



FDA Update

Alberto Gutierrez, Ph.D.

Food and Drug Administration

Office of *In Vitro* Diagnostics and Radiological Health (OIR)

November 16, 2015

CLIAC

Atlanta, Georgia

Summary

- Organizational Update
- Presidential Initiatives
- Approvals and Authorizations
- Guidances
- Workshops and Panels

Organizational Information

- OIR – approx. 280
- New Reviewers
- New Program Support
- Some Changes in Management
- Personalized Medicine/LDT Policy Enhanced



OIR Organizational Update

Director
Alberto Gutierrez, Ph.D.

Deputy Director for New Product Evaluation
Donald St. Pierre

Deputy Director for Patient Safety and Product Quality
James L. Woods

Deputy Director for Radiological Health
Mary S. Pastel, Sc.D.

Deputy Director for Personalized Medicine and Molecular Genetics
Elizabeth A. Mansfield, Ph.D.

Chief Medical Officer
Robert Becker, M.D.

Chief Medical Officer for Radiological Health
Donald L. Miller, M.D.

Secretary
Christine Kellerman

DIHD

**Division of Immunology and
Hematology Devices**

Director

**Leonthena Carrington, M.S.,
MBA, MT**

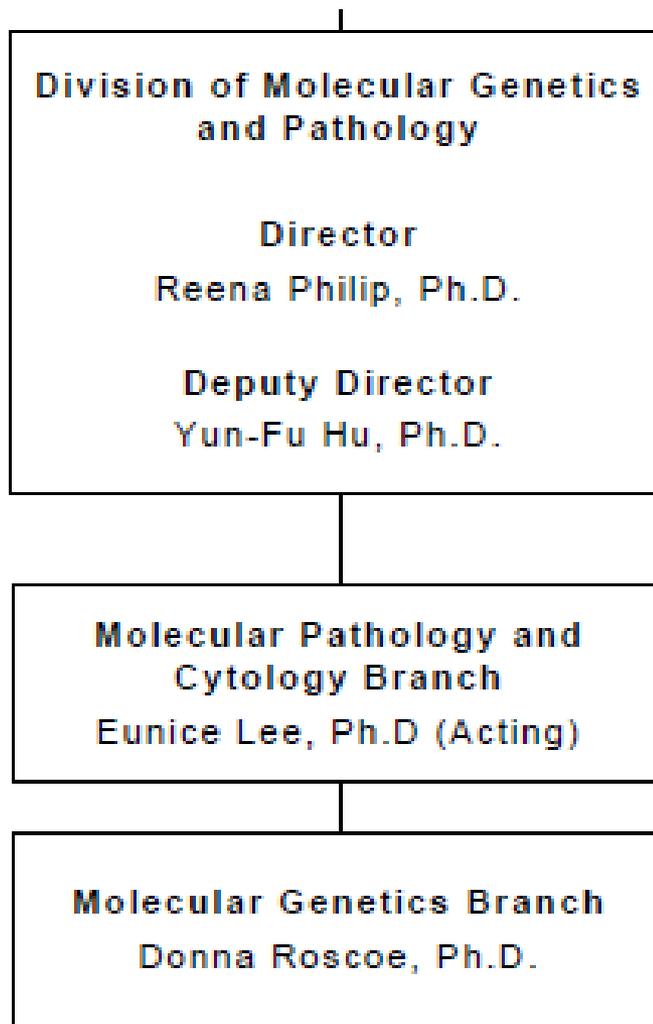
Deputy Director

Kelly Oliner, Ph.D.

