



New Drug Regulatory Program Modernization

Judit Milstein

Chief, Project Management Staff

Division of Ophthalmology

Acting Director of Project Management Staff

Office of Specialty Medicine

Office of Regulatory Operations

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New Drug Regulatory Program Modernization

- Better serve patients
- Better support staff in their work to carry out the Center's mission
- Problem-focused, interdisciplinary, team based approaches
- Meet challenges of evolving science, new drug platforms, new drug targets while incorporating patients voice in development
 - <https://www.fda.gov/drugs/regulatory-science-research-and-education/reorganization-office-new-drugs-corresponding-changes-office-translational-sciences-and-office>
 - <https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder>

New Drug Regulatory Program Modernization Programs and Projects

- Integrated Review for Drug Marketing Applications
- IND Review Management
- Postmarket Safety Management
- Assessing and Developing Talent
- Administrative Operations
- Transition Management and Reorganization of the New Drugs Regulatory Program

Office of New Drugs

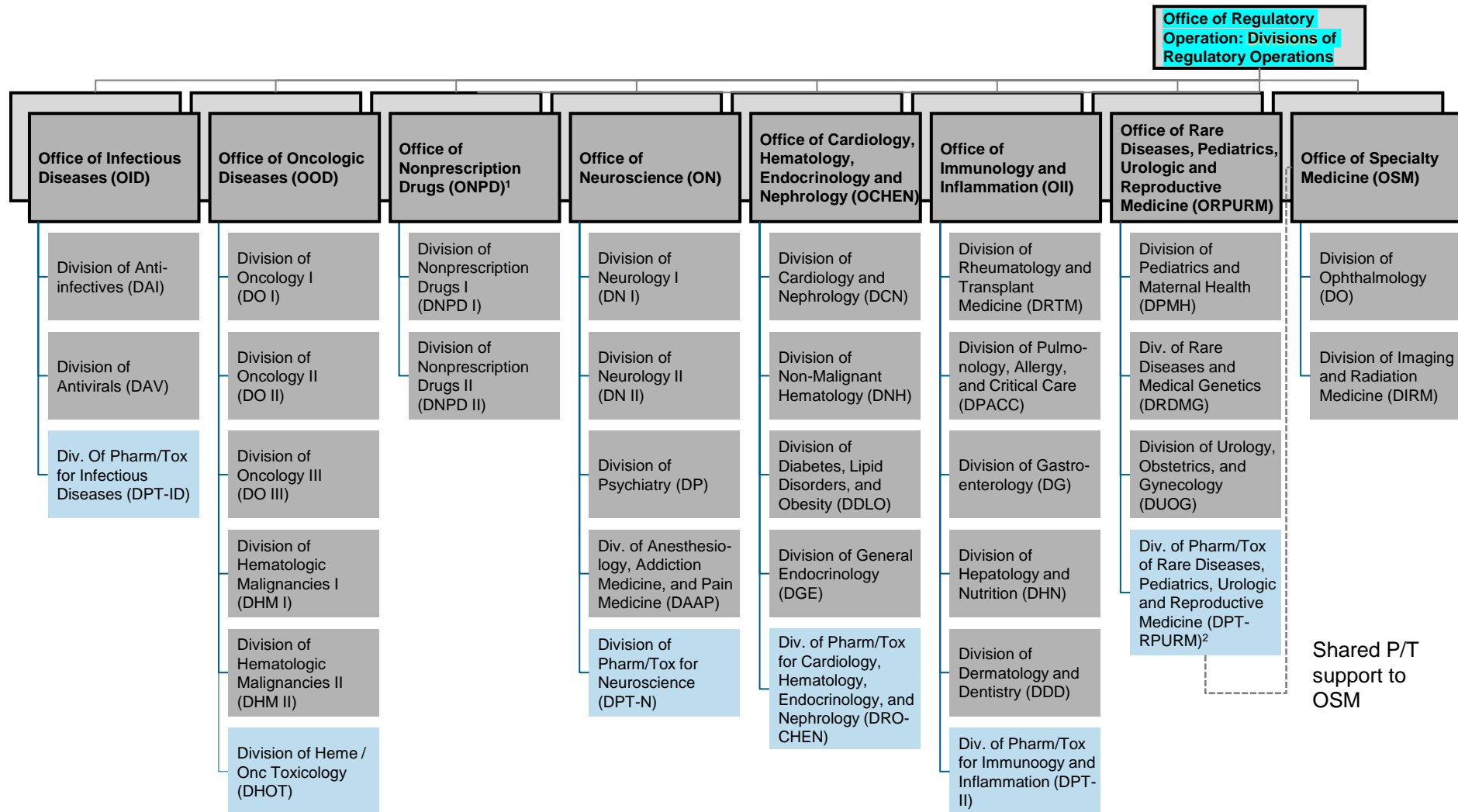
Director: Peter Stein, MD

Deputy Director: Mary Thanh Hai, MD (acting)

