



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Blood Products: New Additions to the CRN Portfolio

**BARDA Industry Day
November 12, 2013**

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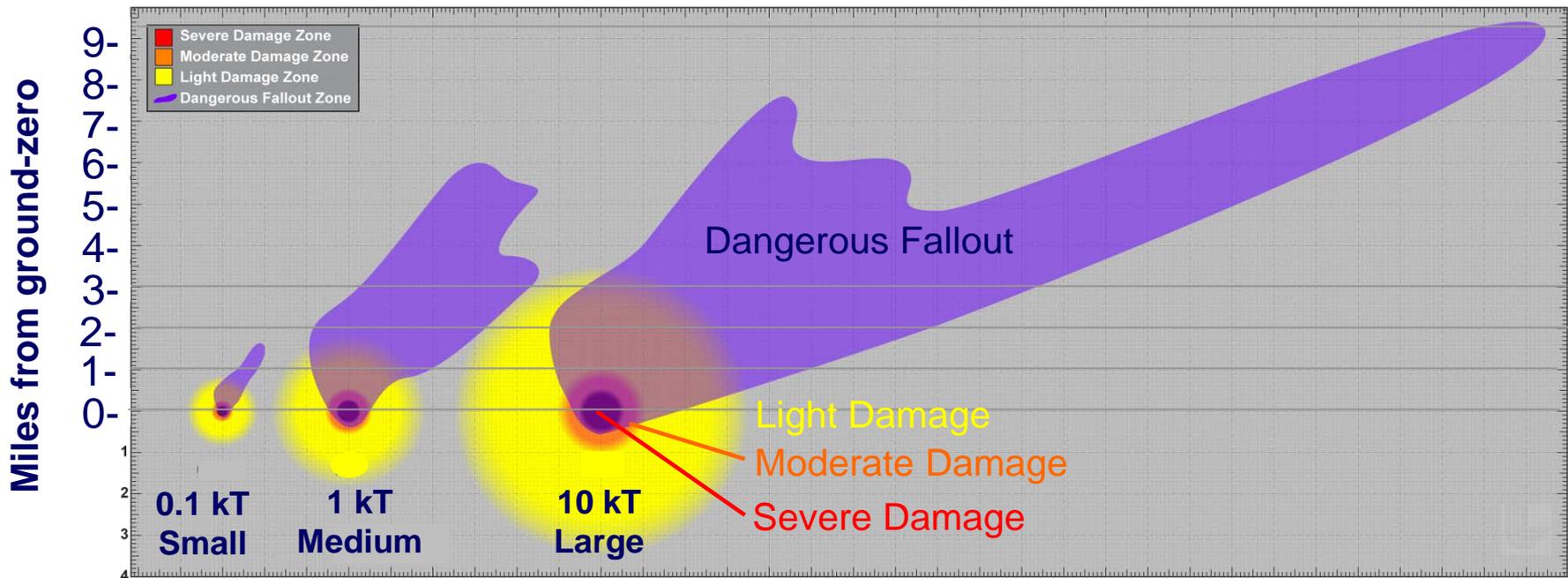


Why Blood Products?

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)**





Blood Products and Cellular Therapies: A Symposium on Emergency Preparedness

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
 - Program description, information, news, announcements
- www.medicalcountermeasures.gov
 - Portal to BARDA: Register to request meeting / Tech Watch
- www.fedbizopps.gov
 - Official announcements and detailed information for all government contract solicitations, including **CBRN-BAA-13-100-SOL-00013**
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