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March 16, 2020

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Dear Ms. Overby, Ms. Herzog, and Dr. Meissner,

I am writing to address the recent events surrounding the Notice of Proposed Rulemaking (NPRM) recommending, among other things, the removal of Shoulder Injury Related to Vaccine Administration (SIRVA) and syncope from the Vaccine Injury Table.

As you are aware, on or about February 14, 2020, the members of the Advisory Committee on Childhood Vaccinations (ACCV) were, for the very first time, delivered a packet containing this NPRM. Each page of the packet was clearly marked as “Confidential for ACCV Only”. Each page also contained express notification that the document was a “Confidential Draft” and was protected by the “pre-decisional deliberative process” and the “attorney-client” privileges.

Only a few weeks after receiving this document, the ACCV convened for an in-person meeting in Washington, DC on Friday, March 6, 2020. To my knowledge, prior to that meeting, there had been no discussion by the ACCV regarding the contents of the NPRM. Further, I am not aware of any waiver of the above-referenced privileges that had been given to the ACCV to discuss this NPRM publicly prior to that meeting. Certainly, if a waiver had been given or conversations had occurred prior to the March meeting, I was never made aware, nor was I invited to participate.

In spite of the fact that a discussion of this NPRM was not on the ACCV meeting agenda and the fact that – as far as I am aware – no waiver of the above-referenced privileges had been given, the issues presented by this NPRM were raised by Dr. Meissner during the March meeting. Notably, it was casually suggested by Dr. Meissner that the issues presented by the NPRM were not something the ACCV needed to consider as a committee. Rather, Dr. Meissner suggested that the ACCV committee members, in their individual capacities, could write a letter as

provided by the NPRM, if they felt the need to do so. Respectfully, I disagree with Dr. Meissner's suggestions; a proper evaluation of the issues presented by this NPRM are a core duty and responsibility of each of the members of this Committee.

The National Vaccine Injury Compensation Program was created by and through the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660 (42 U.S.C. § 300aa-1, *et seq.*) (Vaccine Act). The Vaccine Act not only establishes the National Vaccine Injury Compensation Program (VICP), but it also creates the ACCV and provides direction and instruction for the purposes of the ACCV. Specifically, 42 U.S.C. § 300aa-19(f) states, in pertinent part:

(f) **FUNCTIONS** – The Commission shall –

- (1) advise the Secretary on the implementation of the Program;
- (2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table

These specific functions are expressly incorporated into the ACCV's bylaws which provide the scope of the duties and responsibilities of this Committee.

Additionally, in 2006, the ACCV established "Guiding Principles for Recommending Changes to the Vaccine Injury Table" (Guiding Principles). As expressly recognized in the NPRM, the purpose of these Guiding Principles was to assist the ACCV in evaluating proposed Table revisions and determining whether to recommend changes to the Table to the Secretary.<sup>1</sup> I believe that any suggestion that it is neither within the purview nor the responsibility of the ACCV to address this NPRM is absolutely contrary to federal law, the bylaws of this Committee, and the ACCV's own Guiding Principles.

During the March 2020 ACCV meeting, the presentation by Ms. Overby on behalf of the NVICP Division of Injury Compensation Programs represented that, "Over 54% of petitions filed in the last 2 fiscal years allege shoulder injury related to vaccine administration (SIRVA)".<sup>2</sup> This fact alone demonstrates the significance of the issues presented within the NPRM, and it underscores the importance that the ACCV be allowed the opportunity to gather critical information in order comply with the above-referenced responsibilities and directives established by federal law, the bylaws of this Committee, and the ACCV's Guiding Principles.

As of today, the ACCV has been presented with a draft NPRM and nothing more. In order to fully evaluate the proposed Table changes, the ACCV must be allowed to consider the position of not only the Secretary, but also the multitude of other individuals whose interests may be affected by this proposed Table change including the Office of Special Masters who is charged with the responsibility of acting as the judge and jury for VICP cases, the Department of Justice who is charged with the responsibility of defending VICP cases, and the Vaccine Injured

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<sup>1</sup> NPRM at p. 16.

<sup>2</sup> DICP Presentation, Slide 11, March 6, 2020).

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Petitioner's Bar who represent vaccine-injured people. Additional, critical insight on the effect of the proposed Table changes should be made available to the ACCV including, but in no way limited to, information from vaccine manufacturers, vaccine administrators (including doctors, nurses, pharmacists, and others), and even the general public who may have information to offer. The ACCV absolutely deserves the opportunity to consider the input from each of these groups of individuals on this critically important subject.

Of further significance is the fact that, presently, one-third of the seats available on the ACCV remain vacant. As reflected above, over 54% of the petitions filed in the VICP over the past two years allege SIRVA injuries. Obviously, the decision of whether to eliminate over half of the claims filed under the VICP is of critical importance. This is not a decision that should be taken lightly, and it is certainly not a decision that should be made with one-third of the Committee seats vacant.

Only a few years ago, prior to SIRVA and syncope being added as Table injuries, the ACCV committee conducted extensive investigation and discussion regarding whether these injuries should be added to the Table. This included receiving presentations from individuals at HHS and many other individuals with medical and legal expertise. Substantial information was gathered from multiple sources to assist the Committee in evaluating whether to add these injuries to the Table. And, upon receiving this information, many robust discussions were held amongst the ACCV committee members spanning several ACCV meetings. Like the prior ACCV committees, it is our duty and our responsibility not to rush to conclusions regarding this NPRM, but rather, to obtain the information from the resources available to the Committee to allow it to properly evaluate and discuss this critically important matter. Failing to do so subverts the purpose of this Committee.

Of final note, but certainly not of least importance, over the past couple of days as I have contemplated this letter, we are witnessing a rapidly escalating national emergency, the likes of which our country has never previously experienced. As of this morning, as a nation, we are facing a very high probability that a weeks-long lockdown will be implemented. In light of the many healthcare professionals on this Committee and within the many areas from which this Committee should be looking to obtain information regarding the critical issues presented by the NPRM, prudence mandates that this NPRM should be delayed until we all have a more complete understanding of the dire situation facing our nation.

When I was given the honor of participating on this Committee, I did so with the understanding that it carries both duties and responsibilities. Those duties and responsibilities, as outlined by this Committee's bylaws, are not something I take lightly. Federal law and the bylaws of the ACCV dictate that it is the ACCV's responsibility to fully evaluate the proposed Table changes contained within the NPRM. It is imperative that the ACCV be given the opportunity to receive information necessary to allow its members to fully and completely understand the potential repercussions of the proposed Table changes. Our failure to do so would amount to a dereliction of the crucial duties and responsibilities invested in us.

I thank you for your time and consideration and look forward to continuing to work together to arrive at a meaningful resolution. I also pray that you all will remain safe and healthy during

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these dire times, and I thank each of you who are on the front lines fighting for all of our health and safety.

Sincerely,

*/s/ John Howie, Jr.*

John Robert Howie, Jr.

Cc:

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