



**United States Department of**

**Health & Human Services**

**Office of the Assistant Secretary for Preparedness and Response (ASPR)**

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# **Broad Spectrum Antimicrobial (BSA) Program**

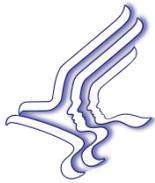
**Biomedical Advanced Research and Development Authority (BARDA)**

**Joe Larsen, Ph.D.**

**Chief, BSA Program**

**HHS/ASPR/BARDA**

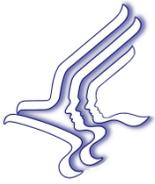
**June 7th , 2011**



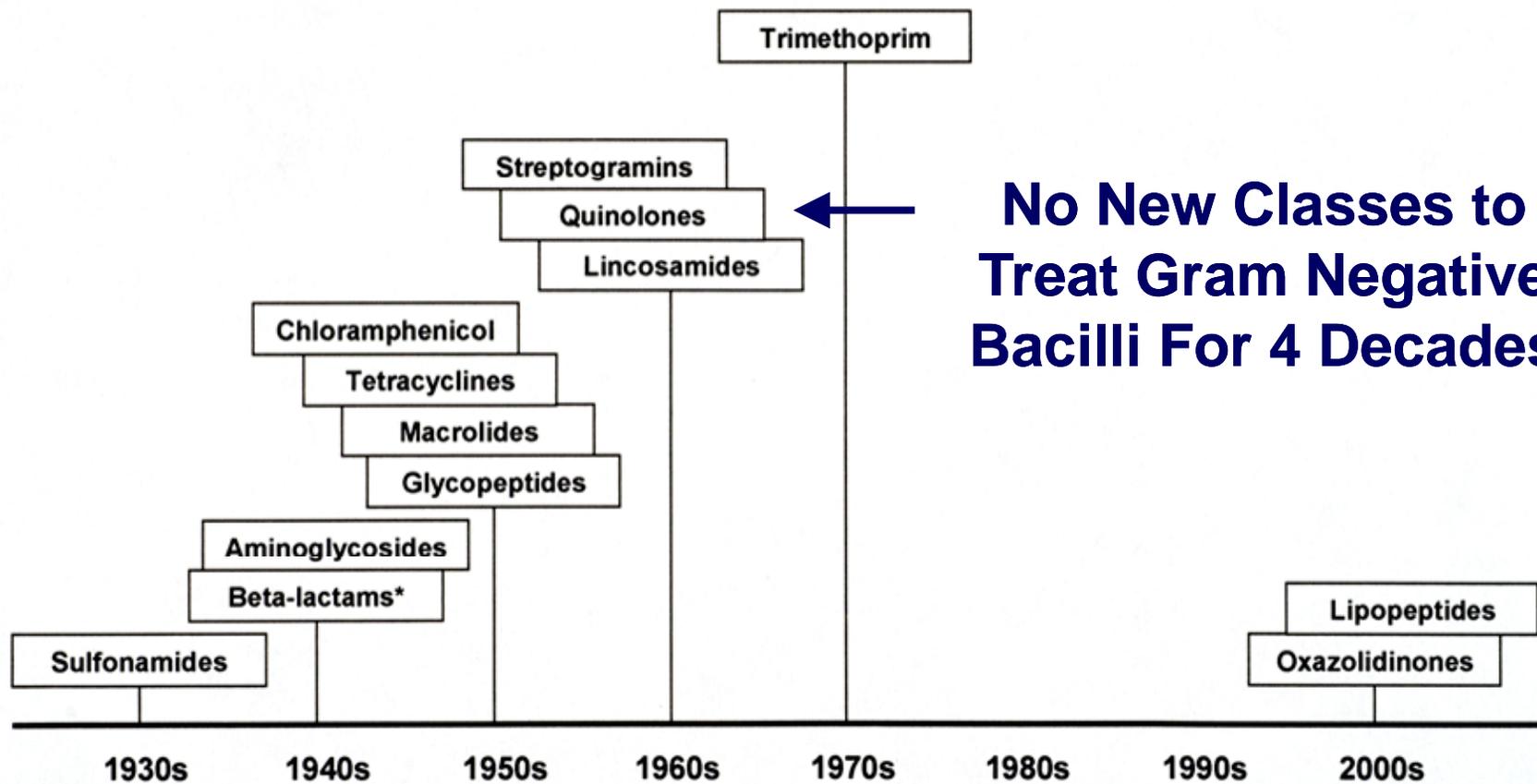
# BSA Program: Public Health Need



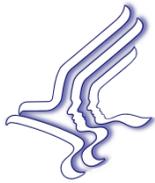
- **Infections are the #3 cause of death in the US**
- **Infections are the #2 cause of death in the world**
  - 14.9 million in 2004 (29% of all deaths)
- **Hospital acquired bacterial infections: 2 million per year in US**
  - 90,000 deaths
- **Antibiotic resistance cost the health care system more than \$8 billion in 2006**
- **Resistance to most classes of antibiotics has increased to an extent that infections in some patients are untreatable by current antibiotics**
- **Large pharma has largely abandoned R&D investment in antimicrobials**



# BSA Program: Public Health Need



Adapted from Monnet DL, 2004

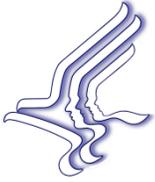


# BSA Program



- **BSA Program Objectives:**

- To re-vitalize the antimicrobial drug pipeline through public support of advanced research and development and procurement of novel antimicrobials.
- To generate antimicrobial treatment and post-exposure prophylaxis options in the event of an attack with a bacterial or viral threat agent.

