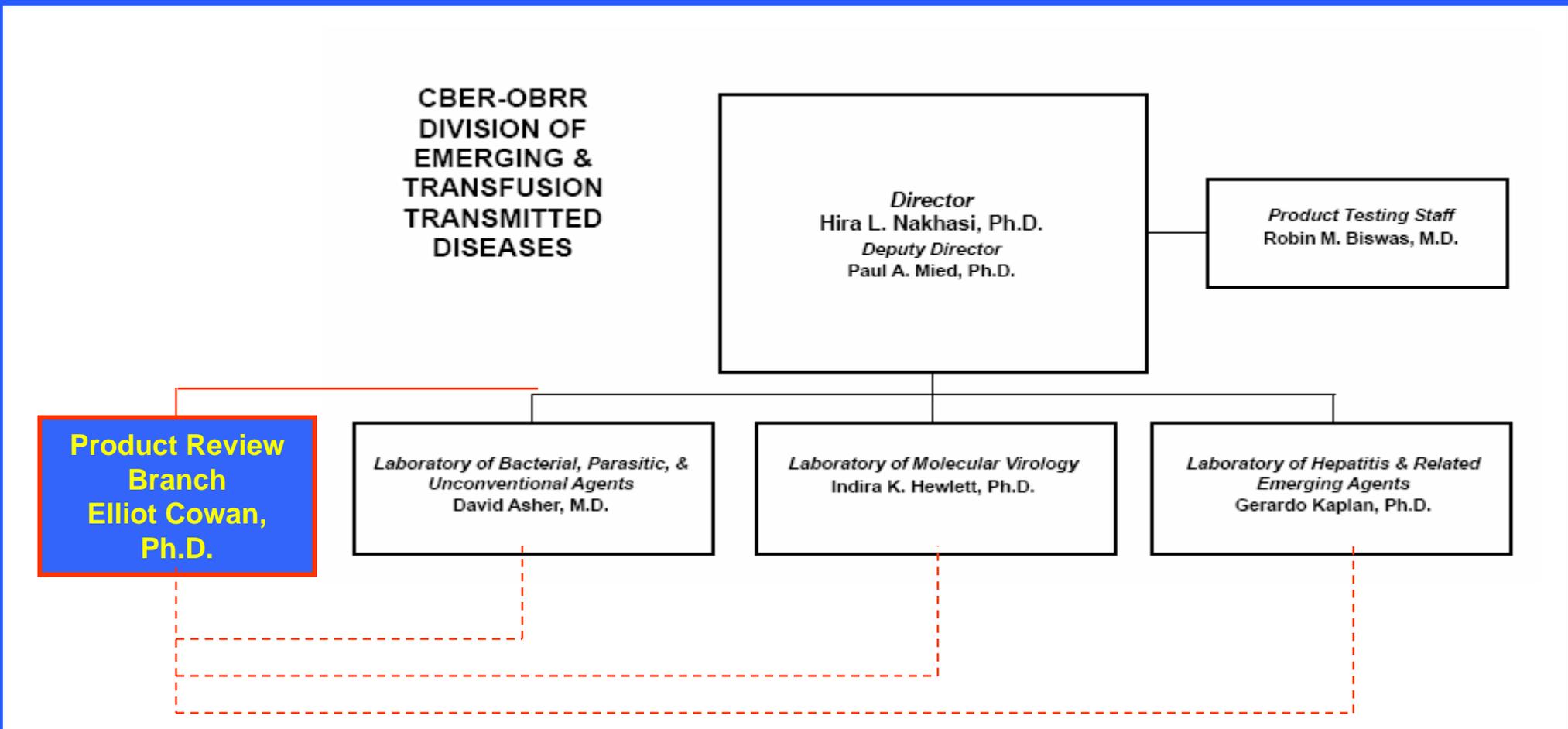


Division of Emerging and Transfusion Transmitted Diseases (DETTD)

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

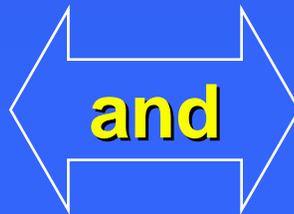
July 13, 2006

Organization of The Division of Emerging and Transfusion Transmitted Diseases (DETTD)



