May 26, 2020

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

Dear Secretary Azar:

I am writing as the previous Chair of the Advisory Committee on Childhood Vaccines (ACCV) and in relation to the letter signed by myself and the Vice Chair of the Committee dated May 20, 2020. The letter of May 20 was submitted following the ACCV meeting held on May 18, 2020. At that virtual meeting, public comment was heard in regard to the proposed changes for the Vaccine Injury Table contained in the Notice for Proposed Rule Making (NPRM). I was one of four committee members who voted to oppose the proposed changes in the NPRM. Here, I wish to explain the reason for my vote and to offer a proposal for your consideration.

I strongly support the need for a change regarding Shoulder Injury Related to Vaccine Administration (SIRVA) as presently described in the Vaccine Injury Table. As a committed advocate for the Childhood and Adult National Immunization Programs and its role in maintaining the health of citizens of the United States (and former member of ACIP), I am concerned about the number of awards that have been made under the category of SIRVA. In recent years, this has been the most common basis for awards listed in the Vaccine Injury Table. The large number of SIRVA claims have clogged the system, resulting in a delay in resolution of some claims and leading to a request by ACCV for additional attorneys to reduce the backlog. Of greater importance, the large amount paid annually from the Vaccine Injury Trust Fund has reinforced vaccine hesitancy among some citizens who incorrectly believe this figure reflects lack of vaccine safety. Inappropriate awards are harmful to the entire vaccine enterprise.

My personal recommendation is that SIRVA should continue to be included in the Table. There may be variable interpretation regarding the wording as to whether SIRVA represents a reaction to vaccine content versus improper administration of a vaccine which physically disrupts the anatomy of the shoulder. However, in my opinion, injury following vaccine administration into the deltoid area in certain settings does appear to be a genuine injury that should be included in the Table. For reasons noted in the ACCV letter of May 20, 2020, removal of SIRVA from the Vaccine Injury Table may adversely impact vaccine acceptance in the United States.

I fully concur that the number of awards for SIRVA are in excess of the true number of cases. I believe It is necessary to thoughtfully re-define what constitutes a true injury following administration of an intramuscular vaccine in the shoulder. During the May 18, 2020 public hearing, two orthopedic surgeons (one on the faculty at Johns Hopkins and the other at University of California, Davis) provided comments regarding their experience caring for patients with SIRVA. They also presented comments regarding research in this area. Following the May 18, 2020 hearing I have been in contact with these presenters to more fully understand their positions.

I believe it will be possible to develop a more rigorous definition of SIRVA based on published, peer reviewed data that is currently available as well as data that is likely to be published in the near future. By providing a more accurate definition of SIRVA it will be possible to retain this injury for those experiencing a true vaccine injury and to reduce the number of inappropriate claims.

If I can be of assistance moving forward on this issue, I would be happy to do so. I conclude by stating I appreciate the opportunity to have served on the ACCV and to have worked with the capable individuals in the program, particularly the Acting Director, Tamara Overby, MBA.

Respectfully,

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