

## **NVIC Public Comment – Advisory Commission on Childhood Vaccines**

### **Theresa Wrangham, NVIC Executive Director**

#### **March 7, 2024 Comment**

My name is Theresa Wrangham and I'm, the executive director for the National Vaccine Information Center. Our co-founders are parents of vaccine-injured children and They worked with Congress to draft and pass the National Child Vaccine Injury Act of one thousand nine hundred and eighty six, which created this committee.

With regard to Commissioner Boyle's concern about adequacy of compensation given disparities in an earlier presentation. I would simply remind the ACCV that several years ago that question was raised, and a report was made by the Banyon or Altarum that actually recommended the some sort of ongoing review of the adequacy of compensation – are awards that are being metted out from VICP adequate to the injuries that petitioners are filing for and subsequently compensated for. There is no mechanism and I have been monitoring this committee for almost twenty years now, and I've seen nothing done with that report or efforts to really look at compensation adequacy.

In terms of ACCV's charter to survey Federal, state, and local levels of what's being done to monitor adverse events, perhaps a better question would be what infrastructure is in place at a state and local levels. I believe that for state immunization information systems part of what was envisioned was that they would act in part to monitor vaccine adverse events at a local level. So perhaps a report on where that is would be helpful to the ACCV.

Regarding research being presented to the committee, and it's quality, I appreciate the overview given today of the guided principles that the ACCV uses, but would also remind the ACCV that the Institute of Medicine also issued a report with regard to the public trust in vaccine safety research, more specific to the data sharing program from the vaccine safety data link (VSD) which is often relied on to provide the Commission with an overview of research during the CDC's ISO update.

That report from 2005 stated that the data sharing program within the VSD was not traditional, and it didn't really meet rigor for a data sharing program that would allow for independent researchers to either validate and confirm the findings of CDC and their partners that participate in VSD. And let's look beyond that.

- There are several databases within the surveillance monitoring system for the Federal Government. What are those data-sharing programs?
- How did CDC implement the IOM recommendations to open up the data sharing to be more traditional so that their findings could be validated, or that other hypotheses could be posed?

The IOM report found that the public had legitimate trust issues, and that they needed to be resolved. If you want trust, then I believe you really have to earn it and open up those systems for scientific rigor, and show some transparency on that that monitoring front. It can't just be Federal agencies and their partners reporting. There needs to be some independent research as well to validate Government findings.

#### **March 8, 2024 Comment**

My name is Theresa Wrangham, as you know, I'm the Executive Director for the National Vaccine Information Center. I provided a comment yesterday, so i'm not going to reintroduce who we are as an organization except to say that we've represented and been a voice for the vaccine-injured and worked with Congress, and sat on this committee over the lifetime of our forty years of existence.

I appreciate the discussion on GBS vs. CIDP, and Commissioner Boyle and others pointing out that, like many injuries, CIDP and GBS injuries may be linked to individual susceptibility. I believe that was the spirit of Mr. Boyle's concern around

brachial neuritis and the need to look at individual susceptibility even when we don't have a public health signal. The purpose of the VICP as our co-founders worked with Congress to get this program established was in part to ensure compensation even in the absence of a public health signal for petitions that may be based on individual susceptibility. The Institute of Medicine, which presents to this committee, noted in 2012 that individual susceptibilities likely played a role in vaccine injuries.

It appears that discussion about this injury has taken place outside of this meeting and away from the public eye, so it was hard to follow some of today's discussion of these shoulder injuries. This committee is subject to the Federal Advisory Committee Act and discussions of this nature should be public, along with materials associated with the discussion, as they inform the committee's decision-making.

Lastly, I would remind the committee that GBS was added to the vaccine injury table not because the IOM made a causality statement, but because HRSA requested it based on the number of petitions already awarded for that injury. The petitions were data-mined to support that statement. Similar data mining of compensation awards for other injuries that may not raise a public health signal and rest on individual susceptibility should be considered.