



*United States Department of*  
**Health & Human Services**  
Office of the Assistant Secretary for Preparedness and Response



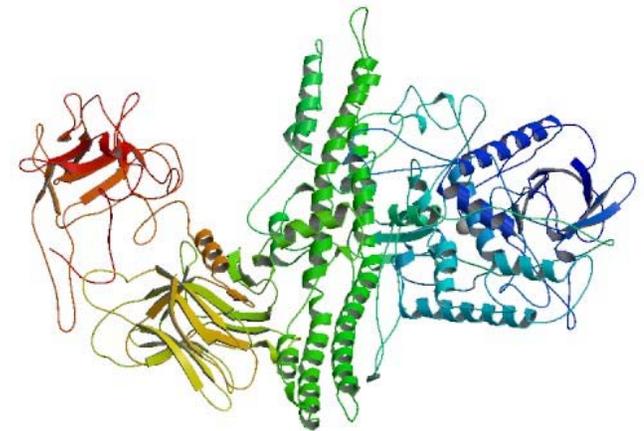
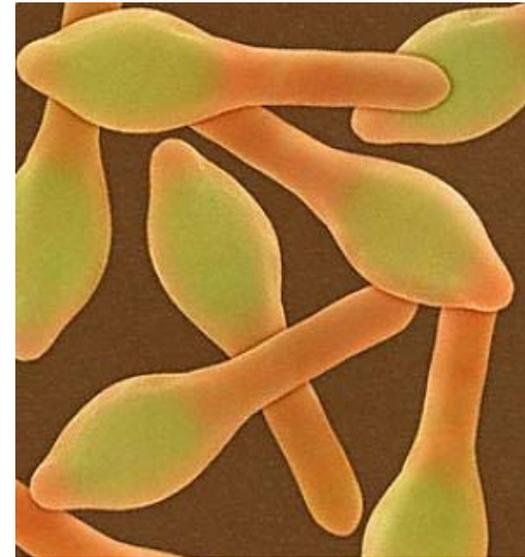
# **Stockpiling of Botulism Antitoxin Heptavalent (BAT) (A, B, C, D, E, F, G) Equine**

