

## **Drug Safety Oversight Board Roster**

### **Chair (Non-voting)**

- Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs  
Center for Drug Evaluation and Research

### **Acting Executive Director (Non-voting)**

- Terry Toigo, RPh, MBA  
Acting Executive Director of the Drug Safety Oversight Board, Associate Director for Drug Safety Operations, Center for Drug Evaluation and Research

### **Center for Drug Evaluation and Research**

#### Primary Member:

- Robert Temple, M.D., Deputy Director for Clinical Science  
Center for Drug Evaluation and Research

### **Office of New Drugs, Center for Drug Evaluation and Research**

#### Primary Members:

- Mwangi Kashoki, M.D.,M.P.H., Associate Director for Safety, Office of New Drugs
- Mary Parks, M.D., Director, Division of Metabolism and Endocrinology Products

#### Alternate Members:

- John Jenkins, M.D., Director, Office of New Drugs
- Sandra Kweder, M.D., Deputy Director, Office of New Drugs
- Ellis Unger, M.D., Deputy Director, Office of Drug Evaluation 1
- Andrea Leonard-Segal, Director, Division of Nonprescription Clinical Evaluation

### **Office of Medical Policy, Center for Drug Evaluation and Research**

#### Primary Member:

- Elizabeth Donohoe, M.D., M.H.S.A., Medical Officer, Immediate Office

#### Alternate Members:

- Kathleen Uhl, M.D., Deputy Director, Office of Medical Policy
- Denise Hinton, CDR, U.S. Public Health Service, Supervisory Senior Program Management Officer

### **Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research**

#### Primary Members:

- Mark I. Avigan, M.D., Director, Division of Drug Risk Evaluation
- Judy Staffa, Ph.D., R.Ph., Acting Associate Director for Regulatory Research

#### Alternate Members:

- Gerald Dal Pan, M.D., Director, Office of Surveillance and Epidemiology
- Henry « Skip » Francis, M.D., Deputy Director, Office of Surveillance and Epidemiology
- Carol A. Holquist, R. Ph., Director, Division of Medical Errors and Technical Support
- Ann McMahan, M.D., M.S., Deputy Director, Division of Drug Risk Evaluation
- Solomon Iyasu, M.D., M.P.H., Director, Division of Epidemiology

## **Office of Translational Sciences, Center for Drug Evaluation and Research**

### Immediate Office

#### Primary Member:

- Marc Walton, M.D., Ph.D., Associate Director, Office of Translational Sciences

#### Alternate Member:

- ShaAvhree Buckman, M.D., Ph.D., F.A.A.P. Acting Director, Office of Translational Sciences

## **Office of Biostatistics**

### Primary Member:

- Robert O'Neill, Ph.D., Director, Office of Biostatistics

### Alternate Member:

- Aloka Chakravarty, Ph.D., Director, Division of Biometrics

## **Office of Clinical Pharmacology**

### Primary Member:

- Darrell Abernethy, M.D., Ph.D., Associate Director of Drug Safety, Office of Clinical Pharmacology

### Alternate Member:

- Shiew-Mei Huang, Ph.D., FCP

## **Office of Communications**

### Primary Member:

- Julie Zawisza, Director, Office of Communications

### Alternate Member:

- Kimberly Rawlings, Deputy Director, Office of Communications
- Gregory Busse, Ph.D., Writer / Editor, Office of Communications

## **Office of Compliance, (CDER)**

### Primary Member:

- Ilisa B.G. Bernstein, Pharm. D., J.D., Acting Deputy Director, Office of Compliance

### Alternate Member:

- Charles E. Lee, M.D.CAPT, USPHS, Div. of New Drugs and Labeling Compliance, Office of Compliance

## **Office of the Center for Drug Evaluation and Research**

### **Safe Use Initiative Team**

#### Primary Member:

- Karen Weiss, M.D. M.P.H., Associate Director for Medical Affairs, Office of the Center Director

#### Alternate Member:

- Dale C. Slavin, Ph.D., Safe Use Initiative, Policy Analyst, Office of the Center Director

### **Office of Pharmaceutical Science, Center for Drug Evaluation and Research**

#### Primary Member:

- Laurie Muldowney, M.D. Medical Officer

#### Alternate Member:

- Nancy Chang, M.D., Office of Generic Drugs

### **Center for Biologics Evaluation and Research, Food and Drug Administration**

#### Primary Member:

- Robert Ball, M.D., M.P.H., M.S.S., Director, Office of Biostatistics and Epidemiology

