May 20, 2020

The Honorable Alex M. Azar II
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

In accordance with the provisions of the charter for the Advisory Commission on Childhood Vaccines (ACCV), and pursuant to its obligations under the National Childhood Vaccine Injury Act of 1986 as amended, (Vaccine Act) we respectfully submit for your consideration a recommendation regarding the implementation of the draft National Vaccine Injury Compensation Program (VICP) Notice of Proposed Rulemaking (NPRM). According to the Vaccine Act, the Secretary of HHS may not propose a regulation or any revision to the Vaccine Injury Table (Table), unless the Secretary has provided a copy of the proposed regulation or revision and afforded the Commission at least 90 days to make such recommendations.

On May 18, 2020, the ACCV held a meeting: 1) to discuss the draft VICP NPRM; 2) to hear from an HHS official regarding the evidence to support the NPRM and comments from the public; and 3) to evaluate the proposed changes in accordance with the ACCV's "Guiding Principles for Recommending Changes to the Vaccine Injury Table". The ACCV heard from 16 individuals and organizations. Three written comments were submitted by individuals or organizations who did not present public comments. Most commenters opposed the draft NPRM. Two individuals supported the NPRM, one individual without a known affiliation and one person from the Department of Justice submitted a written statement. After hearing the commenters and deliberating, the ACCV indicated an interest in discussing SIRVA in the future, especially if new medical and scientific literature is published. The four voting members made the following recommendation and attached is a summary of the reasons that three of the four members voted for the recommendation. The ACCV Chair, Dr. H. Cody Meissner, will send a separate letter explaining the reasons for his vote.

Recommendation

The ACCV voted unanimously to oppose the implementation of the proposed changes to the Vaccine Injury Table. The ACCV further reiterates its previous requests of December 16, 2016 and December 19, 2018 that the Secretary support an increase in the number of Special Masters and the amount of staffing and funding resources for the VICP.

Sincerely,

/s/
H. Cody Meissner
Chair, ACCV

/s/
John Howie
Vice Chair, ACCV

May 18, 2020 ACCV Meeting Summary and Deliberations

On May 18, 2020, the ACCV held a meeting: 1) to discuss the draft VICP NPRM which proposes to make changes to the Table; 2) to hear from an HHS official regarding the evidence and reasoning to support the NPRM and comments from the public; and 3) to evaluate the proposed changes in accordance with the ACCV's "Guiding Principles for Recommending Changes to the Vaccine Injury Table". During its March 6 Meeting, the Commission briefly discussed this draft NPRM; however, no representative from HHS was present to address questions from ACCV members, and discussion of the draft NPRM was not an agenda item. Therefore, ACCV members requested, among other things, a meeting with an HHS official to respond to their questions about the NPRM. Thus, the May 18 Meeting was scheduled, but an HHS official who could respond to the ACCV's questions did not attend.

According to the draft VICP NPRM, HHS is proposing to remove shoulder injury related to vaccine administration (SIRVA) and vasovagal syncope, since HHS's belief is that these injuries generally result from the administration of a vaccine, not the vaccine antigen. In addition, the NPRM proposes removing the new vaccines category (Item XVII) from the Table, because HHS has serious concerns that it is contrary to applicable law, including the procedures described in the Vaccine Act for amending the Table. Specifically, to the extent that Item XVII provides a unilateral mechanism for adding injuries and vaccines to the Table, it may be inconsistent with the Vaccine Act.

The ACCV listened to all of the oral comments from 16 individuals and organizations, including individuals who stated they have SIRVA as an injury and have filed VICP claims, attorneys who represent individuals who file VICP claims, and physicians with expertise in diagnosing and treating shoulder injuries, the National Vaccine Information Center, Vaccinate Your Family, Biotechnology Innovation Organization, National Association of Chain Drug Stores, and National Community Pharmacists Association. The ACCV also reviewed three written comments received prior to the meeting.

Most commenters opposed the implementation of this draft NPRM. Two individuals supported the change, one individual without a known affiliation and one person from the Department of Justice submitted a written statement.

After a discussion of the NPRM, the ACCV voted unanimously to oppose the proposed changes to the Vaccine Injury Table included within the draft NPRM for reasons discussed below.

1) An HHS official who could provide the evidence and reasoning to support NPRM and to explain and discuss the original basis for the inclusion of SIRVA and vasovagal syncope to the Table was not present at the meeting to answer questions from ACCV members
2) Although rare, SIRVA and vasovagal syncope are injuries that can be caused by vaccination, and thus, should be eligible for compensation from the VICP.
3) One intent of the VICP is to provide liability protection to vaccine manufacturers and administrators. However, removing injury claims that truly result from the administration of a vaccine from being filed through the VICP does not provide liability protection to health care professionals who administer vaccines and may

increase medical malpractice claims against them. Considering that health care professionals, including pharmacists, have been instrumental in improving vaccination rates in the U.S., exposing vaccine administrators to being sued in civil court for a vaccine injury could be a disincentive to administering vaccines, and thus, result in lower vaccination rates. An additional concern relates to unanticipated consequences of the proposed change to the cost of a vaccine. If the vaccine administrator or vaccine manufacturer is required to provide separate insurance against an injury, this additional cost likely will be passed on to the consumer resulting in an increase in vaccine cost.

4) The Vaccine Act has a subrogation clause which permits the Federal government to seek recompense if the VICP compensates a claim, but determines later that a health care professional was negligent in administering a vaccine. Thus, injury claims resulting from the administration of vaccines should still be eligible for VICP compensation.
5) The explanations in the NPRM for proposing changes to the Table do not meet the tenets of the ACCV "Guiding Principles for Recommending Changes to the Vaccine Injury Table". The Guiding Principles state, "When recommending changes to the Vaccine Injury Table ("the Table"), members of the Advisory Commission on Childhood Vaccines (ACCV) shall utilize the following overarching guiding principles:
    - The Table should be scientifically and medically credible; and
    - Where there is credible scientific and medical evidence both to support and to reject a proposed change (addition or deletion) to the Table, the change should, whenever possible, be made to the benefit of petitioners."
6) Since enactment of the Vaccine Act and the inception of the program, claims resulting from the administration of a vaccine have been filed and some have been compensated. In the draft NPRM, HHS is proposing to not permit claims resulting from the administration of a vaccine to be filed and compensated. Thus, HHS's reasoning for proposing the changes in the NPRM are based on a new interpretation of the Vaccine Act. However, the ACCV Guiding Principles instruct that changes to the Table should be based on peer-reviewed medical and scientific literature. The ACCV has not been presented with any new peer-reviewed medical or scientific literature on SIRVA or syncope. Thus, since no new medical and scientific literature has been published about the proposed changes, HHS should not be proposing any changes to the Table.
7) The Vaccine Injury Compensation Trust Fund has a balance of over $4 billion; and therefore, funds are available to pay valid claims resulting from the administration of vaccines.
8) One of the reasons that HHS stated in the NPRM and DOJ stated in its written comment for proposing to remove SIRVA from the Table is that SIRVA claims have significantly increased the workload of VICP staff resulting in a backlog. Recognizing that the number of claims filed has increased the workload for VICP staff, the ACCV would like to reiterate its support for the December 16, 2016 and December 18, 2018 recommendations that the Secretary support an increase in the number of Special Masters and the amount of staffing and funding resources for the VICP.