

2000 Current Fiscal Year Report: Antiviral Drugs Advisory Committee

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1. Department or Agency Department of Health and Human Services
2. Fiscal Year 2000
3. Committee or Subcommittee Antiviral Drugs Advisory Committee
3b. GSA Committee No. 789

4. Is this New During Fiscal Year? No
5. Current Charter 02/15/1999
6. Expected Renewal Date 02/15/2001
7. Expected Term Date

8a. Was Terminated During Fiscal Year? No
8b. Specific Termination Authority
8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year Continue
10a. Legislation Req to Terminate?
10b. Legislation Pending?

11. Establishment Authority Authorized by Law
12. Specific Establishment Authority 21 U.S.C. 394
13. Effective Date 11/28/1990
14. Committee Type Continuing
14c. Presidential? No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports 1
16b. Report Date 09/30/2000
Report Title Annual Report to the Secretary

Number of Committee Reports Listed: 1

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 2 **Other Activities** 0 **17d. Total** 3

Meetings and Dates

Purpose	Start	End
Advisory	10/04/1999	- 10/05/1999
Advisory	11/01/1999	- 11/03/1999
Advisory	07/25/2000	- 07/26/2000

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$5,550.00	\$40,227.00
18a(2). Personnel Pmts to Federal Members	\$1,050.00	\$3,094.00
18a(3). Personnel Pmts to Federal Staff	\$70,003.00	\$72,836.00
18a(4). Personnel Pmts to Non-Member Consultants	\$7,650.00	\$19,340.00
18b(1). Travel and Per Diem to Non-Federal Members	\$24,556.00	\$19,014.00
18b(2). Travel and Per Diem to Federal Members	\$1,927.00	\$2,781.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$28,445.00	\$28,371.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	\$0.00	\$0.00
18d. Other (all other funds not captured by any other cost category)	\$24,826.00	\$33,104.00
18e. Total Costs	\$164,007.00	\$218,767.00
19. Federal Staff Support Years (FTE)	1.25	1.25

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates available

data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections. The Committee met on October 4-5, 1999 and discussed issues related to the potential applicability of information from non-U.S. studies of prevention of perinatal human immunodeficiency virus transmission to U.S. clinical settings. Presentations were made regarding the epidemiology of mother-to-child transmission of HIV in the U.S. and the USPHS task force recommendations. An overview of NICHD/CRMC/PAMA clinical trials was presented. The CDC presented information on the conduct of trials in developing nations. The FDA presented information on the safety considerations on conducting these clinical trials and the regulatory considerations in the development of drugs to prevent perinatal transmission of HIV. On November 1, 1999, the committee discussed the new drug, adefovir dipivoxil (Gilead Sciences Incorporated), 60 mg for the treatment of HIV infection. The Committee voted Yes:1 and No:13 to the question, Do the provided data establish that adefovir 60 mg is safe and effective for the treatment of HIV infection? On November 2 and 3, 1999, the committee discussed issues related to testing for development of resistant Human Immunodeficiency Virus (HIV-1), with an emphasis on its potential role in antiretroviral drug development. The committee provided advice and recommendations on the amount and type of resistance data needed to support both preclinical and clinical development of antiretroviral drugs and antiretroviral product labeling. The committee met on July 25-26, 2000. The discussion was as

follows: types of scientific data required to characterize relationships of pharmacokinetic parameters and virologic response to approved antiretroviral drugs used in the treatment of human immuno-deficiency virus (HIV) infections. In addition, the committee explored the use of pharmacokinetic data to improve the evaluation of new formulations, alternative dosing regimens, and choice of dosing in the setting of drug-drug interactions for approved antiretroviral drugs.

20b. How does the Committee balance its membership?

Members are authorities in the fields of clinical pharmacology, internal medicine, infectious diseases, microbiology, virology, psychiatry, statistics, epidemiology, ophthalmology, immunology, pediatrics, hematology, and related specialties. The committee includes one technically qualified voting member who is identified with consumer interests and may include one non-voting member who is identified with industry interests.

