

2021 Current Fiscal Year Report: Advisory Commission on Childhood Vaccines

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1. Department or Agency		2. Fiscal Year	
Department of Health and Human Services		2021	
3. Committee or Subcommittee		3b. GSA Committee No.	
Advisory Commission on Childhood Vaccines		36	
4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	07/21/2020	07/21/2022	
8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date	
No			
9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?	
Continue	Not Applicable	Not Applicable	
11. Establishment Authority	Statutory (Congress Created)		
12. Specific Establishment Authority	13. Effective Date	14. Committee Type	14c. Presidential?
42 U.S.C. 300aa-19	10/01/1988	Continuing	No
15. Description of Committee	National Policy Issue Advisory Board		
16a. Total Number of Reports	No Reports for this FiscalYear		
17a. Open Meetings and Dates	17b. Closed	17c. Partially Closed	Other Activities
4	0	0	0
17d. Total Meetings and Dates	4		
Purpose	Start	End	

The Advisory Commission on Childhood Vaccines (ACCV) conducted its 116th quarterly meeting by teleconference and Adobe Connect on December 3, 2020. The meeting began with program updates from the Division of Injury Compensation Programs (DICP) and the Department of Justice (DOJ). The ACCV Workgroup presented proposed VICP statute of limitations language to add to Vaccine Information Statements (VIS) to the full ACCV. The ACCV voted 3 to 1 to approve adding language stating the minimal timeframe that VICP claims must be filed to the VIS. Following the DICP, DOJ and Workgroup presentations, the ACCV heard from various stakeholders that they invited to give their views about the VICP Notice of Proposed Rulemaking (NPRM), which proposes to amend the Vaccine Injury Table (Table). The VICP NPRM proposes to remove shoulder injury related to vaccine administration (SIRVA) and vasovagal syncope from the Table on the basis that these injuries generally result from the administration of a vaccine, not the vaccine antigen. The ACCV heard presentations and comments from the following: 1. Ms. Theresa Wrangham, Executive Director, National Vaccine Information Center (NVIC); 2. Ms. Christina Ciampolillo, JD, President of the Vaccine Injured Petitioners Bar Association; 3. Mr. Mike Milmoie, JD, Former Vaccine Litigation, DOJ attorney and current attorney with the Law Office of Leah Durant; 4. Marko Bodor, MD, Interventional Spine and Sport Medicine; and 5. Uma Srikumaran, MD, Associate Professor of Orthopaedic Surgery, Johns Hopkins Shoulder and Sports Medicine. The ACCV also received program updates from the Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease (NIH), the Center for Biologics, Evaluation and Research (FDA) and the Office of Infectious Disease and HIV/AIDS Policy (OIDP). Ms. Karen Kain, ACCV Member, would like the ACCV to consider making a recommendation to the Secretary that HHS conduct a study of the health outcomes of vaccinated vs. unvaccinated populations. She led the discussion and distributed an article and a list of other articles as background information. Dr. Jonathan Duffy, CDC, provided an overview of studies relevant to this topic. Since the studies that Dr. Duffy cited were published prior to 2017, Ms. Kain would like to invite individuals who have authored more recent articles on her list to present at the March 2021 ACCV Meeting to support her efforts for the full ACCV to vote to make a recommendation to the Secretary.

12/03/2020 - 12/03/2020

The ACCV conducted its 117th quarterly meeting teleconference and Adobe Connect on March 4, 2021. The morning began with updates from the Division of Injury Compensation Programs (DICP) and the Department of Justice (DOJ). The ACCV also received program updates from the Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease (NIH), the Center for Biologics, Evaluation, and Research (FDA) and the Office of Infectious Disease and HIV/AIDS Policy (OIDP). The ACCV meeting scheduled for June 18, 2021 was cancelled due to the observance of Juneteenth Day.

03/04/2021 - 03/04/2021

06/18/2021 - 06/18/2021

The ACCV conducted its 118th quarterly meeting by Zoom on September 2, 2021. The morning began with updates from the Division of Injury Compensation Programs (DICP) and the Department of Justice (DOJ). The ACCV also received program updates from the Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease (NIH), the Center for Biologics, Evaluation, and Research (FDA) and the Office of Infectious Disease and HIV/AIDS Policy (OIDP). Ms. Karen Kain, ACCV Member, would like the ACCV to consider making a recommendation to the Secretary that HHS conduct a study of the health outcomes of vaccinated vs. unvaccinated populations. Ms. Kain plans to write the recommendation, and provide articles to support her recommendation, to ACCV members for review prior to the December meeting.

09/02/2021 - 09/02/2021

Number of Committee Meetings Listed: 4

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$7,176.00	\$19,136.00
18a(2). Personnel Pmts to Federal Members	\$22,691.00	\$22,495.00
18a(3). Personnel Pmts to Federal Staff	\$257,295.00	\$266,016.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$12,000.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$3,600.00	\$3,650.00

18d. Total	\$290,762.00	\$323,297.00
19. Federal Staff Support Years (FTE)	1.50	1.50

20a. How does the Committee accomplish its purpose?

