ACCV Process Work Group
Quarterly Report
December 5, 2013

The Process Work Group was able to meet in September (as reported during the last Commission meeting), in October and in November. During the telephone meetings we covered a number of issues and these are summarized as follows:

A. The Process Work Group had put together three Recommendations to the Secretary. By approving these, the current commission affirmed the previous ACCV's Recommendations. The first was the Recommendation to the Secretary to consider a vaccine-injured adult or his or her representative as a member of the Commission representing the general public. The two others are the Recommendation to extend the Statute of Limitation and the Recommendation to increase the cap for pain and suffering. The first Recommendation was sent to the Secretary in June. The Letters for the last two Recommendations, once signed by the Chair, David King, and the Vice Chair, Michelle Williams, will be forwarded to the Secretary. Once signed, the copies will be emailed to the commissioners and included in the meeting workbook for December.

B. The work group also discussed the third membership of the legal representatives in the Commission. We discussed the advantages of lawyers who are knowledgeable in regards to the Vaccine Injury Compensation Program and has experience in its current issues. One such advantage is a shortened learning period. The Process Work Group would like to recommend that the Secretary consider appointing a lawyer who represents petitioners as the third member of the legal representatives arm of the ACCV because of their experience with the program. As in the previous Recommendation on the third membership of the general public, this Recommendation would make use of the power of the Secretary to make the change, instead of waiting for a legislative change. Since there is a vacancy coming up, Ed Kraus informed the work group that the Vaccine Injured Petitioners Bar had passed a motion that they will submit a candidate for the third legal member of the ACCV from their membership. The Process Work Group will present this recommendation to the full Commission for discussion and for approval at the December meeting.

C. The work group also discussed the direction we need to take for the work group's future meetings, and as of September, we decided we would proceed as we had originally intended, that is, continue to examine the remaining 2009 Recommendations. As detailed below, the work group decided that any discussion of the remaining 2009 ACCV recommendations are to be discontinued and that our new goal is to focus on pushing the previously passed Recommendations to fruition.

    a. The work group begun the discussion on the next Recommendation in our table – Derivative claims – by first considering how to structure our conversation – such as clarifying concepts, definitions, who the potential claimants are, types of damages and caps, and implication on the Program

and vaccine manufacturers. Dr. Caserta suggested that the discussion should invite the input of all parties that would be impacted by the recommended change because their support is important in getting the change to fruition.

b. Dr. Caserta advised the work group that as a general principle, it is best to limit the number of Recommendations the Commission makes. The Recommendations made are those deemed by the ACCV to have the highest priority. That would help with regards to the Recommendations actually being acted upon. When the Commission makes many Recommendations, it works to diminish the ability of the Department to pursue any of them.
c. After a lengthy discussion, the work group agreed that the best approach to having a good chance that changes occur during its tenure is to focus on the Recommendations already presented: the third membership to each arm of the ACCV membership, the increase in the cap for pain and suffering and death, and the extension of the statute of limitations.
d. David King suggested that the Commission, as a whole, decide on how to increase the level of visibility of the Recommendations, such as holding hearings on these specific topics during a full commission meeting, inviting experts to discuss the need and importance of these topics so that the discussion becomes part of the public record as well. The Process Work Group proposes that the Commission discuss the ways that ACCV can get support in getting the Recommendations implemented or at least moved on to become legislative proposals.
e. Dr. Caserta reminded the work group that he had been given the task of preparing a presentation on how to make the ACCV be more effective, and that he is working with the executive branch on the presentation. His presentation with Mr. Matanoski is part of the December agenda.

D. We also expressed some grievance about the virtual nature of the ACCV meetings and its effectiveness.
    a. As discussed in the September Commission meeting, Dr. Caserta stated that a face-to-face meeting, possibly once a year, had been approved for when the agenda items in the meeting could be better served by a face-to-face meeting. One possibility for a face-to-face meeting is when there are new commissioners. Ed Kraus expressed that choosing the chair and vice chair are more effectively done in person.
    b. Dr. Caserta confirmed that the December meeting of the Commission is telephonic. He suggested that the Commission could request the Secretary directly for the March meeting to be in-person, but with the caveat that there could be no other in-person meetings for the fiscal year 2014.
    c. David King questioned Dr. Caserta as to why NVAC continued to meet in-person regularly but the ACCV had not had an in-person meeting for a year and a half; why both commissions that were created by the same legislation are treated differently; and why ACCV had not had an in-person meeting for a year and a half.
    d. After some discussion, it was agreed upon that the best person to answer the questions is Dr. Wakefield (or her designee). Dr. Caserta agreed that he

would extend the request for Dr. Wakefield to attend the December meeting through the proper channels.

e. The travel issue will once more be in the agenda for the December meeting where we could open the conversation to find other possible actions the Commission as a whole could do to make a face-to-face meeting take place at least once a year, more, if possible.

E. Other matters: FYI

a. There is a public hearing scheduled after the ACCV meeting regarding the rotavirus vaccine and proposed rule making. It is traditional for the hearing to be scheduled after the ACCV meeting to give the commissioners a chance to participate as part of the public. The chair requested that the scheduled time be changed to allow the Commission to finish its business for the day.

b. FYI – On November 21, HRSA staff briefed the Congressional staff of Rep. Issa, (R – CA) and Rep. Cummings, (D –MD) to provide them information about the VICP. After the briefing, Congress may ask the GAO to investigate the Program or a Congressional hearing may be held next year. However, HRSA staff is not sure of the next steps for Congressional staff after the briefing.