U.S. Food and Drug Administration
Protecting and Promoting Public Health

FDA Update

Alberto Gutierrez, Ph.D.
Food and Drug Administration
Office of *In Vitro* Diagnostics and Radiological Health (OIR)

October 8, 2015
AMDM's 2015 IVD Focus Meeting
Los Gatos, California

Summary

- Organizational Update
- CLIA Categorization Administrative Update
- Approvals an Authorizations
- Guidances
- Workshops and Panels

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Organizational Information

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

U.S. Food and Drug Administration
Protecting and Promoting Public Health

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

U.S. Food and Drug Administration
Protecting and Promoting Public Health

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.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DMGP

Division of Molecular Genetics and Pathology

Director
Reena Philip, Ph.D.

Deputy Director
Yun-Fu Hu, Ph.D.

Molecular Pathology and Cytology Branch
Eunice Lee, Ph.D (Acting)

Molecular Genetics Branch
Donna Roscoe, Ph.D.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DCTD

Division of Chemistry and Toxicology Devices

Director
Courtney Lias, Ph.D.

Deputy Director
Katherine Serrano, Ph.D.

Chemistry Branch
Yung W. Chan

Diabetes Branch
Stayce Beck, Ph.D.

Toxicology Branch
Sunita Shukla, Ph.D. (Acting).

Cardio-renal Diagnostic Branch
Kellie Kelm

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DMD

Division of Microbiology Devices

Director
Uwe Scherf, Ph.D.

Deputy Director
Vacant

Viral Respiratory and HPV Branch
Tamara V. Feldblyum, Ph.D.

General Viral and Hepatitis Branch
Stephen J. Lovell, Ph.D.

General Bacterial and Antimicrobial Susceptibility Branch
Rihbi Shawar, Ph.D.

Bacterial Respiratory and Medical Countermeasures Branch
Kristian Roth

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DRH

Division of Radiological Health

Director
Robert Ochs, Ph.D.

Deputy Directors
Michael O'Hara, Ph.D.
CAPT Sean M. Boyd, MPH

Magnetic Resonance and Electronic Products Branch
CPT Patrick Hintz, MSIH, CIH

Diagnostic X-Ray Systems Branch
Thalia T. Mills, Ph.D.

Nuclear Medicine and Radiation Therapy Branch
William Jung, Ph.D.

Mammography, Ultrasound and Imaging Software Branch
Jeffrey Ballyns, Ph.D.(Acting)

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DMQS

Division of Mammography Quality Standards

Director
Helen Barr, M.D.

Deputy Director
Timothy J. Haran

Program Management Branch
Preetham R. Sudhaker

Information Management Branch
Dennis L. Trammell

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DPOM

Division of Program Operations and Management

Director
David (Duffy) R. Warren

Deputy Director
Brendan O'Leary

Program Management Office
Director
Debra Cooper

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Medical Countermeasures Initiative (MCMi)

- 2010- FDA launches MCMi: to identify and resolve regulatory challenges to MCM development- (drug/vaccine/device/diagnostics)
- 2013- Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA): new legal authorities for FDA to support preparedness and response efforts
- Emergency Use Authorization (EUA): Rapid interactive FDA review process- 1st=2009 H1N1

U.S. Food and Drug Administration
Protecting and Promoting Public Health

MCM Diagnostic 510(k)s - 2014-15

- CDC PCR *B. anthracis* detection cleared
- Pandemic Influenza: 3 new and 14 modifications to existing tests cleared
- Several bio-threat diagnostic assays, single and multiplex in the pipeline
- Monthly discussions held with CDC (LRN) and DoD

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Emergency Use Authorizations - 2014-2015

- H7N9 Avian Influenza- 2 assays authorized
- MERS-CoV-asymptomatic contacts added to intended use. Stakeholder Workshop 4/15
- Ebola Zaire - 9 diagnostic assays (commercial & non-commercial –CDC/DoD) authorized – “presumptive detection of ebola nucleic acid or antigen”. WHO/FDA collaborative reviews
- Enterovirus D68- emergency declared 3/15

U.S. Food and Drug Administration
Protecting and Promoting Public Health

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)

