Chemical MCM Development at BARDA

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Chemical Weapons—A Terrifying Threat
BAA Area of Interest #5: Chemical Threat Medical Countermeasures

• Specific Agents of Interest
  — Nerve agents and Pesticides
  — Pulmonary Agents
  — Vesicants
  — Blood and Metabolic Agents
  — Toxic Industrial Chemicals and Emerging Threats

• General Considerations
  — Easy to administer in a mass casualty situation
  — Safe in children, pregnant women, and the elderly
  — Rapidly effective even when administered at delays post-exposure
  — Animal Rule Regulatory Pathway
How do we begin?

• Technical gaps at every level
  – Animal models
  – Candidates
  – Mechanisms of action
  – Acute vs delayed effects
  – Toxic industrial chemicals, pulmonary agents, vesicants, non-traditional agents

• Low-hanging fruit
  – Midazolam anti-convulsant to replace diazepam in SNS ChemPaks
  – Amyl nitrite for cyanide exposure
  – Basic research on decontamination

• Repurposing
  – Galantamine – licensed for Alzheimer’s disease, possible indication for delayed effects of nerve agents

• Animal model development through Nonclinical Development Network
CHEM Near Term Priorities

• Approval of existing MCMs for pediatric use

• Animal Models
  ─ Effects on Juveniles
  ─ Relevant Routes of Exposure
  ─ Non-lethal Endpoints

• New Therapeutics for Chemical Agents

• Mitigation of delayed effects
Repurposing for Chemical Threats

• New indications for pharmaceuticals already in use for related indications
  – Many candidates
  – Still need to demonstrate efficacy for chemical indications

• Pursue Fixed Price Acquisition with cost-reimbursement support of chemical clinical indication
  – Example: Midazolam for nerve agent induced seizure

• Candidate Chemical syndromes include neurological and behavioral delayed effects (nerve agents), burn (vesicants), and eye and lung injury (vesicants and TICs)
Sources Sought Notice: Midazolam Autoinjectors and Multidose Vials

• Posted March 2012

• Requested information on technical and manufacturing capabilities, data and materials for pediatric and adult midazolam-filled autoinjectors, and/or multi-dose vials to treat seizures resulting from exposure to organophosphorus (OP) compounds.

• Midazolam would be an improved anticonvulsant for the CHEMPACK program
CHEM Summary

- Address acute and chronic effects of chemical exposure
- Support improvements in animal models for chemical exposure toxicity
- Develop products that are effective when administered at significant delays after exposure
- Pursue repurposing candidates for chemical indications
Questions?

- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Portal to BARDA
  - Register and Request a Meeting

- Contact Us
  
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