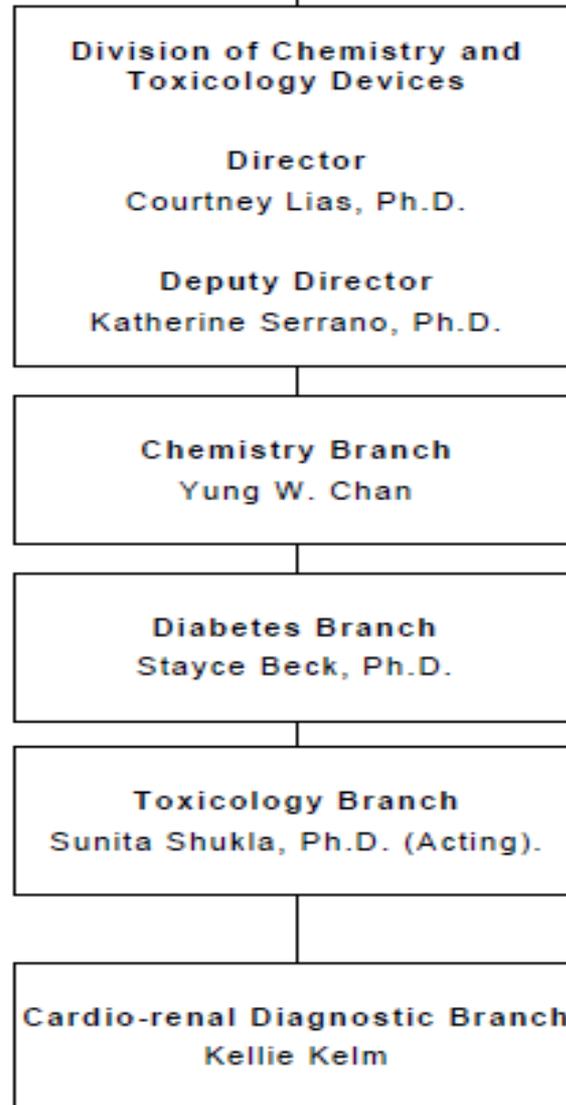
**Hematology Branch
Vacant**

**Immunology and Flow
Cytometry Branch
Elizabeth A. Stafford, Ph.D.**

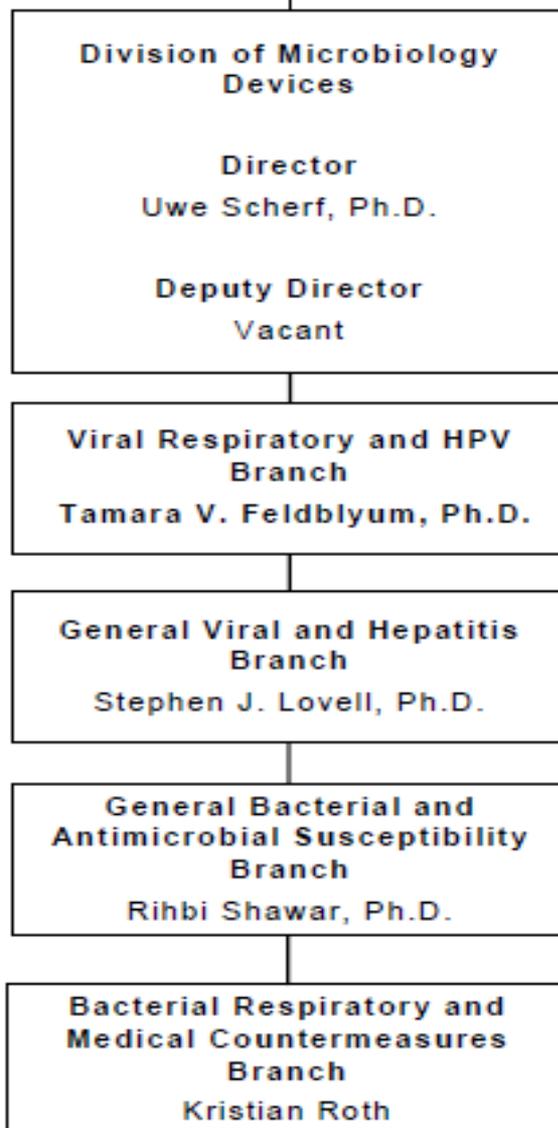
DMGP



DCTD



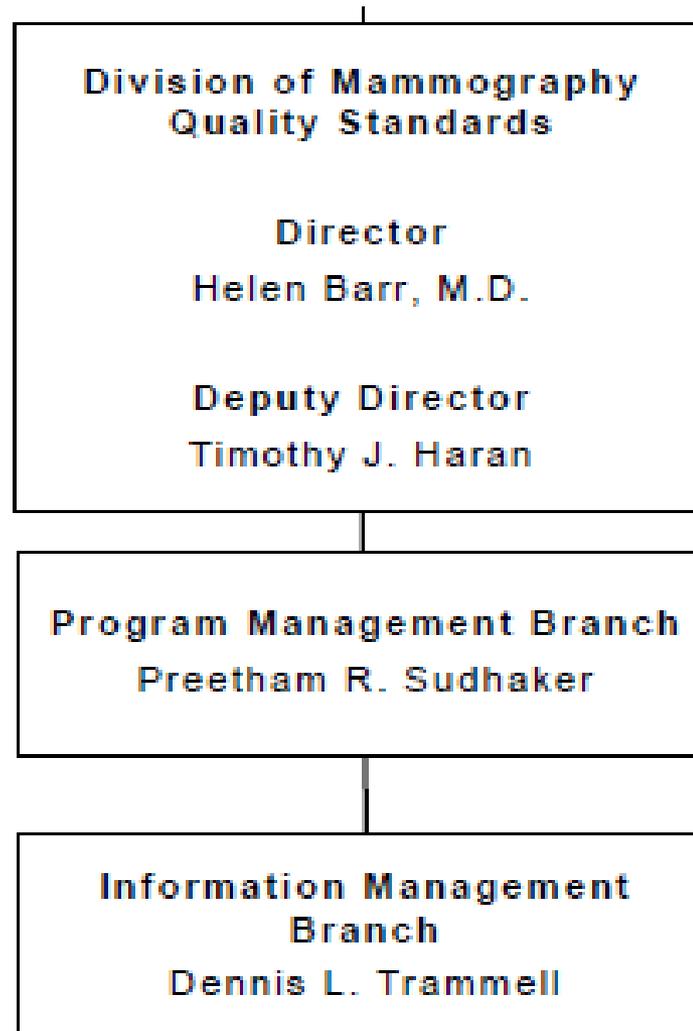
DMD



DRH



DMQS





DPOM

**Division of Program Operations
and Management**

Director

David (Duffy) R. Warren

Deputy Director

Brendan O'Leary

Program Management Office

Director

Debra Cooper