**Melissa S. Willis, Ph.D.**

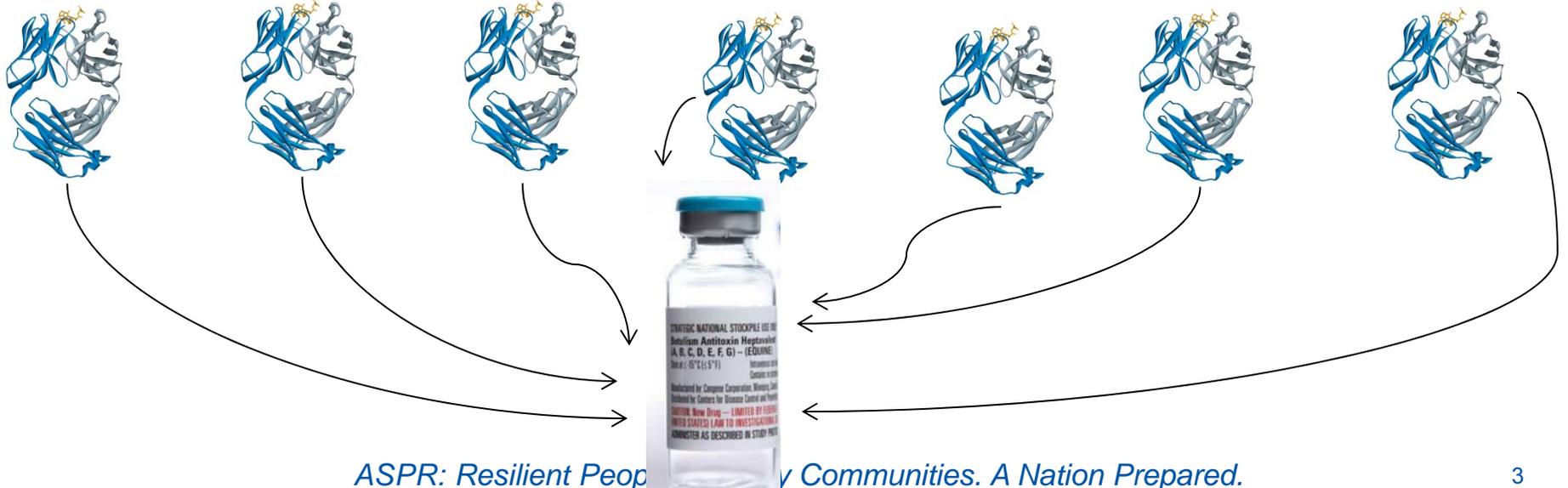
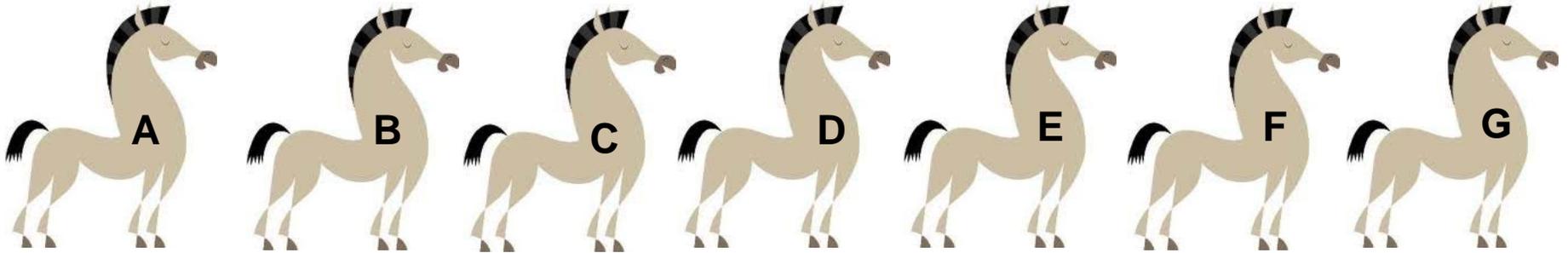
**BARDA Industry Day  
November 12, 2013**

# Botulism

- Agent
  - Botulism caused by neurotoxins secreted by *Clostridium botulinum*
- Botulism clinical manifestations and timelines
  - Symptoms start 6 to 36 hours after exposure (eyes, mouth)
  - Paralysis progresses to limbs, death from paralysis of respiratory system
- Incidence
  - ~145 naturally occurring cases in the U.S. per year



