Drug Safety Oversight Board (DSOB) Roster

Chair

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

Associate Director for Drug Safety Operations

• Amy Ramanadham, Pharm.D., M.S. Center for Drug Evaluation and Research

Food and Drug Administration

Center for Drug Evaluation and Research (CDER)

Office of the Center Director (OCD)

Primary Member:

• Robert Temple, M.D., Deputy Director for Clinical Science

Office of New Drugs (OND)

Primary Member:

• Mary Thanh Hai, M.D., Deputy Director

Alternate Members:

- Peter Stein, M.D., Director
- Helen Edelberg, M.D., Director

Office of Medical Policy (OMP)

Primary Member:

• Leonard V. Sacks, Associate Director, Manager, Supervisory Medical Officer Alternate Member:

• Victor Crentsil, Deputy Office Director

Office of Generic Drugs (OGD)

Primary Member:

Vacant

Alternate Member:

Vacant

Office of Surveillance and Epidemiology (OSE)

Primary Members:

- Mark I. Avigan, M.D., Associate Director for Critical Path Initiatives
- Judy Zander, M.D., Director, Office of Pharmacoviligance and Epidemiology (OPE) Alternate Members:

• Gerald Dal Pan, M.D., M.H.S., Director, OSE

- S. Chris Jones, Deputy Director, Division of Pharmacovigilance (DPV) II
- Judy Staffa, Ph.D., R.Ph., Associate Director for Public Health Initiatives

June 27, 2022

- Cynthia LaCivita, R.Ph, Director, Division of Risk Management (DRM)
- CAPT Dave Moeny, RPH, MPH, Director, Division of Epidemiology (DEPI) II

Office of Translational Sciences (OTS)

Immediate Office

Primary Member:

Vacant

Alternate Member:

• Ameeta Parekh, Ph.D., Senior Advisor, Scientific Collaborations

Office of Biostatistics (OB)

Primary Member:

• Mark Levenson, Ph.D., Director, Division of Biostatistics 7

Alternate Member:

• Mat Soukup, Ph.D., Deputy Director, Division of Biostatistics 7

Office of Clinical Pharmacology (OCP)

Primary Member:

• David Strauss, MD, PhD, Director of Applied Regulatory Science

Alternate Member:

• Keith K. Burkhart, M.D., FACMT, Senior Advisor for Medical Toxicology, Division of Applied Regulatory Science

Office of Communications (OCOMM)

Primary Member

• James-Denton Wyllie, Director

Alternate Member:

• Morgan Jerrick, Deputy Director

Food and Drug Administration

Center for Biologics Evaluation and Research (CBER)

Primary Member:

- Craig Zinderman, M.D., Associate Director for Product Safety, Division of Epidemiology Alternate Member:
- Vacant

Food and Drug Administration

Center for Devices and Radiological Health (CDRH)

Primary Member:

• Kimberly Brown Smith, MD, PHD, Assistant Director, Clinical and Scientific Policy Team #2, Immediate Office, Office of Product Evaluation and Quality

Alternate Member:

June 27, 2022

• Julia Marders, MS, RN, Emergency Preparedness/Operations & Medical Countermeasures (EMCM) Director

Federal Partners

Agency for Healthcare Research and Quality (AHRQ)

Primary Member:

• David Meyers, M.D., Chief Medical Officer, Acting Deputy Director

Alternate Member:

• Vacant

Centers for Medicare and Medicaid Services (CMS)

Primary Member:

• Jeffrey A. Kelman, M.D., MMsc., Chief Medical Officer, Center for Medicare Alternate Member:

• Judith A. Geisler, R.Ph., CHC, Director, Division of Formulary and Benefit Operations

Centers for Disease Control and Prevention (CDC)

Primary Member:

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

Alternate Member:

• CDR Andrew Geller, M.D., USPHS, Medical Officer, Medication Safety Program, Division of Healthcare Quality Promotion

Department of Defense (DoD)

Primary Member:

• CDR Phung Thien Nguyen, PharmD, Integrated Utilization Branch, Pharmacy Operations Division (POD)

Alternate Member:

Vacant

Department of Defense (Clinical)

Primary Member:

• Ashok Ramalingam, PhD, MS, R.Ph, CPPS, Chief, Patient Safety Analysis Center Alternate Member:

• Rosenie Thelus, PhD, MPH, Director, Pharmacovigilance Center, Public Safety Program, Clinical Quality Management, Clinical Support Division Medical Affairs

Indian Health Service (IHS)

Primary Member:

 CAPT Christopher Lamer, PharmD, BCPS, MHS, CDE, USPHS, Indian Health Service IHS Pharmacovigilance / National Pharmacy and Therapeutics Committee Chair Health Education Program June 27, 2022

Alternate Member:

Vacant

National Institute of Health, Clinical Center (NIH/CC)

Primary Member

• Han Feng, PharmD, BCPS, Section Chief, Medication Safety, IC240

Alternate member

• Vacant

Department of Veterans Affairs (VA)

Primary Members:

- Peter Glassman, MBBS, M.Sc., Co-Director, VA Center for Medication Safety, Department of Veterans Affairs, Washington DC
- Fran Cunningham, Pharm.D., Director, Center for Medication Safety, PCSI Program Manager, Pharmacovigilance/Outcomes Assessment, Pharmacy Benefits Management Services (PBM)

Alternate Member:

Vacant

Bureau of Prisons (BOP)

Primary Member:

- CAPT Michael Long, R.Ph, MPh, USPHS, Chief Pharmacist, Federal Bureau of Prisons Alternate Member:
- CAPT Michael Crockett, R.Ph, USPHS, Chief, Pharmacy Logistic Support, Federal Bureau of Prisons, Health Services Division