National Action Plan for Combating Antibiotic- Resistant Bacteria (CARB)

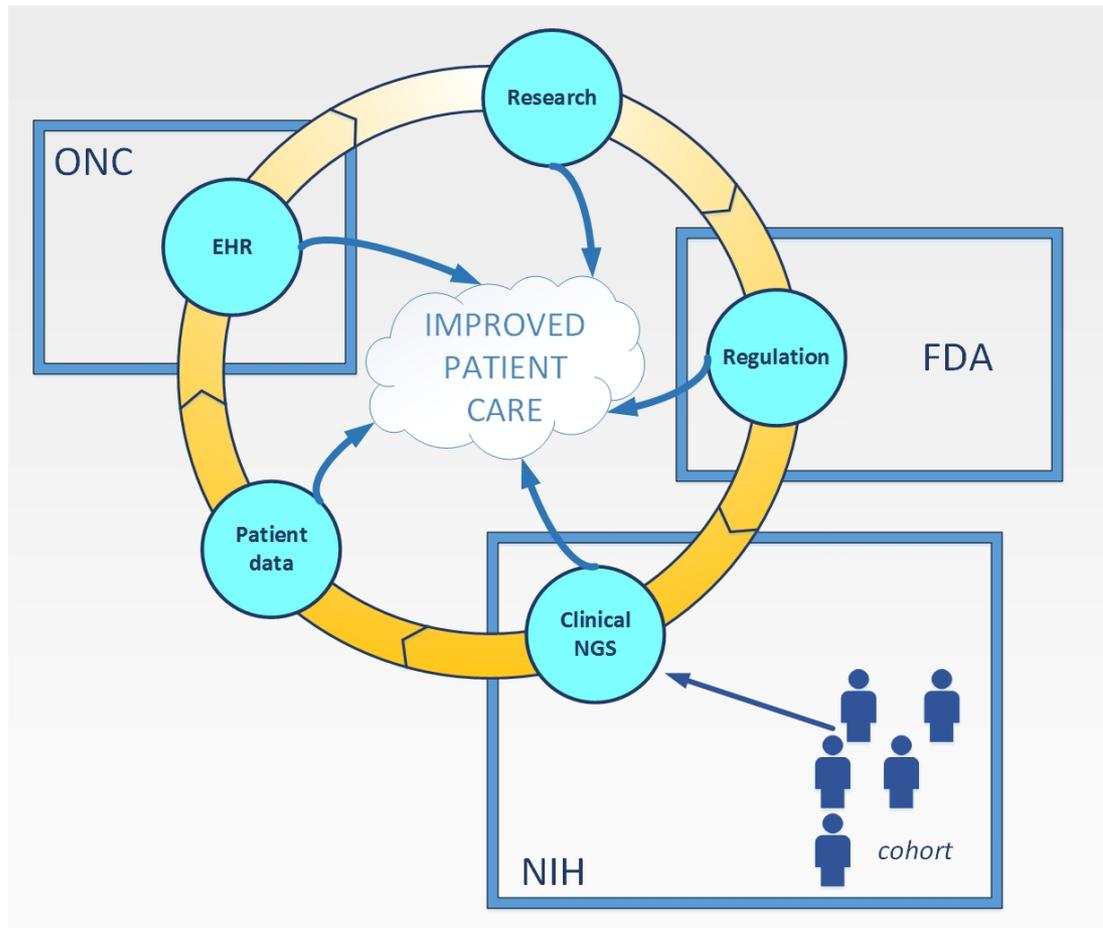
- Streamline regulatory processes for updating (breakpoints) and clearing new AST devices
- CDC/FDA developing well characterized, publically available microbial resistance strain panel for anti-microbial resistance Dx and Tx developers
- Develop and maintain sequence data base of resistant pathogens (ARGOS collaboration)

