

# **Office of Blood Research and Review**

## **An Overview**

**A. Organizational structure and regulatory responsibilities**

**B. Regulatory Science Research Programs**

**Presentation to the BPAC**

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**C.D. Atreya, Ph.D.**

**Associate Director for Research (Acting)**

**OBRR, CBER**

# **Office of Blood Research and Review**

## **An Overview**

### **A. Organizational structure and regulatory responsibilities**

**OBRR  
Structure  
&  
Staff \***  
**(161)**

*Director*  
**Jay S. Epstein, M.D.**

**(13)**

*Deputy Director*  
Jonathan Goldsmith, M.D.

*Associate Deputy director*  
Mark Weinstein, Ph.D.

*Associate Director for Research*  
Acting- C.D. Atreya, Ph.D.

*Associate Director for Regulatory Affairs*  
Acting- S. Nedjar, Ph.D.

*Associate Director  
for Policy*

J. Scharpf, M.P.H.

**Policy and  
Publication Staff**

**Division of Emerging &  
Transfusion  
Transmitted Diseases**  
**(53)**

*Director*  
Hira L. Nakhasi, Ph.D.

*Deputy Director*  
Paul Mied, Ph.D.

**Division of Blood  
Applications**  
**(42)**

*Director*  
Alan E. Williams, Ph.D.

*Deputy Director*  
Sharyn Orton, Ph.D.

**Division of Hematology**  
**(53)**

*Director*  
Basil Golding, M.D.

*Deputy Director*  
Susan Abbondanzo, M.D.

\* Full-Time Equivalents (FTEs)

# What we do in OBRR....

## (Regulatory Responsibilities)

**OBRR** is the primary FDA component that:

- Facilitates the development, approval, and access to safe and effective blood products
  - Product application review, standards development, policy setting, assessment of adverse event reports, pre-license inspections, lot release, investigation of product failures and toxicities
- Evaluates promising new technologies related to blood safety and retroviral testing

**OBRR** is charged to regulate

- Blood and blood derived products
- Medical devices used to collect, test, process or store donated blood
- Retroviral diagnostic tests

# Regulatory Responsibilities (Product based)

- **Division of Emerging and Transfusion Transmitted Diseases**
  - Blood donor screening tests for infectious agents
  - Retroviral diagnostics
- **Division of Hematology**
  - Bacterial detection devices
  - Plasma-derived products (IGIV, albumin, coagulation products, etc.)
  - Blood and blood component collection devices
  - Plasma expanders including hemoglobin-based oxygen carrying solutions
- **Division of Blood Applications**
  - Blood and plasma licenses
  - Blood establishment software
  - Blood grouping and HLA reagents

# **Office of Blood Research and Review**

## **An Overview**

### **B. Regulatory Science Research Programs (Critical Path Research)**

# OBRR Research Programs

**Our core programs are oriented toward detection and control of**

- **Infectious agents relevant to blood products**
- **Characterization and standardization of blood components, plasma derivatives and related devices**

**Additionally, OBRR engages in**

- **Epidemiological studies and methods development research to enhance product review and surveillance.**

**OBRR also leads and collaborates in investigations within the broader spectrum of CBER's program of scientific interests, for example in**

- **HIV immunology**
- **Development of vaccines for parasitic diseases**

# **Vision for research in OBRR**

**Supports the “Critical Path” for product development through:**

- Focus on scientific questions critical to effective regulation**
- Concentration in areas where our unique role as regulators is most contributory**
- Provision of an infrastructure for investigation of product limitations and failures**
- Facilitation of progress towards the goals and promise of 21st century medicine (e.g. genomic and proteomic based medicine; applications of nanotechnology)**

# **OBRR research accomplishment facilitates product development**

*....an example!*

## **Blood safety issue**

- Need for development of technologies and methodologies that can screen blood donors for a large number of pathogens simultaneously

## **Actions**

- Developed proof-of-concept “multiplex” NAT and DNA microarrays for blood donor screening

(Nakhasi's group, J. Mol Diagn., 7: 486-494, 2005; 7: 268-275, 2005)

## **Outcomes (ongoing)**

- Identify critical parameters for assay development
- Standardized panels used as a target for industry and to assess different assays

# OBRR research accomplishment facilitates product development

*....another example!*

## Safety of Smallpox Vaccination

- Smallpox vaccination can cause life-threatening complications in immunodeficient and eczematous individuals

## Issue

- Efficacy of Vaccinia immune globulin (VIG) as treatment cannot be tested in humans

## Actions

- Development of a SCID mouse model to test efficacy  
(Scott's group in DH, FDA Science Forum, A-27, 2005)

## Outcomes

- Transfer of methodology to industry
- Incorporation of this model helps provide a pathway for licensure of new VIGIV products



## **OBRR Research accomplishments (I)**

- **Facilitated the establishment of nucleic acid screening for HIV, HCV, HBV, and West Nile Virus in the blood supply by development of reference reagents**
- **Ongoing studies on the epidemiology and diagnostic implications of HIV and WNV virus variants**
- **Establishing standards for thrombin, anti-D immune globulin and other plasma proteins**
- **Elucidating the basis of toxicity of hemoglobin solutions**
- **Discovered an extracellular role of HIV TAT protein in HIV disease**
- **Examined the potency of vaccinia immune globulin in an animal model**

## **OBRR Research accomplishments (II)**

- **Investigation of potential viremia after smallpox vaccination**
- **Development of a web-based reporting system for blood product and reagent shortages**
- **Studies on surface decontamination of prions**
- **Invention of a prototype oligonucleotide microarray pathogen chip to simultaneously detect multiple blood borne pathogens, including potential bioterrorism agents**
- **Preparation of a live attenuated Leishmania parasite as a potential vaccine candidate**

# Concluding Remarks

- **Research is integral to the mission of OBRR and CBER**
- **OBRR research facilitates product development and is aligned with FDA's model of "Critical Path" Research**

**Thank you!!**