Office of Blood Research and Review Mission

**Enhance
Product Safety,
Purity and
Potency**



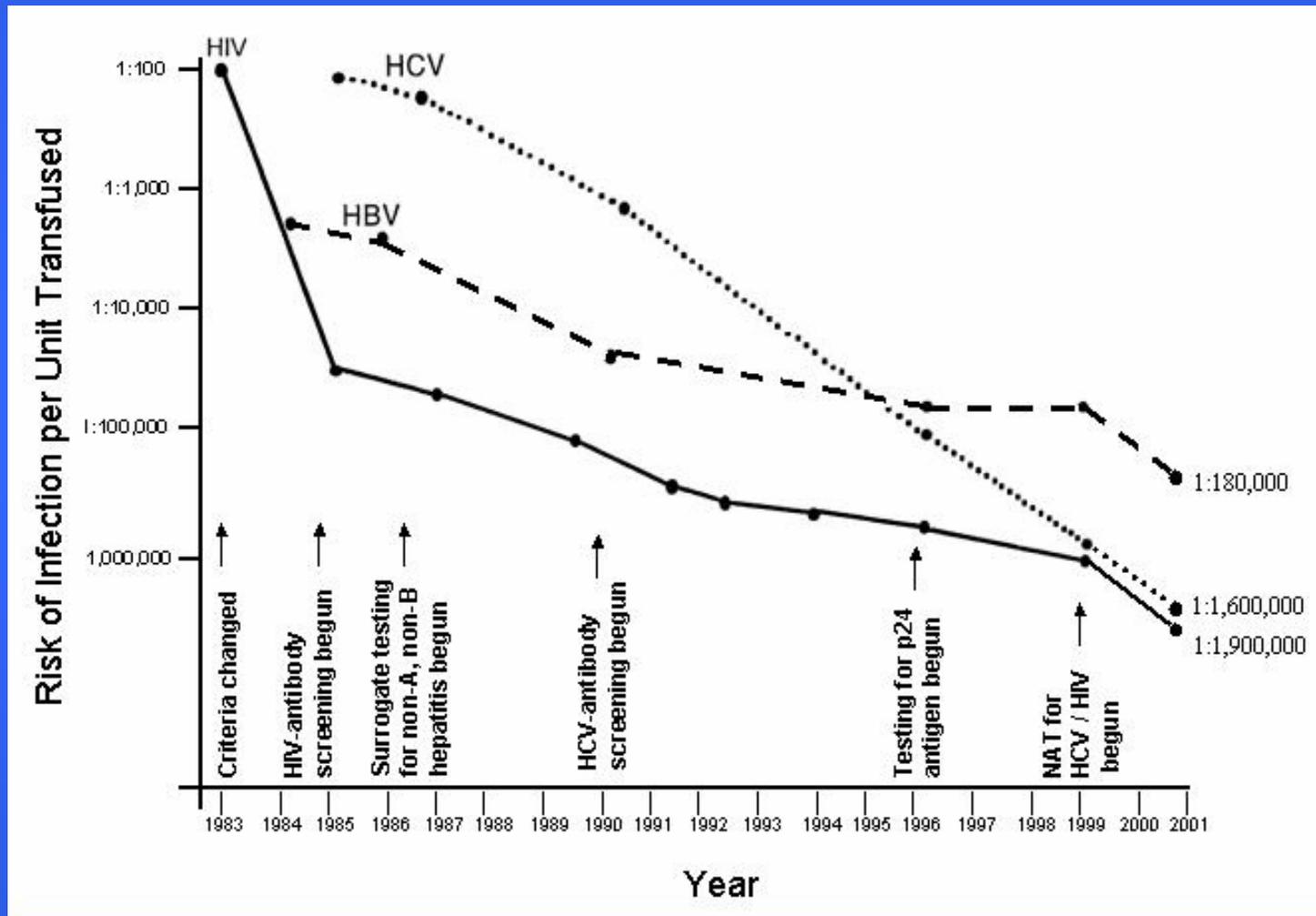
**Avoid Product
Shortages**

Improve blood product safety, efficacy and availability while minimizing disruptions to the blood system

Impact on the US Public Health: Blood Safety and Availability

- **Millions of units are transfused annually**
- **Risk of transmission through transfusion has significantly reduced with the introduction of tests**

The Impact of Testing for HIV, HBV, and HCV on the Safety of the US Blood Supply



Testing has significantly reduced the risk of transmission

Impact on the US Public Health: Blood Safety and Availability

- **Emerging pathogens** threaten the blood safety
 - HIV drug resistant and recombinant variants and HBV mutants
 - Ability of existing tests to identify such variants
- **New Emerging pathogens:** WNV, SARS-CoV, Influenza virus, BT agents, Mumps virus
- **Existing Parasitic agents** (Malaria, Chagas, *Leishmania*)
- Significant **donor loss** based on exposure to **TSE** agents
parasitic agents
- **No screening** assays for **TSE** and **Parasitic** agents
- Reentry of uninfected donor to ensure **blood availability**

Division of Emerging and Transfusion Transmitted Diseases (DETTD)/OBRR/CBER Mission

- ◆ Proactively ensuring the safety of the blood supply through:
 - ☞ **Regulation** of tests for blood screening and diagnostic to detect infectious contaminants of blood products. (Retroviral, Hepatitis, Parasitic (Malaria, Chagas, Leishmania), TSE, Emerging Infectious agents (WNV, SARS, Vaccinia, BT agents)
 - ☞ **Evaluation** of new technologies for rapid and flexible screening of the blood supply
 - ☞ Develops and revises **FDA Guidance** for users of blood screening and diagnostic products.

Division of Emerging and Transfusion Transmitted Diseases (DETTD)/OBRR/CBER

Mission

- ◆ **Lot-release testing:**
 - for approval of investigational tests and of licensed products.
 - develops reference materials for lot-release testing.
- ◆ **Inspections:**
 - of manufacturers of licensed products, manufacturing facilities.
- ◆ **Consultation:**
 - provide expert scientific and technical advice to other Agency and Government components.
- ◆ **Outreach:**
 - safety and efficacy of blood donor screening testing at the Blood Product Advisory Committee, TSE Advisory Committee, DHHS Blood Safety Availability Committee

Division of Emerging and Transfusion Transmitted Diseases (DETTD)/ OBRR/CBER Mission

◆ Plan and conduct research

- Pathogenesis of blood borne infectious agents
- Evaluation of donor screening and diagnostic assays for blood borne pathogens
 - ☞ Standards/Panel development
 - ☞ Multiplex Detection
 - ☞ Improved Sensitivity of Assays
 - ☞ Assays for Blood Product Safety (**Pathogen Inactivation**)
 - ☞ Assays to Enhance Blood Availability (**Donor Entry**)
- Due to the unique expertise in the CBER
 - ☞ Vaccine safety of blood borne parasitic agents

**Mission Relevant Research in
viral, parasitic, TSEs diseases
improves OBRR/CBER's ability
to evaluate the safety and
efficacy of blood and blood
products and vaccines**