# What is Botulism Antitoxin (BAT)?





# Product Information



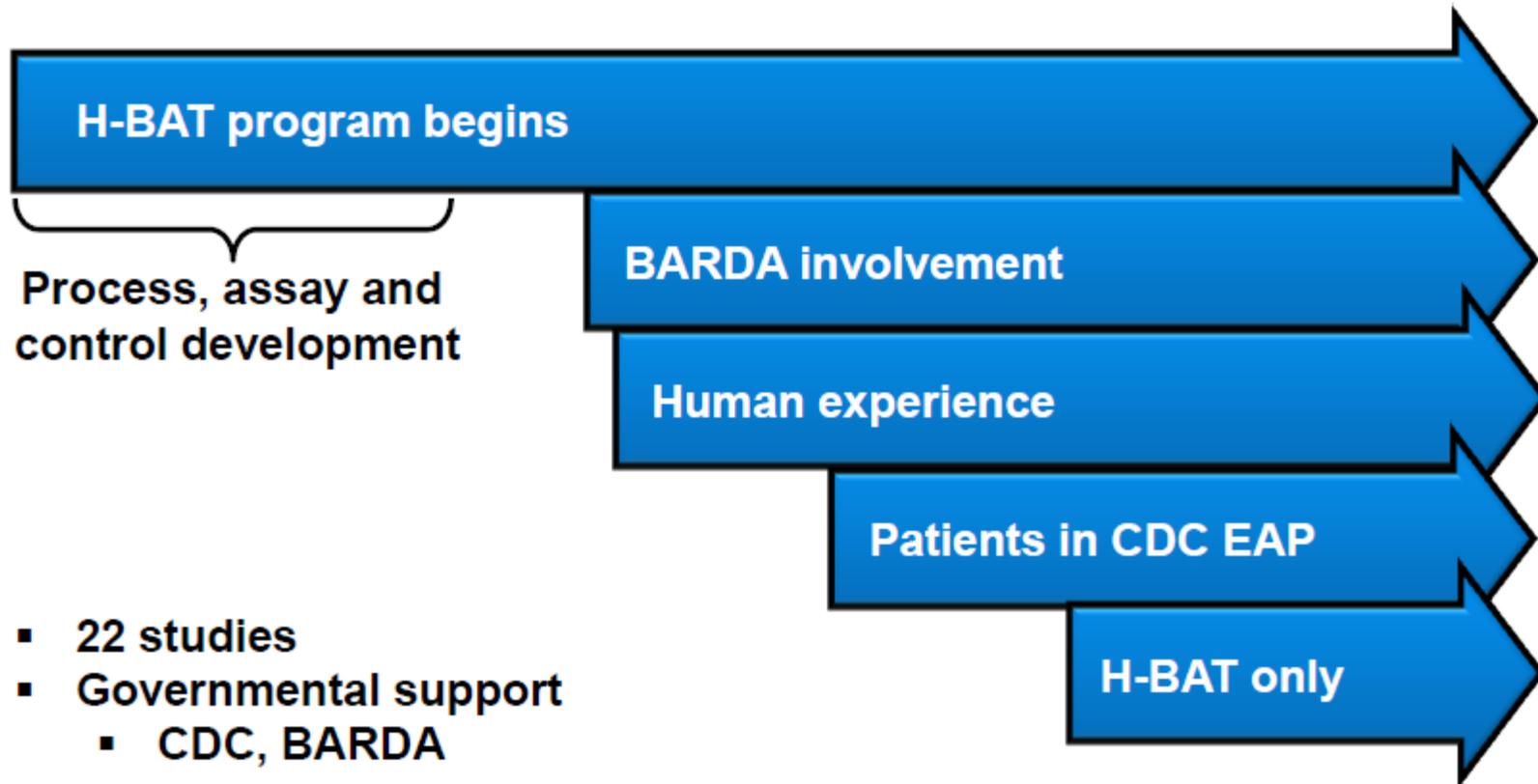
- Indication – for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients
- Potency – each vial contains
  - 4,500 U for serotype A antitoxin
  - 3,300 U for serotype B antitoxin
  - 3,000 U for serotype C antitoxin
  - 600 U for serotype D antitoxin
  - 5,100 U for serotype E antitoxin
  - 3,000 U for serotype F antitoxin
  - 600 U for serotype G antitoxin



# BAT Stockpiling and Use



2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
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# Clinical Use



- BAT given to 56 people in clinical trials
- In March 2010 BAT became the only drug distributed by the CDC for non-infant botulism
- 285 people treated with BAT (10 days – 85 years old) since 2008

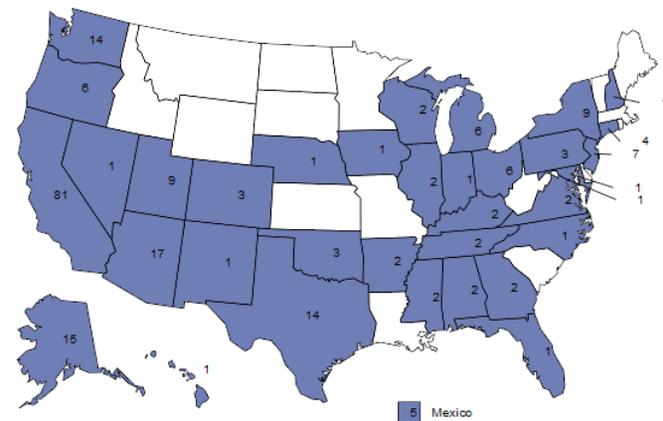




# Product Availability



- BAT is available from the SNS or can be purchased directly from the manufacturer
- BARDA added funds in 2011 to collect and store additional plasma for future use
- Shelf life: currently 4 years at -20°C with stability studies ongoing
- Licensed on March 22, 2013 under the Animal Rule





# 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