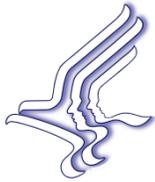


# BSA Program



- **BSA Program Methods:**

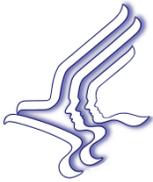
- Actively seek public: private partnerships with large and small pharmaceutical and biotechnology companies
- Concurrently develop antimicrobial drugs (antiviral or antibacterial) for biodefense and clinically prevalent infectious disease indications to mitigate developmental risk for biothreat indications.
- Develop animal models for pathogen which recapitulate the disease observed in humans



# BSA Program



- **BSA Program Accomplishments:**
  - Program established June 2010
  - First contract awarded August 2010 to Achaogen, Inc for the development of a next generation aminoglycoside antibiotic
  - Contract awarded to Chimerix, Inc in February 2011 for the development of a smallpox antiviral drug (broad spectrum efficacy against dsDNA viruses)
  - BARDA invited to participate on the Interagency Task Force for Antimicrobial Resistance
  - Established transition agreements with DoD to facilitate the transfer of S&T programs to advanced development

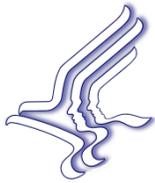


# BSA Program



- **The Application Process**

- BAA: BARDA-CBRN-BAA-11-SOL-00009
- Phase I is a ~10 page white paper
- Reviewed by panel of SMEs on a quarterly basis
- Offeror will receive Invite/Do Not Invite for a Full Proposal
- Feedback and templates provided for Phase II Invitees
  - Chance for a face to face meeting or telecon to clarify items prior to proposal submission
- Phase II proposal submitted (~100 pages)
- Proposal reviewed; notification sent to offeror
  - Cat I-Cat III designation
- Proceed to contract negotiations
- Average time to contract award : 263 business days
  - BSA contracts: ~180 business days

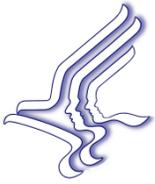


# BSA Program



- **BSA Areas of Interest**

- Novel antimicrobials with broad spectrum activity (more than 2 threat agents of interest)
  - PEP or treatment
  - Multiple formulations seen as an advantage
  - Concurrent commercial development viewed as a strength
- Antiviral drug candidates for the variola virus, filovirus , and arenavirus infection/exposure
- Products capable of making significant positive impacts in addressing the threat of biological threat agents, as well as antimicrobial resistance

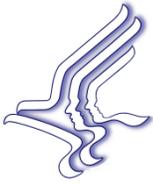


# BSA Program



- **BSA Program Do's and Don'ts**

- Do contact the technical POC for feedback prior to submission
  - Definitely request a meeting if selected for Phase II submission
- Do try to obtain some biodefense related results prior to applying
  - *In vitro* MIC, murine efficacy data
- Do have your product at or approaching a Phase I clinical study prior to submitting
- Do keep proposals succinct and to the point
- Do propose a partnership
  - Average BSA awards to date have been \$50-100M over 4-5 years

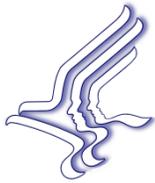


# BSA Program



- **BSA Program Do's and Don'ts continued**

- Do propose rational Go/No Go decision points at the end of every year/period in the proposal
- Don't gloss over weaknesses, state them and provide a plan to address them
- Don't make your biodefense development plan secondary to your commercial indication
- Don't give up if your are not selected from your initial submission
  - BARDA can provide guidance on how to strengthen future submissions

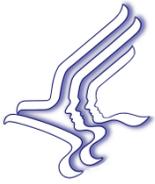


# BSA Program



- **Practical Considerations**

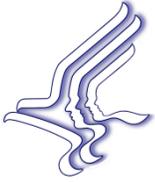
- Antimicrobial drugs should be efficacious when administered a period of time *after* pathogen exposure and a dosing regime that could reasonably accommodate drug delivery in an emergency situation
- Protection against disease needs to include prevention of relapse after therapy concludes
- Efficacy tests should incorporate a suitable comparator and the comparison model should extend back into *in vitro* and proof of concept experimental design
- Drug synthesis should involve reagents, synthesis steps, and purification requirements that are not unrealistic for a commercial drug.



# BSA Program



- **What to expect working with the BSA Program:**
  - Government Contract—NOT a Grant
  - Quality Technical Oversight
  - Involvement
  - Reporting
  - Frequent Communication and Feedback
  - EVMS
  - COA Process



# BSA Program



- **Summary:**

- The BSA program will continue to support the development of novel antimicrobials for the treatment and prevention of biological threat agent infection while concurrently addressing the growing public health threat of antimicrobial resistance
- Actively seek partnership opportunities with companies to bolster antimicrobial development and mitigate risk for biodefense drug development
- Additional contract awards projected in FY12

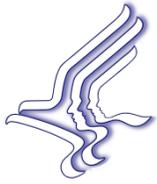


# Interfacing with BARDA

- [www.phe.gov](http://www.phe.gov)
  - Program description, information, news, announcements
- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- [www.fedbizopps.gov](http://www.fedbizopps.gov)
  - Official announcements and detailed information about all government contract solicitations



**Technical POC for Research Area #3: Antimicrobial Drugs:**  
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# BSA Program



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## Questions?