Center for Biologics and Evaluation

Blood Safety Team

FDLI

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Annual U.S. Blood Donation and Utilization

- 8 million unpaid volunteers donate approximately 15 million units of Whole Blood
- 4.5 million patients receive about 29 million units of blood components
- ~2.4 million units of “recovered plasma” from Whole Blood donation are sold for further manufacturing, including fractionation
- One million paid apheresis donors provide an additional ~10 million liters of Source Plasma for fractionation

Types of FDA-Regulated Blood and Related Device and Drug Establishments

- Blood Collection Centers - ~1,300
  - Community Based (90% of collections)
  - Hospital Based (8% of collections)
  - Military (2% of collections)
- Hospital Transfusion Services - ~5,000
  - Vast majority only cross match and dispense
- Plasmapheresis Centers - ~300
- Plasma Derivative Manufacturers - ~20
- Device Manufacturers - ~400
  - Test Kits, Blood Grouping Reagents
  - Apheresis machines, blood warmers, etc.
- Drug Manufacturers (e.g. anticoagulants) - ~30

Legal Framework for FDA Regulation

- U.S. Blood and plasma are collected, processed and distributed by private industry regulated by the U.S. Food and Drug Administration (FDA) under two national laws
  - Public Health Service (PHS) ACT (42 USC 202 et. seq.)
    - Section 351 (biologics regulation*)
    - Section 361 (communicable disease control)

  *Licensed biological products concurrently are drugs or devices under the FD&C Act
  - Federal Food, Drug and Cosmetic (FD&C) Act (21 USC 302 et. seq.)
    - Addresses drugs and medical devices
- Blood organizations also comply with State laws and voluntary standards (e.g. AABB, PPTA)

Regulations Implementing the PHS and FD&C Acts

- To implement the PHS and FD&C Acts, the FDA promulgates regulations under Title 21, Code of Federal Regulations (CFR)
- FDA additionally publishes guidance documents which:
  - Represent the FDA's current thinking
  - Do not bind the FDA or the public
- Alternative approaches can be used if they satisfy the requirements of applicable statutes and regulations

The Overlapping Layers of Blood Safety

- DONOR ELIGIBILITY
  - Potential donors are provided educational materials to permit self deferral. Specific questions ask about their health and medical history
- TESTING FOR COMMUNICABLE DISEASES
  - Donated blood is tested for HIV, HBV, HCV, HTLV , WNV, T. Cruzi and syphilis
- DONOR DEFERRAL REGISTRIES
  - Blood establishments must keep current a list of individuals who have been deferred as blood or plasma donors
- QUARANTINING OF UNSUITABLE BLOOD
  - Blood products are quarantined until the products have been thoroughly tested and the donation records have been verified
- INVESTIGATION OF PROBLEMS
  - Blood establishments must investigate any breaches of these safeguards and correct all system deficiencies
- PATHOGEN REDUCTION
  - Some products undergo viral inactivation procedures

Current FDA/CBER Initiatives: Blood Safety Team

- CBER established a Blood Safety Team in July 2006
- Goals
  - To formalize Center operating procedures
  - To establish roles and responsibilities in the management of blood safety issues

Current FDA/CBER Initiatives: Blood Safety Team

- Major objectives are:
  - To improve ***CBER responses to blood safety issues*** through defined cross Office collaboration creating increased sensitivity to safety signals
  - To improve the ***value of safety information*** and broaden public and regulated industry access to the information
  - To improve the ***processing of blood safety information*** through establishment of a forum for review and evaluation permitting discussions in a non-crisis mode and facilitating anticipation of events
  - To ***enhance external outreach, evaluation and risk communication***

Current FDA/CBER Initiatives: Blood Safety Team

- Membership
  - CBER Offices
    - Office of Biostatistics and Epidemiology (OBE)
    - Office of Blood Research and Review (OBRR)
    - Office of Communication, Training and Manufacturers Assistance (OCTMA)
    - Office of Compliance and Biologic Quality (OCBQ)
    - Office of the Director (OD)

Activities of the Blood Safety Team

- Coordinates investigations of potential shortages of life saving biologics
  - Investigation of impact of manufacturing changes
  - Impact of recalls
- Reviews Biologic Product Deviation Reports (BPDRs) and potential enhancements to reduce reporting burdens
  - Provides oversight for the annual report
  - Reviews the benefit of continued implementation of post donation information (PDI)

Activities of the Blood Safety Team

- Evaluates manufacturing issues and potential safety impacts
  - Effect of changes in manufacturing and bioburden excursions
- Investigates approaches to threats to the blood supply
  - Review of existing scientific information and support of public Workshops
- Implements a rapid response to urgent safety events
  - Investigates the impact of adulterated pharmaceutical ingredients on injection biologics and devices used to screen donors and to diagnose viral diseases

ONGOING BST CHALLENGES

- Development and Formalization of best Cross Office approaches to key Safety Areas:
  - Donor - identify risk factors for fatalities
  - Recipients - improve understanding of adverse outcomes
  - BPDRs - increase value to FDA and regulated industry
  - Emerging Infectious Diseases (EIDs) - explore improvements in informatics
  - Denominators - investigate role of hospital based transfusionists to improve databases

CBER's Blood Safety Team

- Functions as a coordinated, agile, inter-Office team that evaluates, processes, investigates and responds to a variety of blood safety issues
- Plays an important role in external outreach and risk communication