The President's Precision Medicine Initiative (PMI)

To enable a new era of medicine through research and technology that empowers patients, researchers, and providers to work together toward development of individualized treatments.



Precision Medicine Initiative



PMA Approvals IVDs

- Roche's cobas® KRAS Mutation Test
 - aid in the identification of CRC patients for whom treatment with Erbitux® (cetuximab) or with Vectibix® (panitumumab) may be indicated based on a no mutation detected result.

- Gastric Emptying Breath Test (GEBT)
 - for use in the measurement of the rate of gastric emptying of solids and as an aid in the diagnosis of delayed gastric emptying (gastroparesis) in adult humans who are symptomatic for gastroparesis.

PMA Approvals IVDs

- Elecsys® Anti-HCV II Immunoassay and Elecsys® PreciControl Anti-HCV
 - aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection.
- VENTANA ALK (D5F3) CDx Assay
 - aid in identifying patients eligible for treatment with XALKORI® (crizotinib).

PMA Approvals IVDs

- Roche's cobas® HBV Test
 - aid in the management of patients with chronic hbv infection undergoing anti-viral therapy.
- Roche's cobas® HCV Test
 - aid in the diagnosis of hcv infection in the following populations: individuals with antibody evidence of hcv with evidence of liver disease, individuals suspected to be actively infected with hcv antibody evidence, and individuals at risk for hcv infection with antibodies to hcv.

PMA Approvals IVDs

- **Dako's PD-L1 IHC 22C3 PHARMDEX**
 - aid in identifying nslc patients for treatment with keytruda (pembrolizumab).
- **Dako's PD-L1 IHC NIVOLUMAB PHARMDEX**
 - associated with enhanced survival from opdivo (nivolumab).
- **Dexcom's G4 Platinum (Pediatric) Continuous Glucose Monitoring System**

PMA Approvals IVDs

- T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM
 - Sensor augmented insulin pump.
- Roche's KRAS Mutation Test
 - aid in the identification of CRC patients for whom treatment with Erbitux® (cetuximab) or with Vectibix® (panitumumab) may be indicated based on a no mutation detected result.

***De Novo* Classifications**

- BioFire's FilmArray
Meningitis/Encephalitis (ME) Panel
 - cerebrospinal fluid (CSF) nucleic acid-based test for simultaneous detection of multiple pathogens that can cause central nervous system infections.

CLIA Waivers by Application

- Alere's TM Influenza A & B
- Alere I Strep A
- Roche's cobas Liat System Influenza A/B
- Roche's cobas Liat System Strep A
- Therano's HSV-1 Assay

Final Guidances

- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
- Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions
- Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

Final Guidances

- Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures
- Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices

Draft Guidances

- Adaptive Designs for Medical Device Clinical Studies
- Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices
- Procedures for Meetings of the Medical Devices Advisory Committee
- Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types

Draft Guidances

- Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States
- Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices
- Patient Preference Information Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling

Draft Guidances

- Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)
- Unique Device Identification: Direct Marking of Devices

Notable Meetings

- Workshop - 8th Annual Medical Device and Diagnostics Statistical Issues, Co-Sponsored by AdvaMed and FDA, April 29-30, 2015
- Public Workshop FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data, September 28, 2015
- Public Workshop - Non-Microbial Biomarkers of Infection for In Vitro Diagnostic Device Use, October 16, 2015

Notable Meetings

- Public Workshop - In Vitro Diagnostic Testing for Direct Oral Anticoagulants, October 26, 2015
- Public Workshop - Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants, November 13, 2015



Thanks