

CDER Staff:

The Office of Medical Policy (OMP) has been reorganized into a Super Office. Within its organizational structure are the Office of Medical Policy Initiatives and the Office of Prescription Drug Promotion. Led by Rachel Sherman and her Deputy, Kathleen Uhl, OMP plays a critical role in directing medical policy programs and strategic initiatives.

This includes directing regulation of prescription drug promotion and advertising, providing leadership and scientific advice on clinical trial design, providing consultation and direction in policy issues related to human subject protection and good clinical practices, supporting the recent Health Care Reform Act that provides new legislation for Biosimilars, and developing regulation, guidance documents, and procedures related to medical policy issues.

- Rachel Sherman, Director, Office of Medical Policy
- Kathleen Uhl, Deputy Director, Office of Medical Policy
- Janet Norden, Associate Director for Regulatory Affairs

### **The Office of Prescription Drug Promotion**

The Division of Drug Marketing, Advertising, and Communications has been reorganized and elevated into the Office of Prescription Drug Promotion (OPDP).

This reorganization will leverage OPDP's resources and processes to provide for the highly effective oversight of prescription drug promotion.

OPDP consists of an Immediate Office, the Division of Professional Promotion (DPP), and the Division of Direct-to-Consumer Promotion (DDTCP). The new structure will help prevent misleading promotion about prescription drugs and enhance the quality of communications about prescription drugs and other health information developed by companies.

- Thomas Abrams, Director, Office of Prescription Drug Promotion
- Mark Askine, Associate Director, Office of Prescription Drug Promotion
- Marci Kiester, Associate Director of Operations, Office of Prescription Drug Promotion
- Catherine Gray, Acting Director, Division of Professional Promotion
- Robert Dean, Acting Director, Division of Direct-to-Consumer Promotion

### **The Office of Medical Policy Initiatives**

A newly created Office of Medical Policy Initiatives (OMPI) consists of an Immediate Office, the Division of Medical Policy Programs (DMPP), and the Division of Medical Policy Development (DMPD).

This office will develop and coordinate medical policy regulations and guidances that address the policy and program areas covered by the Super Office. The organization of the divisions supports the continued implementation and successful advancement of the Sentinel Initiative, the Clinical Trials Transformation Initiative (CTTI), and the Patient Medication Information (PMI) Initiative.

Within this reorganization, the Patient Labeling Team (PLT) will be moving from the Office of Surveillance and Epidemiology (OSE), Division of Risk Management (DRISK) to OMP, Division of Medical Policy Programs. The goal of the Patient Labeling Team is to promote the safe and effective use of prescription medications by providing accurate and easily understood patient medication information. OMP will reach out to affected offices with procedural details on the PLT's transfer.

- Denise Hinton, Director, Office of Medical Policy Initiatives
- Richardae Araujo, Deputy Director, Office of Medical Policy Initiatives & Acting Division Director, Division of Medical Policy Programs
- Paula McKeever, Division Director, Division of Medical Policy Development

Janet Woodcock