



The National Vaccine Injury Compensation Program (VICP)

Division of Vaccine Injury Compensation Update

Advisory Commission on Childhood Vaccines

June 5, 2014

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Department of Health and Human Services
Health Resources and Services Administration

ACCV Meeting Highlights

- Clarification on Proposed Changes to the Vaccine Injury Table
- Update from the Department of Justice Vaccine Litigation Office
- Petition to Add Diabetes Mellitus as an Injury for MMR to the Vaccine Injury Table
- Report from the ACCV Process Workgroup
- Review of Vaccine Information Statements
- Updates from ACCV Ex Officio Members — FDA, CDC, NIH, NVPO

Number of Petitions Filed as of May 6, 2014

Average annual number of petitions filed during FY 2009-2013 = 427

Fiscal Year	Total
FY 2009	397
FY 2010	449
FY 2011	386
FY 2012	400
FY 2013	503
FY 2014	311

Number of Adjudications as of May 6, 2014

Fiscal Year	Compensable	Dismissed	Total
FY 2009	134	231	365
FY 2010	181	292	473
FY 2011	261	1,370	1,631
FY 2012	259	2,439	2,698
FY 2013	365	627	992
FY 2014	148	98	246

Adjudication Categories for Non-Autism Claims FY 2012 – FY 2014 as of May 6, 2014

Adjudication Category	FY 2012	FY 2013	FY 2014 As of 5/6/14
Compensable	259 (100%)	365 (100%)	148 (100%)
❖ Concession	13 (5%)	21 (6%)	19 (13%)
❖ Court Decision (includes proffers)	30 (12%)	21 (6%)	17 (11%)
❖ Settlement	216 (83%)	323 (88%)	112 (76%)
Not Compensable	144	88	64
Adjudication Total	403	453	212

Award Amounts Paid as of May 6, 2014

<u>Fiscal Year</u>	<u>Petitioners' Award</u>	<u>Attorneys' Fees & Costs</u>
FY 2009	74,142,491	11,203,212
FY 2010	179,387,341	9,826,786
FY 2011	216,319,428	17,163,229
FY 2012	163,511,999	23,148,927
FY 2013	254,666,326	9,758,308
FY 2014	128,193,096	12,828,134

Vaccine Injury Compensation Trust Fund

- Balance as of March 31, 2014
 - \$3,475,302,680.15
- Activity from October 1, 2013 to March 31, 2014
 - Excise Tax Revenue: \$95,277,401
 - Interest on Investments: \$30,317,260
 - Net Income: \$125,594,662
 - Interest as a Percentage of Net Income: 24%

Source: U.S. Treasury, Bureau of Public Debt (May 6, 2014)

Significant Activities

- 2nd Public Hearing for Rotavirus NPRM was held on April 28, 2014 at which time no comments were received.
- Notice Adding Seasonal Influenza Vaccines to the Vaccine Injury Table
 - Federal Register Notice Published on November 12, 2013
 - As of November 12, 2013, petitions may be filed for all vaccines against seasonal influenza which are not already covered under the VICP. All trivalent vaccines have been covered under the VICP since July 1, 2005.

Significant Activities

- GAO Study of the VICP - Background
 - Requested by the House Committee on Oversight and Government Reform
 - Objectives/Key Questions
 - What are the current timeframes for processing VICP claims and what factors are associated with longer processing timeframes?
 - What changes have been made to the Vaccine Injury Table and what are the criteria for changing the Table?
 - How have the funds in the Trust Fund been spent?
 - What is know about the experience of claimants who have filed claims with the VICP?
 - How has HHS publicized the existence of the VICP?

Significant Activities

- GAO Study of the VICP – Status
 - In March, HRSA and DOJ had separate entrance conference meetings with GAO.
 - HRSA is responding to GAO's requests for information.
 - GAO has met with specific categories of ACCV members.
 - GAO has met with the Court.
 - GAO would like to complete its study in August and a report will be generated thereafter.

Proposed Table Change

- To modify category XIV on the Table from “Trivalent influenza vaccines” to “Seasonal influenza vaccines”

ACCV Recommendation Options

1. Modify category of “Trivalent influenza vaccines” to “Seasonal influenza vaccines”
2. Do not modify category of “Trivalent influenza vaccines” to “Seasonal influenza vaccines”

Proposed Table Changes

- Currently, category IX is Haemophilus influenzae type b polysaccharide conjugate vaccines
- Propose to modify category IX from Haemophilus influenzae type b polysaccharide conjugate vaccines to Haemophilus influenzae type b vaccines

ACCV Recommendation Options

1. Modify category IX from Haemophilus influenzae type b polysaccharide conjugate vaccines to Haemophilus influenzae type b vaccines
2. Do not modify category IX from Haemophilus influenzae type b polysaccharide conjugate vaccines to Haemophilus influenzae type b vaccines

Proposed Clarifying Language to Add to the QAI

“...an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

(A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesions, psychiatric illness, dementia, genetic disorder...”

Proposed Clarifying Language to Add to the QAI

“Individuals who return to their baseline neurologic state, as confirmed by clinical findings, in **less than 6 months from the date of vaccination** shall not be presumed to have suffered residual neurologic damage from that event...”

Proposed Clarifying Language to Add to the QAI

“...Thrombocytopenic purpura does not include cases of immune thrombocytopenic purpura that are mediated for example, by viral or fungal infections...**However, if...testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect”**

Proposed Clarifying Language to Add to the QAI

- “SIRVA manifests as shoulder pain and limited range of motion after the administration of a vaccine intended for intramuscular administration in the upper arm”



Public Comment/Participation in Commission Meetings

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