National Vaccine Information Center

Your Health. Your Family. Your Choice

NVIC.org & NVICAdvocacy.org

NPRM to Remove SIRVA & Syncope Consumer Perspective

Theresa Wrangham, Executive Director - National Vaccine Information Center

ACCV Presentation – December 3, 2020

- NVIC/DPT Invited to draft and helped to pass National Childhood Vaccine Injury Compensation Act of 1986.
- Participation on and appointed to 1986 Act FACA committees;
- Invited by IOM to coordinate vaccine safety workshops and opine on safety of the schedule.

NVIC – Informed Consent & Vaccine Safety Concerned Consumer Watchdog

- **Injury Compensation –** no fault, generous, and expeditious and giving injured benefit of doubt;
- **Establish Vaccination Plan -** Optimal prevention of infectious diseases and vaccine adverse events.
- **Research Mandate**
  - Promote vaccine development with fewer and less serious adverse reactions than 1987 vaccines;
  - Assure vaccine refinements and improvements in all aspects to reduce risks vaccine adverse events;

DHHS Requirements Under 1986 Act – Partial List

Institute of Medicine (IOM) Causality Conclusions Inform Vaccine Injury Table

- Injection Related – Considered “potential consequences associated with direct trauma from the administration of various injected vaccines and *not necessarily attributable* to the contents of the vaccine;
- Did not rule out vaccine as cause.

IOM Causality Conclusions – SIRVA & Syncope

- IOM SIRVA – Atanasoff et al. (2010) were consistent with deltoid bursitis and established a strong temporal relationship between injection of a vaccine and development of deltoid bursitis. Furthermore, the observations made by MRI by Atanasoff et al. (2010) ***suggest*** that the injection, and not the contents of the vaccine, contributed to the development of deltoid bursitis.

- NPRM - “the injection, and not the contents of the vaccine, contributed to the development of deltoid bursitis.” - Missing the word SUGGEST

IOM Causality Conclusions – SIRVA

- IOM Syncope – Noted severe injuries due to syncope and stated “The latency, of 15 minutes or less, between injection of a vaccine and the development of syncope in many of the cases described above ***suggests*** vasovagal syncope as the mechanism.”
- NPRM – “…the Department noted that the IOM found that syncope did not result from any particular antigen, but instead from the act of the injection.” Missing the word SUGGESTS

IOM Causality Conclusions – Syncope

- **IOM SIRVA** - Conclusion 12.2 & 12.3 : The evidence convincingly supports a causal relationship between the injection of a vaccine and deltoid bursitis and syncope;
- Recommended by HRSA (2012 – 2016 via presentations), adopted by ACCV March 2012 and added to Table January 2017;
- No DHHS/HRSA presentation of new evidence to ACCV justifying proposed changes to Table, though requested.

SIRVA & Syncope – History

- Research continues to suggest HPV vaccine has disproportionately high rates of syncope compared to other vaccines – suggesting vaccine is in play;
- Research continues to be published on SIRVA and health professionals have shared their clinical observations that they believe vaccines are in play with SIRVA;
- ACCV guidelines state erring on the side of petitioner.

- Table petitions - 74% before 1995, 2% by 2015 (Holland 2018, GAO 2001 & 2014)
- Overall, 2/3 of claims have been denied;
- Vaccine injuries in children rarely compensated;

$4.4+ billion and 7,600+ vaccine injury awards later...

- GAO 1999 – *"far more claims have historically been associated with injuries HHS removed from the table than with injuries HHS added to it. For example, about half of the awards made since the program's inception have been for neurological injuries that HHS later removed from the table in 1995 and 1997. Removing these injuries shifts the burden of proof to the petitioner, making it more difficult to qualify for compensation under VICP."*

$4.4+ billion and 7,600+ vaccine injury awards later…

- Overwhelming public comment support to retaining these injuries and VICP Trust can cover compensation;
- VICP process already excludes claims without merit;
- Removal
  - conflicts with spirit and intent of 1986 Act;
  - reverses expeditious compensation;
  - increases costs and provides no relief to caseloads;
  - a return to 2% for Table claims - adversarial;
  - increases distrust in government.

Removal of table injuries makes VICP more adversarial…

National Vaccine Information Center

Your Health. Your Family. Your Choice

NVIC.org & NVICAdvocacy.org

THANK YOU!