The Advisory Commission on Childhood Vaccines (ACCV) accomplishes its purpose by meeting in full session and establishing special topic workgroups. In Fiscal Year (FY) 2021, the ACCV continued to meet and have discussions on topics regarding the National Vaccine Injury Compensation Program (VICP). Each meeting included representatives from various federal government agencies, as well as other stakeholders (i.e. vaccine manufacturer, petitioner's attorney).

20b. How does the Committee balance its membership?

The ACCV members consist of three health professionals who are not employees of the federal government, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two are pediatricians; three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death; and three attorneys, of whom at least one is an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and one who is an attorney whose specialty includes representation of vaccine manufacturers.

20c. How frequent and relevant are the Committee Meetings?

The ACCV meets four times a year to advise the Secretary of HHS on matters related to the implementation of the VICP. However, due to June 18th being designated a federal holiday, the ACCV only met three times in FY 2021.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The ACCV members represent the various stakeholders that have an interest in the VICP, and provide scientific, legal and practical advice and recommendations to the Secretary of HHS. This expertise is not available within HHS.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

No Reports for FY 2021. Member Barbara Pahud's term end date changed from 1/1/2023 due to this member resigning from the ACCV in July 2021. Patricia Woodi's term end date

changed from 8/30/2022 due to this ex-officio being replaced by Jonathan Duffy at CDC in FY 2021. ACCV had no Chair for FY 2021; only a Vice-Chair, Karen Kain. ACCV member William Spiegel was erroneously missing in the FY 2020 ACR. Their appointment term is 05/10/2020 thru 05/10/2023.

Designated Federal Officer

Tamara Overby Acting Director, Division of Injury Compensation Programs

Committee Members	Start	End	Occupation	Member Designation
Boyle, Daniel	08/29/2021	08/01/2024	Member of the General Public	Special Government Employee (SGE) Member
Deshon, Dana	08/29/2021	08/01/2024	Health Professional	Special Government Employee (SGE) Member
Duffy, Jonathan	01/01/2020	01/01/2023	Immunization Safety Office, CDC	Ex Officio Member
Holloway, Albert	08/29/2021	08/01/2024	Health Professional, Pediatrician	Special Government Employee (SGE) Member
Howie, John	09/08/2017	12/31/2020	Howie Law, PC	Special Government Employee (SGE) Member
Kain, Karen	08/01/2019	07/31/2022	General Public - Parent of Vaccine Inured Child	Special Government Employee (SGE) Member
Kim, David	12/02/2016	12/31/2022	Director, Office of Infectious Disease and HIV/AIDS Policy	Ex Officio Member
Marshall, Valerie	12/08/2011	12/31/2021	Immediate Office of the Director, Office of Vaccine Research and Review, FDA	Ex Officio Member
Mulach, Barbara	01/01/2002	12/31/2021	National Insitute of Allergy and Infectious Disease, NIH	Ex Officio Member
Pahud, Barbara	01/01/2020	07/15/2021	Research Director, Pediatric Infectious Disease, University of Missouri-Kansas City School of Medicine	Special Government Employee (SGE) Member
Spiegel, William	05/10/2020	05/10/2023	General Attorney, Rawle and Henderson, LLP	Special Government Employee (SGE) Member

Number of Committee Members Listed: 11

Narrative Description

The ACCV provides advice and makes recommendations to the Secretary of HHS regarding the VICP.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input checked="" type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>

Other

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

None

Unable to Determine

Under \$100,000

\$100,000 - \$500,000

\$500,001 - \$1,000,000

\$1,000,001 - \$5,000,000

\$5,000,001 - \$10,000,000

Over \$10,000,000

Cost Savings Other

Cost Savings Comments

Due to COVID outbreak the ACCV held all of the meetings virtually. Therefore no travel reimbursements were made in FY 21.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

63

Number of Recommendations Comments

These recommendations provide advice to the Secretary of HHS regarding the VICP.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

44%

% of Recommendations Fully Implemented Comments

These recommendations have been implemented to improve aspects of the VICP. No new recommendations were made in FY 21 but recommendations made in previous years were implemented.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

5%

% of Recommendations Partially Implemented Comments

These recommendations have been implemented to improve aspects of the VICP.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes No Not Applicable

Agency Feedback Comments

The Secretary of HHS acknowledges receipt of the ACCV recommendations, and thanks the ACCV for providing advice and recommendations on the VICP. The public can obtain information on agency feedback at the ACCV website:

<https://www.hrsa.gov/advisory-committees/vaccines/index.html>

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

- Reorganized Priorities
- Reallocated resources
- Issued new regulation
- Proposed legislation
- Approved grants or other payments
- Other

Action Comments

In FY 2021, the ACCV recommended that the Secretary support efforts to increase the number of Special Masters and the amount of staffing and funding resources for the VICP. This recommendation was included in a letter sent to the Secretary on December 2, 2020. All ACCV recommendations are posted on the ACCV website at <https://www.hrsa.gov/advisory-committees/vaccines/reports-recommendations.html>.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO



Online Agency Web Site



Online Committee Web Site



Online GSA FACA Web Site



Publications



Other



Access Comments

N/A