionals. This is due in part to program efforts to make people aware of this potential injury. We cannot attribute the increase in SIRVA to any particular issue or root cause with currently available data.

- 2) In 2016, the Advisory Commission on Childhood Vaccines (ACCV) issued a recommendation to the HHS Secretary that the number of special masters in the VICP be doubled and that HRSA staff be increased, what has HHS/HRSA done to advance that request?

HRSA Response: For answers on the funding for the Office of Special Masters, we suggest you contact the U.S. Court of Federal Claims. The President's budget for both FY 2018 and FY 2019 supports increases in the administrative funding for the VICP functions at HHS. As to the allocation of the requested funding, this is a question for the Congress.

Follow-up question:

Given that the recommendation was sent directly to the HHS Secretary, and not to the U.S. Court of Federal Claims or Congress, what if anything has HHS/HRSA done to elevate that recommendation to either of those entities?

Follow-up answer:

Although ACCV recommendations are directed to the Secretary, the information contained in them is not confidential and the contents of those recommendations are available to policy makers for their understanding and consideration. The U.S. Court of Federal Claims is aware of the recommendation sent to the Secretary since the ACCV consulted them to obtain information to develop the recommendation. In FY 2018, HRSA received an increase in the appropriation to administer the VICP from \$7.75 million to \$9.2 million.

- 3) Attorneys from the Vaccine Injury bar indicate there is now a standard HHS/DOJ delay of at least 6 months to review incoming cases in compliance with Rule 4- due to the backlog in the VICP.
- (a) What is the HHS/HRSA response to that claim, and what is the cause?
 - (b) Are there any proposed solutions?

HRSA Response: In FY 2017, HHS experienced a backlog of claims because the increased number of claims filed exceeded the level of funding available to conduct medical reviews. At the end of FY 2017, 394 claims were in the backlog. As of March 8, 2018, FY 2018, 144 claims are in the backlog. The cumulative total of claims in the backlog is 538.

This backlog results in delays in reviewing claims, which may lead to delays in compensating petitioners.

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- 4) If Congress were reviewing the National Childhood Vaccine Injury Act and how the program functions, what would be HHS/HRSA's 3 biggest needs and recommendations?

HRSA Response: As previously indicated, the Administration's FY 2018 and FY 2019 budget requests support increases in the administrative funding for the VICP. If additional funding were received, the VICP would increase staff for the review of medical claims.

Follow-up question:

Aside from additional staff being needed for review of medical claims, what are the VICP's two additional "biggest needs?"

Follow-up answer:

The program's priority is conducting timely reviews of medical claims. Therefore, increasing staff and/or contractors to review medical claims is the biggest need.

- 5) What, if anything, is HRSA doing with regard to issuing directives or better educating vaccine administrators on proper vaccine administration techniques?

HRSA Response: Again, we would direct you to the CDC for more information.

- 6) HRSA has previously acknowledged a priority of better publicizing the existence of the Vaccine Injury Compensation Program. What is HRSA doing to advance that goal?
(a) What is HRSA's advertising budget for the program?

HRSA Response: Anyone who receives a vaccine covered by the VICP receives a Vaccine Information Statement (VIS). VISs are information sheets produced by the CDC that explain both the benefits and risks of a vaccine and include information about the VICP. Federal law requires that health care staff provide a VIS to a patient, parent, or legal representative before each dose of vaccines covered by the VICP. Therefore, VISs are one of the primary ways that the public is informed of the existence of the VICP.

The VICP does not have a dedicated budget for promotional activities, so it leverages its available staffing resources each fiscal year to conduct various VICP outreach activities. These outreach activities include conveying comprehensive information regarding the VICP on the web for both the public and healthcare professionals, and regularly conveying

information regarding the VICP to government and private sector medical groups to raise awareness of the VICP so they can be informed about the VICP and provide information about the VICP to their respective patients.

Follow-up questions:

What is the procedure for oversight of the above-mentioned VIS issuance process? For example, are there spot checks of vaccine administrators to make sure the VIS is being provided to patients? Are there any repercussions for failure to provide a VIS?

Follow-up answer:

This is a question for the CDC.

- 7) Since SIRVA is an injury primarily caused by human error in vaccine administration, what does HHS/HRSA do to notify the vaccine administrators who caused the error in each case?
- (a) What is the threshold (number of SIRVA injuries caused) after which they are recommended to obtain re-training to prevent similar errors in the future?
- *Note: The petitioners' attorneys we've interviewed noted that in each SIRVA case, the filing includes a document of vaccine administration indicating the date, location and name/signature of the vaccine administrator who is alleged to have caused the injury.

HRSA Response:

Again, we would direct you to the CDC for more information.

Follow-up questions:

The CDC indicates it can only access VAERS data for its reviews and it does not have VICP data which includes the vaccine administrator's name and location for each SIRVA case. Since HRSA is the agency with access to that information, what if anything does HRSA do to notify a vaccine administrator of the corresponding SIRVA case?

Follow-up answers:

The VICP is subject to a confidentiality provision in the National Childhood Vaccine Injury Act that prevents the release of information submitted in a VICP proceeding to someone who is not a party to the proceeding, absent express written consent of the person who submitted the information. See 42 U.S.C. § 300aa-12(d)(4)(A). Therefore, to avoid violating this provision, HRSA has not used information submitted by petitioners in VICP proceedings to notify a vaccine administrator of the corresponding SIRVA case.

Follow-up question:

The CDC's Dr. Tom Shimabukuro has indicated that the CDC is now working with HRSA to conduct an epidemiologic assessment of SIRVA claims. Please describe what that entails.

Follow-up answer:

We would refer you to CDC since they are taking the lead in conducting this assessment.