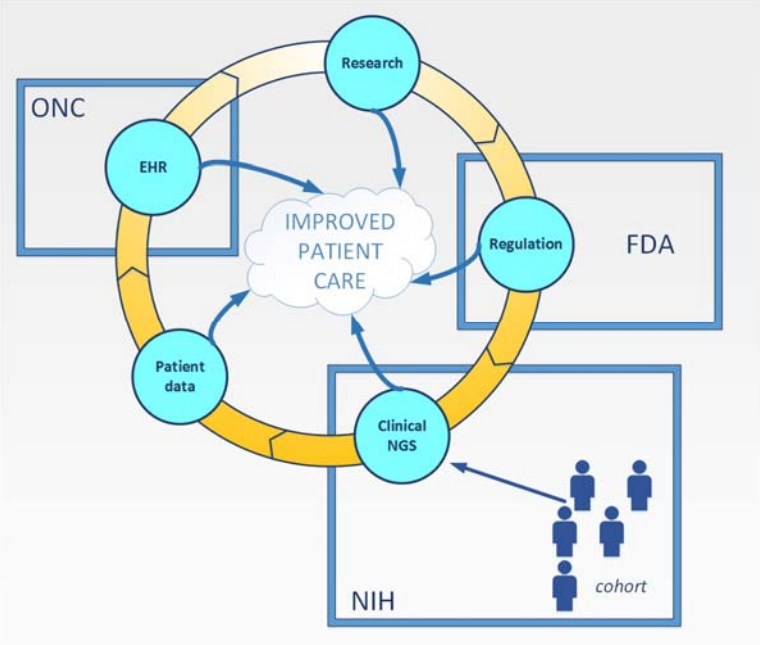
U.S. Food and Drug Administration
Protecting and Promoting Public Health

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.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Precision Medicine Initiative



U.S. Food and Drug Administration
Protecting and Promoting Public Health

PMA Approvals

- QIAGEN's *therascreen*® KRAS RGQ PCR Kit

  Intended for the detection of seven somatic mutations in the human KRAS oncogene, using DNA extracted from formalin-fixed paraffin-embedded (FFPE), colorectal cancer (CRC) tissue. The *therascreen*® KRAS RGQ PCR Kit is intended to aid in the identification of CRC patients for treatment with Erbitux® (cetuximab) and Vectibix® (panitumumab) based on a KRAS no mutation detected test result.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

PMA Approvals

- Roche's cobas® HPV Test

  HPV DNA test for women 25 and older that can be used alone to help a health care professional assess the need for a woman to undergo additional diagnostic testing for cervical cancer.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

PMA Approvals

- Exact Science's Cologuard

  Stool-based colorectal screening test that detects the presence of red blood cells and DNA mutations that may indicate the presence of certain kinds of abnormal growths that may be cancers such as colon cancer or precursors to cancer

U.S. Food and Drug Administration
Protecting and Promoting Public Health

PMA Approvals IVDs

- QIAGEN's artus® CMV RGQ MDx Kit
  - aid in the management of solid organ transplant patients who are undergoing anti-CMV therapy
- Myriad's BRAC*Analysis* ® CDx™
  - aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants eligible for treatment with Lynparza™ (olaparib)

U.S. Food and Drug Administration
Protecting and Promoting Public Health

PMA Approvals IVDs

- 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 gastoparesis.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

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).

U.S. Food and Drug Administration
Protecting and Promoting Public Health

PMA Approvals IVDs

- Dako's PD-L1 IHC 22C3 PHARMDX
  - aid in identifying nsclc patients for treatment with keytruda (pembrolizumab).
- T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM
  - Sensor augmented insulin pump

U.S. Food and Drug Administration
Protecting and Promoting Public Health

De Novo Classifications

- CDC's Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS
  - To detect and measure the concentration of specific organophosphate metabolites in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning

De Novo Classifications

- Abbott's Vysis EGR1 FISH Probe Kit
  - An early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system is intended to detect the EGR1 probe target on chromosome 5q in bone marrow specimens from patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). The assay results are intended to be interpreted only by a qualified pathologist or cytogeneticist.

De Novo Classifications

- Affymetric's CytoScan DX

  CytoScan® Dx Assay is a qualitative assay intended for the postnatal detection of copy number variations (CNV) in genomic DNA obtained from peripheral whole blood in patients referred for chromosomal testing based on clinical presentation.

De Novo Classifications

- Illumina's MiSeqDX
  - Cystic Fibrosis 139-Variant Assay
  - Cystic Fibrosis Clinical Sequencing Assay
  - MiSeqDx instrument - Class II exempt
  - MiSeqDx Universal Kit – Class I

U.S. Food and Drug Administration
Protecting and Promoting Public Health

De novos

- Dexcom's STUDIO on the Cloud Data Management Software
  - for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis, and evaluation of historical CGM data to support effective diabetes management.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

De novos

- EnLite™ Neonatal TREC Kit
  - an aid in screening newborns for severe combined immunodeficiency disorder (SCID)

U.S. Food and Drug Administration
Protecting and Promoting Public Health

De novos

- 23andMe Personal Genome Service Carrier Screening Test for Bloom Syndrome

U.S. Food and Drug Administration
Protecting and Promoting Public Health

De novos

- NOVA View Automated Fluorescense Microscope

U.S. Food and Drug Administration
Protecting and Promoting Public Health

CLIA Waivers by Application

- Chembio's DPP ® HIV 1/2 Assay
- Alere Determine ™ HIV-1/2 Ag/Ab Combo
- Alere's ™ Influenza A & B
- QUIDEL's Sofia ® Strep A+ FIA
- diagnostics direct Syphilis Health Check ™
- Alere I Strep A
- Roche's cobas Liat System Influenza A/B
- Roche's cobas Liat System Strep A

