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

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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

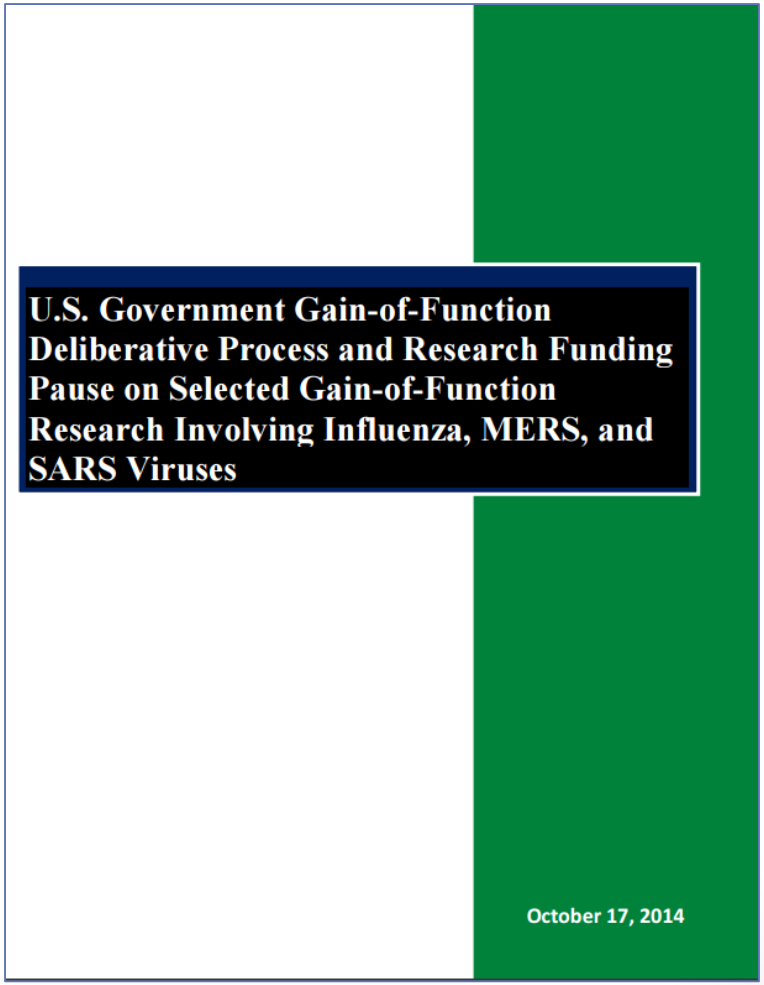
- 2011-2012: National Science Advisory Board for Biosecurity (NSABB) reviews two papers on making highly pathogenic H5N1 avian influenza transmissible between mammals via the respiratory route
  - Fall 2011: Recommends publication of redacted versions
  - March 2012: Recommends publication of revised 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 17th, 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.



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*