- Clinical Offices
 - 8 Offices
 - 27 Clinical Divisions
 - 6 Divisions of Pharmacology/Toxicology
- Office of Regulatory Operations (ORO)

<https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs>

Clinical Offices and Divisions Names



Office of Regulatory Operations (ORO)

- Director: Jennifer Mercier (Acting)
- Deputy Director: Jacqueline Ware, PharmD (Acting)
- 8 Divisions of Regulatory Operations aligned with the corresponding clinical offices
 - Director of Project Management Staff

Office of Infectious Diseases

Director: John Farley, MD, MPH

Deputy Director: Adam Sherwat, MD (Acting)

- Division of Anti-Infectives
- Division of Antivirals
- ORO-DRO-ID-Director of Project Management Staff: Maureen Dillon-Parker (Acting)

Division of Anti-Infectives (DAI)

- Director: Sumathi Nambiar, MD, MPH
- Deputy Director: Dmitry Iarikov, MD, PhD
- ORO-Chief Project Management Staff:
 - Maureen Dillon Parker
 - Carmen DeBellas, PharmD, RPh

Antibacterial, antifungal, antimycobacterial, most antiprotozoal and sepsis drug products

Division of Antivirals (DAV)

- Director: Debra Birnkrant, MD
- Deputy Director: Jeffery Murray, MD, MPH
- ORO-Chief Project Management Staff;
 - Karen Winestock
 - Linda Akunne, MPH (Acting)

Antiviral drugs

Office of Oncologic Diseases

Director: Richard Pazdur, MD

Deputy Director: Marc Theoret, MD (Acting)

- Division of Oncology 1 (DO1)
- Division of Oncology 2 (DO2)
- Division of Oncology 3 (DO3)
- Division of Hematologic Malignancies 1(DHM1)
- Division of Hematologic Malignancies 2 (DHM2)
- ORO-DRO-OD-Director of Project Management Staff: Melanie Pierce

Division of Oncology 1

- Director-Julia A. Beaver, MD
- Deputy Director: Amna Ibrahim, MD
- ORO-Chief Project Management Staff:
 - Christy Cottrell, BS
 - Rajesh Venugopal, MPH, MBA (Acting)

Breast, gynecologic, and genitourinary cancers as well as supportive care (non-hematologic) products

Division of Oncology 2

- Director-Harpeet Singh, MD
- Deputy Director: vacant
- ORO-Chief Project Management Staff: Missiratch (Mimi) Biable, MS (Acting)

Thoracic Head and Neck, Neuro-oncology, rare cancers, pediatric solid tumors

Division of Oncology 3

- Director: Steven Lemery, MD (Acting)
- Deputy Director: Lola Fashoyin-Aje, MD (Acting)
- ORO-Chief Project Management Staff: Norma Griffin, BS (Acting)

Gastrointestinal, superficial cutaneous cancers, melanoma and sarcoma

Division of Hematologic Malignancies 1 (DHM1)

- Director: Angelo DeClaro, MD
- Deputy Director: Vacant
- ORO-Chief Project Management Staff: Amy Baird

Acute Leukemia and Myelodysplasia and Chronic Myeloid Leukemia

Division of Hematologic Malignancies 2 (DHM2)

- Director: Nicole Gormley, MD
 - Deputy Director: Vacant
 - ORO-Chief Project Management Staff: Theresa Carioti, MPH
- Lymphoma, Chronic Lymphocytic Leukemia, Multiple Myeloma and other plasma cell malignancies

Office of Non Prescription Drugs
Director: Theresa Michelle, MD (Acting)
Deputy Director: Karen Mahoney, MD (Acting)

- Division of Nonprescription Drugs 1 (DNPD1)
- Division of Nonprescription Drugs 2 (DNPD2)
- ORO-DRO-NPD-Director of Project Management Staff: Celia Peacock, RDN, MPH, CAPT USPH (Acting)

Division of Non Prescription Drugs 1 (DNPD 1)

- Director: Karen Mahoney, MD (Acting)
- Deputy Director: Nushin Todd, MD
- ORO-Chief Project Management Staff: Dan Brum, PharmD, MBA, CAPT USPHS

Anesthesiology, Addiction and Pain Medicine, Dermatology, Gastroenterology, Neurology, Pulmonary, Allergy and Critical Care and Psychiatry

Division of Non Prescription Drugs 2 (DNPD 2)

- Director: Francis Becker, MD (Acting)
- Deputy Director: Vacant
- ORO-Chief Project Management Staff: Elizabeth Thompson, (Selected)

