Blood Products: New Additions to the CRN Portfolio

BARDA Industry Day
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Why Blood Products?

Box 1: High-Priority Threats

- *Bacillus anthracis* (anthrax)*
- *Clostridium botulinum* toxin (botulism)*
- Cyanide
- Emerging infectious diseases (including pandemic influenza)
- Gram negative organisms
- Multi-drug resistant *Bacillus anthracis* (MDR anthrax)
- Nerve agents
- Radiological agents (e.g., radiological dispersal devices)
- Nuclear agents
- Variola virus (smallpox)*
- Viral Hemorrhagic Fevers

- **Trauma**
- **Acute Radiation Syndrome (ARS)**
Lessons from Market Research

November 2012, NIH Campus

Key Lessons

1. Community:
   1. Small commercial market, limited AR&D investment
   2. Decentralized community of suppliers
   3. Challenging regulatory environment for new products

2. Products:
   1. Requirements: Likely shortfalls of key blood components
   2. Limitations: shelf-life, deployment, usability
   3. Emerging science: Donor variability, “Fresh” vs. “Old”
BARDA Priorities

• Develop “next-generation” blood components:
  • Plasma
  • Platelets
  • Red Blood Cells (RBCs)

• Key Considerations:
  1. Commercial sustainability
     • Indications for routine clinical use (trauma, oncology, etc)
     • Strategy for integration
  2. Concept-of-Operations (CONOPs)
     • Ease-of-use
     • Robust storage and deployment
     • Amenable to managed inventory and/or surge capacity
  3. Addresses emerging issues
     • Technical (consistency, quality, shelf-life, etc.)
     • Regulatory
Previous Contract Awards for Blood Products

**Cellerant Therapeutics:**
- **CLT-008**: cryopreserved hematopoietic stem cell-based therapy for blood disorders
  - 2008 (1st contract): $11.3 million
  - 2010 (2nd contract): $80 million, options up to $170 million

**Velico Medical:**
- **Spray-dried plasma system** (both disposable and device components)
  - 2012: $9.0 million, options up to $38.6 million

**Cellphire, Inc.:**
- **Thrombosomes**: freeze-dried human platelet-derived hemostatic agent
  - 2013: $11.0 million, options up to $56.7 million
Interfacing with BARDA

- [www.hhs.gov/aspr/barda](http://www.hhs.gov/aspr/barda)
  - Program description, information, news, announcements

- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Portal to BARDA: Register to request meeting / Tech Watch

- [www.fedbizopps.gov](http://www.fedbizopps.gov)
  - Official announcements and detailed information for all government contract solicitations, including CBRN-BAA-13-100-SOL-00013

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