

# Gain-of-Function Policy Development Process to Date and Next Steps

**Gerald L. Epstein, Ph.D.**

Assistant Director for Biosecurity and Emerging Technologies  
Office of Science and Technology Policy

May 24, 2016



# The Overarching Challenge

*How can we reliably identify, and where necessary and possible mitigate, risks while protecting scientific autonomy, discovery and innovation, public health, national security, and other critical interests*

# Gain-of-Function, Round 1

- 2011-2012: National Science Advisory Board for Biosecurity (NSABB) reviews two papers on making highly pathogenic H5N1 avian influenza transmissible between mammals via the respiratory route
  - Fall 2011: Recommends publication of redacted versions
  - March 2012: Recommends publication of revised versions in full (one unanimously; one with 12-6 vote)
- March 2012: US issues Policy on Oversight of Dual Use Research of Concern
- June 2012: H5N1 papers published in Science and Nature

# Gain-of-Function, Round 2

- Laboratory biosafety incidents in mid-2014 prompt HHS to ask the U.S. government to reassess the risk/benefit calculus that underpinned funding for certain gain-of-function studies
- Multiple stakeholder groups call for science-based deliberation
  - Cambridge Working Group
  - Scientists for Science
  - European Academies Science Advisory Council and other efforts
- Highest concern for respiratory pathogens with pandemic potential (MERS, SARS, and influenza)

# GOF Deliberative Process

- On October 17<sup>th</sup>, 2014, the U.S. Government announced the launch of a deliberative process to assess the potential risks and benefits associated with gain-of-function studies and inform the development of new U.S. government policy.
- Pending adoption of a new policy, the U.S. Government instituted a pause on funding for certain kinds of gain-of-function experiments involving influenza, SARS, and MERS viruses.

**U.S. Government Gain-of-Function  
Deliberative Process and Research Funding  
Pause on Selected Gain-of-Function  
Research Involving Influenza, MERS, and  
SARS Viruses**

October 17, 2014

# Key Voices

## **National Science Advisory Board for Biosecurity (NSABB)**

- Provide the U.S. government with recommendations on policy for the funding and conduct of gain of function research
- Serve as the official federal advisory body for providing advice on oversight of this area of dual use research
- Operate under the Federal Advisory Committee Act, which has transparency and public input requirements

## **National Academies**

- Convene two public conferences to facilitate broad discussion of the issues associated with gain of function research, to include discussion of the NSABB draft recommendations.
- Provide summary of public discussions and feedback on the NSABB draft recommendations

# NSABB Process

## **Working Group on the Design and Conduct of Risk and Benefit Assessments of Gain of Function Studies**

- Task 1: Advise on risk and benefit assessments
- Task 2: Develop recommendation on funding and conduct of gain-of-function research

## **Risk and Benefit Analysis of Gain of Function Research (Gryphon Scientific)**

## **Formal NSABB adoption and transmittal of policy recommendations**

# Subsequent U.S. Government Policy Development

- White House (OSTP and NSC) to lead interagency policy formulation process
- Entire deliberative process record to be considered
  - NSABB recommendation
  - National Academies sessions
  - Gryphon risk/benefit analysis
  - Public comment (including comments on the final NSABB recommendation that NSABB will continue to accept as a courtesy, even after it has formally reported)
- Resulting US policy to supersede funding pause



# For More Information

- *NSABB WG Working Paper on Gain-of-Function Studies (May 2016)*  
<http://osp.od.nih.gov/sites/default/files/NSABB%20Working%20Group%20Draft%20Report%20-%20Recommendations%20for%20the%20Evaluation%20and%20Oversight%20of%20Proposed%20Gain-of-Function%20Research%205-6-2016.pdf>
- *Risk and Benefit Analysis of Gain of Function Research – Final Report (Gryphon Scientific, April 2016)*  
<http://www.gryphonscientific.com/gain-of-function/>
- *U.S. Government Deliberative Process and Funding Pause on Certain Types of Gain-of-Function Research (October 2014)*  
<http://www.phe.gov/s3/dualuse/Pages/default.aspx>
- *Department of Health and Human Services Framework on H5N1 Dual Use Research of Concern (2013)*  
<http://www.phe.gov/s3/dualuse/Pages/HHSh5n1Framework.aspx>