Anti-Infectives, Antivirals, Cardiology and Nephrology, Dentistry, Diabetes, Lipid Disorders and Obesity, Ophthalmology, Otic, Urology, Obstetrics and Gynecology

Office of Neuroscience

Director: Billy Dunn, MD (Acting)

Deputy Director: Eric Bastings (Acting)

- Division of Neurology 1
- Division of Neurology 2
- Division of Psychiatry
- Division of Anesthesiology, Addiction Medicine and Pain Medicine
- ORO-DRO-ON-Director of Project Management Staff: Paul David, RPh (Acting)

Division of Neurology 1

- Director: Eric Bastings, MD (Acting)
- Deputy Director: Therese Buracchio, MD (Acting)
- ORO-Chief Project Management Staff: Heather Bullock, RN, BSN, MSHS (Acting)

Neurodegenerative Disorders, movement disorders, neuromuscular disorders

Division of Neurology 2

- Director: Nick Kozauer, MD (Acting)
- Deputy Director: Paul Lee, MD (Acting)
- ORO-Chief Project Management Staff: Jacqueline Ware, PharmD

Treatment of seizures, epilepsies, medical countermeasures, migraine, other headaches, traumatic brain injury, inner ear disorders, stroke and neuroimmunologic disorders (e.g. Multiple Sclerosis)

Division of Psychiatry

- Director: Tiffany Farchione, MD (Acting)
- Deputy Director: Bernie Fisher, MD (Acting)
- ORO-Chief Project Management Staff:
 - Hiren Patel, PharmD, MS, CDR USPHS (Acting)
 - Keith Kiedrow, PharmD, MS, CAPT USPHS (Acting)

Psychiatric diseases and conditions

Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP)

- Director: Rigoberto Roca, MD (Acting)
- Deputy Director: Naomi Lowy, MD (Acting)
- ORO-Chief Project Management Staff:
 - Matthew Sullivan, MS
 - Swati Pathwardan (Acting)

Acute pain, chronic pain, addiction products, surgical, procedural or ICU settings

Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)

Director: Ellis F. Unger, MD

Deputy Director: Mary Thanh Hai, MD

- Division of Cardiology and Nephrology (DCN)
- Division of Non-malignant Hematology (DNH)
- Division of Diabetes, Lipid Disorders and Obesity (DDLO)
- Division of General Endocrinology (DGE)
- ORO-DRO-CHEN-Director of Project Management Staff: Julie van der Waag, MPH (Acting)

Division of Cardiovascular and Nephrology

- Director: Norman Stockbridge, MD
- Deputy Director: Aliza Thompson, MD
- ORO-Chief Project Management Staff: Edward Fromm, RPh

Cardiovascular conditions and diseases, kidney conditions and diseases

Division of Nonmalignant Hematology (DNH)

- Director: Ann Farrell, MD
- Deputy Director: Albert Deisseroth, MD, PhD
- ORO-Chief Project Management Staff: Charlene Wheeler, MSHS (Acting)

Clotting disorders (deep venous thrombosis/pulmonary embolism), abnormalities of red cells (anemia, sickle cell disease), white cells, and platelets (ITP), bone marrow failure disorders (aplastic anemia), and some supportive care products for use with chemotherapy and bone marrow transplantation (stem cell mobilization).

Division of Diabetes, Lipid Disorders and Obesity (DDLO)

- Director: Lisa Yanoff, MD
- Deputy Director: Vacant
- ORO-Chief Project Management Staff:
 - Callie Capel-Lynch, PharmD (Acting)
 - Liz Goodwin, MSHS (Acting)

Type 1 and Type 2 diabetes mellitus, weight loss and weight management, geriatric frailty and sarcopenia, Lipodystrophy, Vasopressins (central diabetes insipidus, nocturnal enuresis, Vitamin Deficiency (except Vitamin D)

Division of General Endocrinology (DGE)

- Director: Theresa Kehoe, MD (Acting)
- Deputy Director: Vacant
- ORO-Chief Project Management Staff: Elisabeth Hanan, MS (Selected)

Growth Hormone related conditions, adrenal and ACTH disorders, anabolic steroids, cachexia, hypo- and hypertyroidism, hyperparathyroidism, Cushing's syndrome, developmental disorders, geriatric frailty and sarcopenia

Office of Immunology and Inflammation (OII)

Director: Julie Beitz, MD

Deputy Director: Victor Crentsil, MD (Acting)

- Division of Dermatology and Dentistry (DDD)
- Division of Gastroenterology (DG)
- Division of Hepatology and Nutrition (DHN)
- Division of Pulmonology, Allergy and Critical Care (DPACC)
- Division of Rheumatology and Transplant Medicine (DRTM)
- ORO-DRO-II-Director of Project Management Staff: Renmeet Grewal, PharmD, MS, CDR USPHS (Acting)

