Hearing of the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

The Role of the National Institute of Allergy and Infectious Diseases in Research Addressing Ebola Virus Disease

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9/11 Attacks

2001 Anthrax Attacks

Category A pathogens
- Anthrax (Bacillus anthracis)
- Botulism (Clostridium botulinum toxin)
- Plague (Yersinia pestis)
- Smallpox
- Tularemia (Francisella tularensis)
- Viral hemorrhagic fever viruses (e.g., Ebola, Marburg, Lassa, and Machupo)

Viral Hemorrhagic Fever Viruses
- High lethality and high infectivity upon contact
- Therapy: Mainly supportive
- Vaccine: Not available at present

Product Development Pipeline

- Early concept and product development
- Advanced development
- Commercial manufacturing
- Regulatory review

NIH | BARDA | Industry | FDA
Ebola Therapeutics in Development

- ZMapp (Mapp Biopharmaceutical)
  - Combination of 3 artificially produced antibodies directed against the Ebola virus
- BCX4430 (BioCryst)
  - A novel drug (nucleoside analogue) that interferes with the reproductive process of the virus
- TKM-Ebola (Tekmira Pharmaceuticals)
  - Small inhibitory RNA molecule that interferes with the replication of the virus (supported by DOD)
- Brincidofovir (Chimerix)
  - DNA polymerase inhibitor; in vitro activity against Ebola
  - Good safety record in phase 3 trial for CMV and adenovirus
- Favipiravir (MediVector/Toyama/Fuji)
  - Polymerase inhibitor; modest activity against Ebola
  - Currently in phase 3 trials for influenza

NIAID Ebola Vaccines in or Approaching Phase 1 Trials

- NIAID/GSK (chimp adenovirus vector)  Phase 1 trials initiated September 2014 at the NIH
- NewLink (VSV vector)  Phase 1 trials initiated October 2014 at the NIH and WRAIR
- Crucell (adenovirus vector)  Phase 1 trials expected fall 2015

Other vaccines in development: Profectus (VSV vector); Bavarian Nordic (MVA vector); NIAID intramural, Thomas Jefferson Univ. (rabies vector)