



ANNUAL REPORT  
OF THE  
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2004 through September 30, 2005

FUNCTION

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met three times during the reporting period. Meetings were held in Bethesda, Maryland. One meeting was held by teleconference.

The dates of those meetings were February 16-17, 2005, March 15, 2005, and September 22, 2005.

The meetings on February 16-17, 2005, and September 22, 2005 included closed sessions to permit discussion of secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

February 16-17, 2005 meeting in Bethesda, MD. The Committee reviewed and discussed the following topics: the strain selection for the Influenza Virus Vaccine for the 2005-2006 season including strain characterization; the FDA Critical Path Initiative; and the research programs in the Laboratory of Biophysics, and the Laboratory of Pediatrics and Respiratory Viral Diseases. In the afternoon of February 17, 2005, the Committee held a closed session to make recommendations on personnel and program actions for the Laboratory of Biophysics, and the Laboratory of Pediatrics and Respiratory Viral Diseases. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review. Also, in closed session the Committee heard an update on a Phase III trial for a vaccine manufactured by GlaxoSmithKline. Disclosure of the information reviewed involved trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The vaccine, Fluarix, was licensed by FDA.

September 22, 2005 via teleconference on the National Institutes of Health campus in Bethesda, Maryland. The Committee discussed and reviewed the Laboratory of Retroviruses, the Laboratory of Immunoregulation, the Laboratory of Respiratory and Special Pathogens, and the Laboratory of Methods Development and Quality Control. The Committee held a closed session to make recommendations on personnel and program actions for the Laboratory of Retroviruses, the Laboratory of Immunoregulation, the Laboratory of Respiratory and Special Pathogens, and the Laboratory of Methods Development and Quality Control. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

Detailed information related to these meetings is available in the annual report.

October 26, 2005  
Date

Christine A. Walsh  
Christine A. Walsh, R.N.  
Executive Secretary

# Vaccines and Related Biological Products Advisory Committee

## Committee Roster

### ***Chair***

#### **Gary D. Overturf, M.D.**

Expertise: Pediatrics  
Term: 02/01/02 - 01/31/06  
Professor of Pediatrics and Pathology  
University of New Mexico Center  
Ambulatory Care Center, 3rd Floor  
2211 Lomas Avenue, N.E.  
Albuquerque, New Mexico 87131

#### **Monica M. Farley, M.D.**

Expertise: Bacterial Infectious Diseases  
Term: 02/01/04 - 01/31/08  
Professor of Medicine  
Department of Medicine  
Emory University School of Medicine  
VA Medical Center  
Research - Infectious Diseases (151)  
1670 Clairmont Road  
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#### **Ruth A. Karron, M.D.**

Expertise: Pediatrics & Infectious Diseases  
Term: 02/01/03 - 01/31/07  
Associate Professor  
Division of International Health  
Johns Hopkins School of Hygiene and Public Health  
624 N. Broadway  
Hampton House, Room 117  
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#### **Philip S. LaRussa, M.D.**

Expertise: Pediatrics / Virology  
Term: 02/01/04 - 01/31/08  
Professor of Clinical Pediatrics  
Columbia University, PH-4 West - 462  
622 West 168th Street  
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#### **David M. Markovitz, M.D.**

Expertise: Infectious Diseases  
Term: 04/01/02 - 01/31/06  
Professor  
Division of Infectious Diseases  
Department of Internal Medicine  
University of Michigan Medical Center  
1150 West Medical Center Drive, Room 5220  
Ann Arbor, Michigan 48109

### ***Executive Secretary***

#### **Christine Walsh, R.N.**

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#### **Cindy Lyn Province, R.N., M.S.N.\***

Expertise: Consumer Representative  
Term: 04/10/03 - 01/31/07  
Associate Director  
Bioethics Center of St. Louis  
P.O. Box 6134  
Chesterfield, Missouri 63006

#### **Walter Royal, III, M.D.**

Expertise: Infectious Diseases / Neurology  
Term: 02/01/03 - 01/31/07  
Associate Professor of Medicine  
Morehouse School of Medicine  
720 Westview Drive, S.W.  
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#### **Steven Self, Ph.D.**

Expertise: Biostatistics  
Term: 02/01/04 - 01/31/08  
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Fred Hutchinson Cancer Research Center  
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#### **Bonnie M. Word, M.D.**

Expertise: Pediatric Infectious Diseases  
Term: 02/01/04 - 01/31/08  
Assistant Professor of Pediatrics  
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Texas Children's Hospital  
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6621 Fannin Street, Suite 1740.01  
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