#### Alternate Member:

- David Martin, MD., M.P.H., Acting Director, Division of Epidemiology, Office of Biostatistics and Epidemiology

### **Center for Devices and Radiological Health, Food and Drug Administration**

#### Primary Member:

- Murray Malin, M.D., MBA, Acting Director Medical Countermeasures Program

#### Alternate Member:

- Robert L. Becker, Jr., M.D., Ph.D., Chief Medical Officer, Office of In Vitro Diagnostic Device Evaluation and Safety

## **Federal Partners**

### **Agency for Healthcare Research and Quality**

#### Primary Member:

- Anne E. Trontell, M.D., M.P.H., Sr. Advisor on Pharmaceutical Outcomes and Risk Management

#### Alternate Member:

- Scott R. Smith, Ph.D., Director, Pharmaceutical Outcomes Research, Center for Outcomes and Evidence

### **Centers for Medicare and Medicaid Services**

#### Primary Member:

- Jeffrey A. Kelman, M.D., MMsc., Chief Medical Officer

#### Alternate Members:

- Judith A. Geisler, R.Ph., CHC, Director, Division of Formulary and Benefit Operations
- Monica Reed, PharmD., LT, USPHS, Division of Formulary and Benefit Operations

### **Centers for Disease Control and Prevention**

#### Primary Member:

- Dan Budnitz, M.D., M.P.H., CAPT, USPHS, Director, Medication Safety Program, Division of Healthcare Quality Promotion

Alternate Member:

- Nadine Shehab, PharmD., M.P.H., Division of Healthcare of Quality Promotion

**Department of Defense**

Primary Member:

- William G. Davies, R.Ph., M.S., Director, DoD Pharmacy Utilization Management/ TRICARE Mgmt. Activity

Alternate Member:

- George E. Jones, Jr., Colonel, USAF, BSC, Deputy Chief, Pharmaceutical Ops Directorate

**Department of Defense (Clinical)**

Primary Member:

- Ron Wyatt, M.D., Chief of Patient Safety Center

Alternate Member

- John Kugler, M.D., Deputy Chief Medical Officer

**Health Resources and Services Administration**

Primary Member:

- Karen C. Williams, MBA, PharmD, Senior Program Management Officer, Office of Pharmacy Affairs

Alternate Member:

- Jae Choi, PharmD., LtCDR USPHS, Office of Pharmacy Affairs
- Dorcas Ann Taylor, PharmD., J.D., Policy Analyst, Office of Pharmacy Affairs

**Indian Health Service**

Primary Member:

- Michael Lee, Pharm.D.,NCPS, BCPS, CDR, USPHS, Director, Pharmacoeconomic and Therapeutics Research, Vice-Chair (A), IHS National P&T Committee

Alternate Member:

- Joseph Bryant, Pharm.D.,BCPS, LCDR, U.S. Public Health Service, Supervisor, Pharmacy Support Branch, IHS National Supply Service Center

**National Institutes of Health, National Cancer Institute**

Primary Member:

- Kevin Conlon, M.D., Senior Investigator, Metabolism Branch

Alternate Member:

- Pamela Jo Harris, M.D.,F.A.C.P., Senior Investigator, Investigational Drug Branch, Cancer Therapy Evaluation Program

**National Institute of Health, Office of Director**

Primary Member:

- Jacqueline Corrigan-Curay, M.D., J.D., Acting Director, Office of Biotechnology Activities

Alternate Member:

- Brenda R. Friend, R.Ph.,J.D., Senior Health Science Policy Analyst, Office of Biotechnology Activities

**Department of Veterans Affairs**

Primary Member :

- C. Bernie Good, M.D., M.P.H., Chairman, Medical Advisory Panel for Pharmacy Benefits Management, Veterans Administration Pittsburgh Healthcare System

Alternate Members:

- Peter Glassman, MBBS, M.Sc., Staff Physician, Department of Veterans Affairs, VA Greater Los Angeles Healthcare System
- Walid F. Gellad, M.D., M.P.H., Department of Veterans Affairs, Veterans Administration Pittsburgh Healthcare System

Primary Member #2

- William E. Duncan, M.D.,PhD,MACP, Associate Deputy Under Secretary for Health for Quality and Safety