Division of Dermatology and Dentistry (DDD)

- Director: Kendall Marcus, MD
- Deputy Director: Shari Targum, MD (Acting)
- ORO-Chief Project Management Staff: Barbara Gould

Acne, actinic keratosis, aesthetic indications, atopic dermatitis, condyloma acuminata, dental caries, gingivitis, psoriasis, rosacea, superficial basal cell carcinoma, wound healing/ulcers, xerostomia

Division of Gastroenterology (DG)

- Director: Jessica J. Lee, MD (acting)
- Deputy Director: Juli Tomaino, MD, MS
- ORO-Chief Project Management Staff: Richard Whitehead, MS (Acting)

Inflammatory bowel conditions, gastroesophageal reflux diseases, duodenal/gastric ulcers, celiac disease, eosinophilic gastrointestinal disorders, motility disorders, constipation, bowel cleansing agents, anorectal disorders, anti-diarrheal agents, anti-emetics, pancreatic agents

Division of Hepatology and Nutrition (DHN)

- Director: Joseph Toerner, MD (Acting)
- Deputy Director: Frank Anania, MD
- ORO-Chief Project Management Staff: Ayana Augustus Bryant, PhD

Liver diseases and nutritional disorders

Division of Pulmonary, Allergy and Critical Care (DPACC)

- Director: Sally Seymour, MD
- Deputy Director: Banu Karimi-Shah, MD
- ORO-Chief Project Management Staff: Ladan Jafari

Asthma, Chronic Obstructive Pulmonary Disease, Allergic Rhinitis, Cough and Cold symptoms (RX drug products), Anaphylaxis, Cystic Fibrosis, Product for critical care (epinephrine), surfactants for infant respiratory distress syndrome

Division of Rheumatology and Transplant Medicine (DRTM)

- Director: Nikolay Nikolov, MD (Acting)
- Deputy Director: Ozlem Belen, MD, MPH (Acting)
- ORO-Chief Project Management Staff: Sandra (Sandy) Barnes
Rheumatological conditions and solid organ transplantation
rejection medicines

Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM)

Director: Hylton Joffe, MD (Acting)

Deputy Director: vacant

- Division of Rare Diseases and Medical Genetics (DRDMG)
- Division of Pediatric and Maternal Health (DPMH)
- Division of Urology, Obstetrics and Gynecology (DUOG)
- ORO-DRO-RPURM-Director of Project Management Staff: Pamela Lucarelli (Acting)

Division of Rare Diseases and Medical Genetics (DRDMG)

- Director: Kathleen (Katie) Donohue, MD (acting)
 - Deputy Director: Patroura Smpokou, MD (acting)
 - ORO-Chief, Project Management Staff: Matthew White, PhD
- Aminoacid Metabolism Disorders, Lipoprotein Metabolism Disorders, Organic Acid Disorders, Lysosomal Storage Diseases, Mitochondrial Disorders

Division of Pediatric and Maternal Health (DPMH)

- Director: Lynne Yao, MD
- Deputy Director: John Alexander, MD, MPH
- ORO-Chief, Project Management Staff
 - Rosemary Addy, MHS
 - George Greely, MS, MBA (Acting)

Internal processes and guidance in support of PREA (Pediatric Research Equity Act), BPCA (Best Pharmaceuticals Childrens' Act)

Division of Urology, Obstetrics, and Gynecology (DUOG)

- Director: Christine Nguyen, MD (acting)
- Deputy Director: Audrey Gassman, MD
- ORO-Chief Project Management Staff:
 - Margaret (Margie) Kober, RPh, MPA
 - Samantha Bell, BS, BA (Acting)

Prevention or treatment of reproductive and urologic conditions

Office of Specialty Medicine

Director: Charles Ganley, MD (acting)

Deputy Director: Alex Gorovets, MD (acting)

- Division of Imaging and Radiation Medicine (DIRM)
- Division of Ophthalmology (DO)
- ORO-DRO-SM-Director of Project Management Staff: Judit Milstein (Acting)

Division of Imaging and Radiation Medicine (DIRM)

- Director: Libero (Lou) Marzella, MD (acting)
 - Deputy Director: vacant
 - ORO-Chief Project Management staff: Kyong (Kaye) Kang
- Image-base diagnosis and monitoring of diseases, radiology, nuclear medicine, products used in the treatment of injury caused by radiation or radioactive materials

Division of Ophthalmology (DO)

- Director: Wiley A. Chambers, MD (acting)
- Deputy Director: vacant
- ORO-Chief Project Management Staff:
 - Diana Willard, BS

Ophthalmic products used in the diagnosis, management and treatment of ocular diseases, otic products except those indicated for otitis media.