

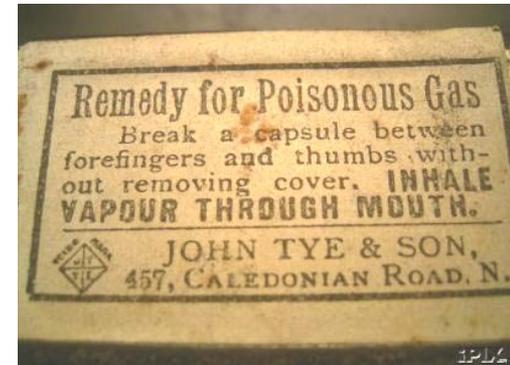


# Chemical MCM Development at BARDA

Self Aid



Emergency Personnel Aid

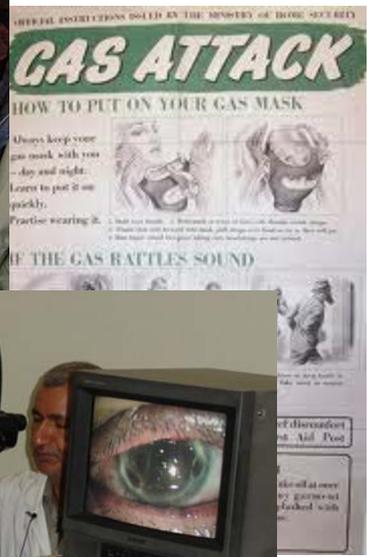


Judy Laney

December 10, 2012



# Chemical Weapons—A Terrifying Threat



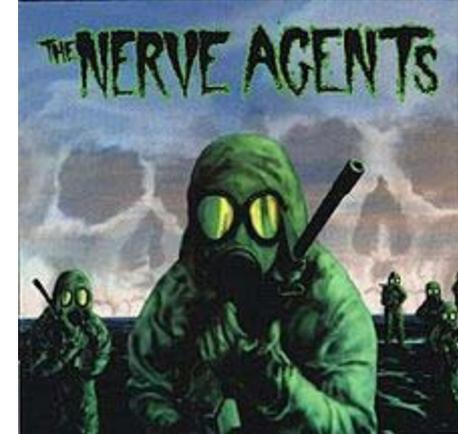


# BAA Area of Interest #5: Chemical Threat Medical Countermeasures



- 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

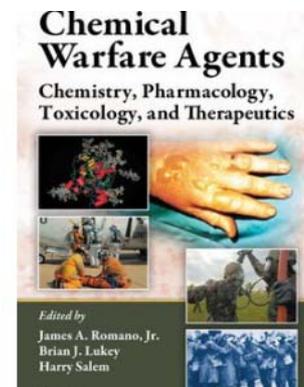


# How do we begin?



- 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

- 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



- 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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