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

The committee met three times in FY 2000 and anticipates holding six meetings in FY 2001. The committee will continue to provide relevant advice to the agency on the safety and efficacy of new molecular entities and supplementary indications for prescription antiviral, antimycobacterial, and antifungal drug products, as well as on trial design and other issues as requested.

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

Members of the committee are drawn from academia, research, and/or clinical practice. Their

advice and input lends credibility to regulatory decisions made and helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at great expense to the government.

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

FDA is required to close portions of meetings to permit discussion of trade secret data and/or confidential commercial information (5 U.S.C. 552b(c)(4) and 21 U.S.C. 331(j)).

21. Remarks

Designated Federal Officer

Nancy Chamberlin Health Science Administrator, Advisors and Consultants Staff, Center for Drug Evaluation and Research, FDA, HFD-21

Committee Members	Start	End	Occupation	Member Designation
Diaz, Pamela	10/01/1999	09/30/2000	Med Dir, Communicable Diseases, Chicago Dept Of Health, Chicago, IL	Special Government Employee (SGE) Member
El-Sadr, Wafaa	10/01/1999	09/30/2000	Dir, Div of Infectious Diseases, Harlem Hospital Ctr., New York, NY	Special Government Employee (SGE) Member
Feinberg, Judith	10/01/1999	09/30/2000	Assoc Prof of Clin. Med., Holmes Hospital, Univ of Cincinnati, OH	Special Government Employee (SGE) Member
Fletcher, Courtney	10/31/1999	10/31/2003	University of Minnesota	Special Government Employee (SGE) Member

Gulick, Roy	10/01/1999	09/30/2000		Special Government Employee (SGE) Member
Gulick, Roy	10/31/1999	10/31/2000	N.Y. Presbyterian Hospital	Special Government Employee (SGE) Member
Hamilton, John	10/01/1999	09/30/2000	Prof. of Medicine, Div of Inf. Dis and International Health, Duke Univ. Med. Ctr., NC	Special Government Employee (SGE) Member
Hammer, Scott	10/01/1999	09/30/2000	Dir., Res. Virology Lab., Div. of Infectious Disease, New England Deaconess Hospital, Boston, MA	Special Government Employee (SGE) Member
Kumar, Princy	10/31/1999	10/31/2003	Georgetown University	Special Government Employee (SGE) Member
Lipsky, James	10/01/1999	09/30/2000	Director, Clinical Pharmacology, Mayo Clinic, Rochester, MN	Special Government Employee (SGE) Member
Masur, Henry	10/01/1999	09/30/2000	Chief, Critical Care Medicine, NIH, Bethesda, MD	Special Government Employee (SGE) Member
Mathews, William	10/31/1999	10/31/2003	University of California at San Diego	Special Government Employee (SGE) Member
Pomerantz, Roger	10/01/1999	09/30/2000	Chief, Div. of Inf. Disease, Thomas Jefferson Univ., PA	Special Government Employee (SGE) Member
Stanley, Sharilyn	10/31/1999	10/31/2003	Texas Department of Health	Special Government Employee (SGE) Member
Wong, Brian	01/01/1999	10/31/1999	Chief, Infectious Diseases, VA Connecticut Health Care System, West Haven, Conn.	Special Government Employee (SGE) Member

Woolson, Robert	01/01/1999	10/31/1999	Professor and Director, Division of Biostatistics, University of Iowa	Special Government Employee (SGE) Member
Yogev, Ram	01/01/1999	10/31/1999	Director, Section of Pediatric and Maternal HIV Infection, Children's Memorial Hosp., Chicago	Special Government Employee (SGE) Member

Number of Committee Members Listed: 17

Narrative Description

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

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

Outcome Comments

What are the cost savings associated with this committee?

	Checked if Applies
None	<input checked="" type="checkbox"/>
Unable to Determine	<input type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>

- \$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

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

0

Number of Recommendations Comments

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

%

% of Recommendations Fully Implemented Comments

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

%

% of Recommendations Partially Implemented Comments

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

Yes No Not Applicable

Agency Feedback Comments

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

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

No

Grant Review Comments

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