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Final Guidances

- Molecular Diagnostic Instruments with Combined Functions
- 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

U.S. Food and Drug Administration
Protecting and Promoting Public Health

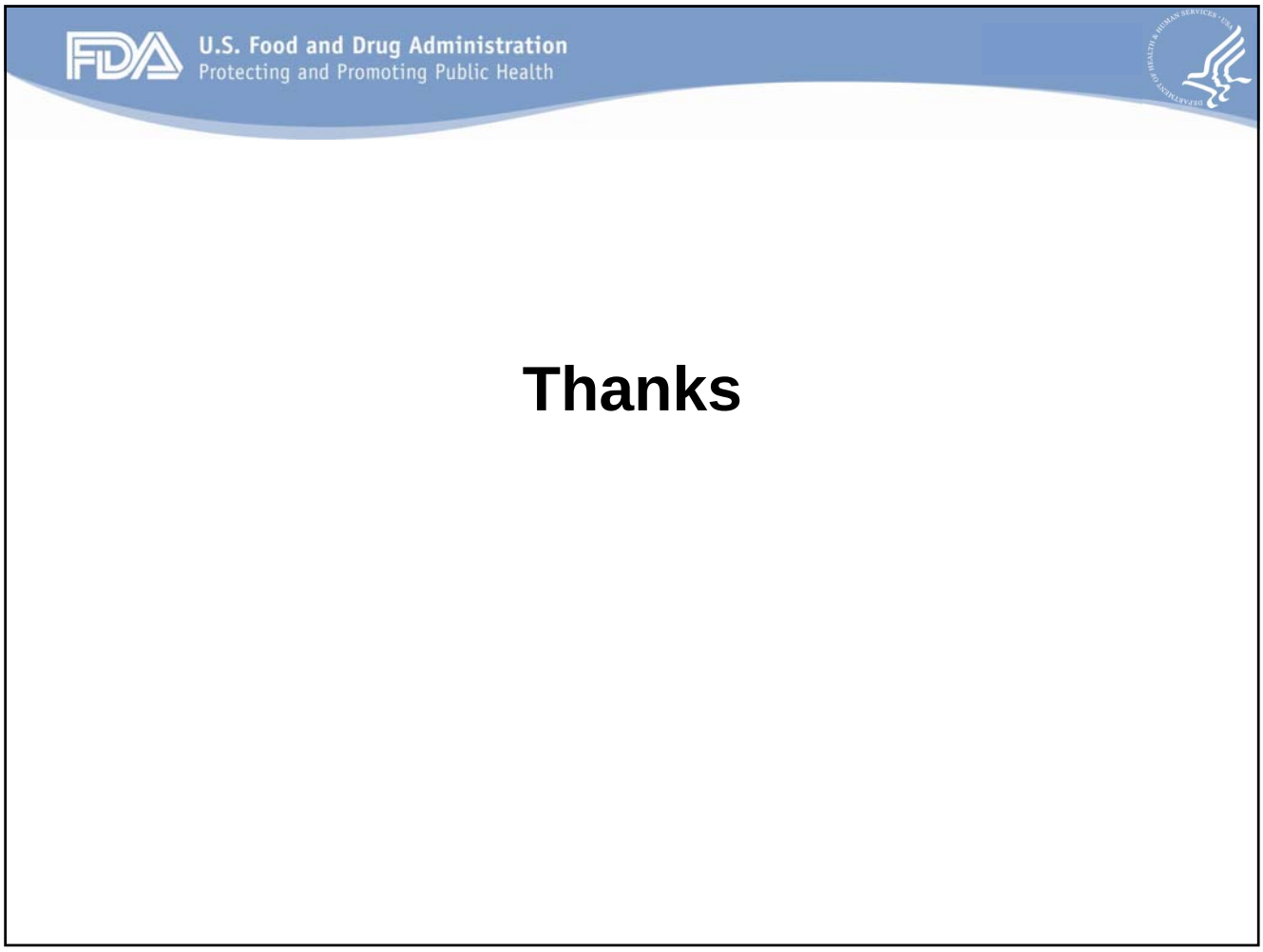
Draft Guidances

- Radiation Biodosimetry Devices
- Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices
- Procedures for Meetings of the Medical Devices Advisory Committee

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Notable Meetings

- Regulatory Science Considerations for Software Used in Diabetes Management, November 13, 2014
- Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), January 8-9, 2015
- Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests Public Workshop, February 20, 2015
- Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies, March 24, 2015


U.S. Food and Drug Administration
Protecting and Promoting Public Health
Thanks