Today’s Guest

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Advocacy and Gain of Function Research of Concern

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What is “gain of function” research?

Gain of function (GoF) research gives an organism a new property or enhances an existing one. Examples include: viruses, bacteria, fungi, rodents, birds, fish.
Gain of function is not just for pathogens

Basic microbial science at all levels
Genetics
Cancer
Cystic fibrosis
Insulin production for people with diabetes
Crop resiliency
Vaccine development (including COVID-19)
....Just to name a few
Why is it center stage (again)?

• The current P3CO Framework is at the center of some controversy
• Some Members of Congress do not think the framework was effectively applied to certain research grants
• These grants are independent from the source of SARS-CoV-2 but are being conflated.
• Only two ways for the origin of the pandemic (natural spillover, lab spillover)
• Many ways for the origin of SARS-CoV-2 (no data pointing to GoF)
• I try not to use GoF and origin of pandemic in the same sentence. It can be misinterpreted for political reason without scientific evidence
A Brief History of Pathogen Research Oversight

- Biological and Toxins Weapons Convention (1972)
  - 1989–gain of function for the development of biological weapons banned
- CDC Classification of Etiologic Agents on the Basis of Hazard (1974)
  - Established concept of ascending levels of containment corresponding to risk
- Asilomar Conference (1975) – landmark conference on DNA technology
- NIH Guidelines for Research Involving Recombinant DNA Molecules (1976)
  - Required Biosafety officers and Institutional Biosafety Committees at NIH-funded orgs
- Select Agent regulations put into place (1996-97)
  - Expanded select agents and toxins list and required individual registration (FBI clearance)
A Brief and Recent History of Current Policy

• **Anthrax attacks in 2001**—ASM did extensive work in the years to follow
  • NASEM convened a Committee, led by Gerry Fink (called the “Fink Committee”)
    o Made many recommendations, including creation of the NSABB
  • National Science Advisory Board for Biosafety (NSABB) created (2003)
    o Authorized by law and housed under NIH; first meeting in 2005
  • H5N1 Flu outbreak and related research led to a pause on gain of function research of concern from 2014-2017 (21 GOF studies of influenza, MERS, and SARS viruses.)
  • NSABB makes recommendations (2016)
  • HHS “P3CO” Framework published (2017)
    o Defines “potential pandemic pathogen (PPP)” and “enhanced PPP”
Challenges Facing Us in Today’s Environment

• COVID-19 origin theories– conflation with gain of function research
• Anti-China sentiment and concerns about research security
• Fear caused by a deadly disease that many people do not understand; looking to assign blame
• Perception that the framework was not properly applied; and perceived lack of transparency (focus on certain grants)
• Political polarization along lines of science and public health
  ○ Partisan “investigations” into COVID origins and P3CO research
• Many legislative “opportunities” (and pressure) to “do something”
Tracking Current Proposals

- FY 2022 Appropriations bills—Labor HHS report language
- U.S. Competition and Innovation Act
- Energy Sciences for the Future Act (DOE Office of Science reauthorization)
- American COMPETES Act
- PREVENT Pandemics Act (likely in next iteration)
- Stand-alone bills

*Also monitoring oversight activities by Subcommittees
ASM first and foremost takes a collegial approach on everything we do. It is our core principle.

• Areas where we “follow”
• Areas we do not cover
• Areas where we lead (GoF/DURC is an area where we lead. It is a quintessential microbiological problem)
What is ASM Doing?

• Meeting with House and Senate Offices/Committee Staff
  ○ Bringing in member experts for key meetings (proactive and reactive)
  ○ Bipartisan approach
  ○ Larger group briefings and "one off" meetings
  ○ Focus especially on House Energy & Commerce, House SST Committees, Senate HELP Committee, and appropriators

• Touching base with Agencies and OSTP

• Op-ed published in STAT (December 23, 2021)

• Journal Commentary
What is ASM Doing?

• Developing educational materials for policy audiences
• Marshaling the community to voice concern about problematic legislative provisions/ report language
  ○ Thank you to those groups/institutions who joined our letter to House and Senate Appropriators earlier this year
• Stakeholder Call scheduled **Feb 4 at 2 pm** for government relations staff at peer organizations and institutions
A Word on Publishing

ASM Journals DURC/GOF/P3 Process

SCREEN
- Author Discloses
- ASM Editorial Staff Screens and flags manuscript
- Reviewer Notes biosafety concern
- Editor Evaluates and consults EiC

DISCUSS
- ARPC ASM Responsible Publication
- Outside Advice

DECIDE
ARPC Recommends:
- Publish
- Publish w/ Editoria
- Reject
- Redact

Consultations May Include:
- Corresponding Author
- NIH
- Institutional Safety Officer
THANK YOU!
Join us next time!

Thursday, February 10, 2022, 2:15 p.m. ET

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