



**National Vaccine Information Center Oral Public Comment  
Office of the U.S. Secretary of Health & Human Services  
National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table Hearing  
January 14, 2016**

My name is Theresa Wrangham and I am Executive Director for the National Vaccine Information Center. NVIC's mission since 1982 has been preventing vaccine injuries and deaths through public education and securing informed consent protections in public health policies and laws. Our comments today are made on behalf of NVIC's more than 150,000 donor supporters and followers.

At the request of congressional staff, NVIC co-founders worked for four years with parents and Congress on the 1986 National Childhood Vaccine Injury Act that created the vaccine injury compensation program (VICP) and the Vaccine Injury Table (VIT).<sup>1 2</sup> While NVIC supports the proposed addition of new vaccine injuries to the Table, we note that the Institute of Medicine (IOM) findings related to these additions are miniscule when compared to ongoing deficits in vaccine safety evidence highlighted by IOM that has hampered the ability of IOM committees to make definitive conclusions about causation for more than 20 years.<sup>3 4 5 6</sup>

While the numbers of federally recommended vaccinations have tripled between 1986 and 2016, vaccine risk knowledge gaps have increased. This has resulted in the majority of vaccine injury claims submitted to the VICP being litigated as off-Table injury claims and denial of much needed compensation to two out of three petitioners. The 1986 law's legislative history makes it clear that the VICP was to be an expedited, non-adversarial, and just alternative to bringing a vaccine injury lawsuit in civil court.<sup>7 8 9</sup> As a participant in that legislative history, NVIC opposes any revision of the VIT relating to the definition of encephalopathy that results in making it more difficult for the vaccine injured to obtain federal compensation.

The VIT was created as the VICP's centerpiece to facilitate the administrative claims process. Acute and chronic encephalopathy (encephalitis,<sup>10 11</sup> encephalomyelitis<sup>12</sup>) was appropriately included on the Table as one of the most well known serious complications of vaccination deserving of federal compensation.<sup>13</sup>

Since the first vaccines for smallpox and rabies, brain inflammation or acute and chronic encephalopathy<sup>14 15</sup> (encephalitis,<sup>16 17</sup> encephalomyelitis<sup>18</sup>) has historically been acknowledged as a serious complication of vaccines, including for pertussis (DPT/DTaP),<sup>19</sup> measles (MR, MMR)<sup>20</sup> and other federally recommended vaccines.<sup>21 22</sup> When the 1986 law was enacted, encephalopathy was defined in the VIT as "*any acute or chronic significant acquired abnormality of, or injury to, or impairment of function of, the brain,*" which remains consistent with encephalopathy definitions in the scientific literature.

Importantly, the 1986 law acknowledged biodiversity and specified that individual susceptibilities manifested by pre-existing health conditions, which are aggravated or triggered by vaccination, do not disqualify a person from receiving federal compensation. The law also specified that the IOM conduct reviews of vaccine safety science because of its reputation for assembling committees with broad representation and utilization of a deliberative, transparent public engagement process when addressing scientific and controversial public policy issues.

In 1991 the IOM reported on the adverse effects of pertussis and rubella vaccines<sup>23</sup> and took great care in defining encephalopathy and reaffirmed their definition again in 1994.<sup>24</sup> The definition was described as a “constellation of symptoms and signs reflecting a generalized disturbance in brain function” that include more than a dozen clinical symptoms recognized by NIH.<sup>25 26 27 28</sup>

In their 2012 report on adverse effects of vaccines, the IOM also highlighted the fact that vaccine science is evolving and there are biological, genetic, environmental and other high risk factors, which increase an individual’s susceptibility to vaccine reactions but which doctors do not yet understand and cannot predict.<sup>29</sup>

But despite wide acceptance of the IOM’s definition of encephalopathy, the VIT definition was narrowed by DHHS in 1995<sup>30</sup> and limited vaccine injury compensation awards. The proposed changes by DHHS to the definition of encephalopathy under consideration today continue that trend.

Vaccine risk knowledge gaps, biodiversity and individual susceptibility to vaccine reactions cannot be ignored by capriciously narrowing the definition of encephalopathy and making the vaccine injury compensation program more adversarial when it was designed to err on the side of the vaccine injured.

Given lack of knowledge about biological mechanisms and high risk factors for vaccine injury, the proposed changes to encephalopathy are without ethical, scientific or legal justification. VIT definitions should be flexible and consistent with IOM’s widely accepted definition for encephalopathy and facilitate vaccine injury compensation.

NVIC urges rejection of the proposed QAI language for encephalopathy because it penalizes and unfairly discriminates against those born with certain genes or pre-existing health conditions that may be triggered or significantly aggravated by federally recommended and state mandated vaccines.

**Courtesy Copy Submitted to HRSA January 14, 2016**

## References

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<sup>2</sup> Holland MS, Krakow RJ. [Brief of Amici Curiae National Vaccine Information Center, Its Co-Founders and 24 other organizations in support of petitioners](#). In: *Bruesewitz v. Wyeth* filed with Supreme Court of the United States June 1, 2010.

<sup>3</sup> Institute of Medicine Vaccine Safety Committee. [Adverse Effects of Pertussis and Rubella Vaccines](#). Washington, DC. *The National Academies Press*. 1991. [Afterword on Research Needs](#). (p. 206).

<sup>4</sup> Ibid. [Executive Summary](#) (p. 17).

<sup>5</sup> Ibid. [Risk-Modifying Factors](#) (p. 307).

<sup>6</sup> Johann-Liang R. [Updating the Vaccine Injury Table following the 2011 IOM Report on Adverse Effects of Vaccines](#). ACCV Presentation (pg 17). Mar. 8, 2012.

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<sup>8</sup> [Written testimony of Barbara Loe Fisher, NVIC Co-founder and President](#). *Criminal Justice, Drug Policy and Human Resources Subcommittee, House Government Reform Committee*. Sept. 28, 1999.

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<sup>10</sup> Medline Plus. [Encephalitis: Symptoms \(Infants\) and Emergency Symptoms](#). Aug. 1, 2012.

<sup>11</sup> HealthGrades. [What Are Symptoms of Encephalitis?](#) and [What are Causes of Encephalitis?](#) Aug. 9, 2013.

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