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INSIGHT

Improved Oversight of Pathogen Research: Recent Recommendations

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Introduction

The United States has multiple, overlapping policies that guide oversight of pathogen research. These include, among others:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines;
- Federal Select Agent Program (FSAP);
- U.S. Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC); and
- Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO).

Many of these policies and guidelines are framed around biosafety and biosecurity. According to a recent U.S. Government Accountability Office (GAO) report, biosafety includes "the practices and equipment that ensure that lab workers, the community, and the environment are protected from infectious pathogens and biological hazards," while biosecurity includes "practices to ensure the protection and control of biological materials in laboratories to protect them from theft, loss, or misuse."

While some oversight mechanisms are required by law and apply to certain pathogen research conducted in the United States or by U.S. researchers, others are guidance issued by federal agencies and apply only to research and researchers they fund. Privately funded research, or research conducted outside the United States, may therefore not be covered by certain U.S. oversight mechanisms.

Two recent reports, one from GAO and a draft report from the National Science Advisory Board for Biosecurity (NSABB), evaluated current U.S. polices related to research with enhanced potential pandemic pathogens (ePPP) and broader biosafety/biosecurity issues related to life-sciences research. While each report provided a separate set of recommendations based on its findings, when considered together, three broad focus areas emerge:

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1. Clarifying language and developing standards to identify research that requires review under the P3CO policy,
2. Increasing transparency around the P3CO review and approval processes, and
3. Expanding oversight to include privately funded research.

Congress may examine the findings and recommendations put forth in both reports to determine whether it wants to direct agencies to consider them and whether additional authorities and appropriations are required for the agencies to implement them.

GAO Report

The 2020 Coronavirus Aid, Relief, and Economic Security Act tasked GAO with examining the Department of Health and Human Services' (HHS's) oversight of ePPP research and identifying potential gaps that exist in HHS's current policies governing such research, including the P3CO, DURC, and FSAP policies.

The resulting GAO report, released in January 2023, made two recommendations related to P3CO and one related to FSAP:

- Develop and document a standard for "reasonably anticipated" to ensure consistency in identifying research for departmental review that is "reasonably anticipated to create, transfer or use enhanced potential pandemic pathogens."
- Identify and share non-sensitive information with researchers, Congress, and the public about the departmental review process for research involving enhanced potential pandemic pathogens, including information on who is involved in the review process, their expertise, and how the evaluation criteria are applied.
- Adding a new pathogen to FSAP may burden diagnostic and treatment facilities with additional reporting and inspection requirements. The Director of the Centers for Disease Control and Prevention should assess and document the risk posed by the limitations of the existing FSAP exemptions for public health emergencies and seek legislative authority as needed. Currently, exemptions are for a maximum of 60 days.

GAO also repeated its recommendation from a 2009 report for HHS to identify a single government entity to assess the risk posed by the lack of oversight of privately funded research.

NSABB Draft Report

In January 2020, HHS charged the NSABB with evaluating, and providing recommendations to improve, the effectiveness of U.S. biosecurity policy frameworks that govern ePPPP research and Dual Use Research of Concern (DURC). The COVID-19 pandemic disrupted NSABB commencing its evaluation. It reconvened in February 2022 and was given an updated charge by HHS.

The resulting draft NSABB report, released in January 2023, made 13 recommendations based upon 13 findings from two working groups focused on the implementation of P3CO and DURC. Selected recommendations include:

- Clarify definitions of research and expand the scope of biological agents requiring review under P3CO and DURC.
- Remove certain exclusions for surveillance and vaccine development research.
- Specify roles and responsibilities for investigators and institutions.

- Make P3CO consistent with the 1979 Belmont Report on guidelines for the protection of human research subjects.
- Monitor for ePPP throughout the entire research life-cycle.
- Increase transparency in the review/approval process.
- Ensure equivalent review, evaluation, and ongoing oversight of research funded at international institutions.
- Engage stakeholders and publishing groups to address information hazards.
- Develop an integrated approach to oversight of research that raises significant biosafety and biosecurity concerns.
- Expand oversight to non-federally funded research at institutions and private companies.

Congressional Considerations

Federal agencies that fund research covered by P3CO, DURC, and FSAP could implement many of the NSABB and GAO recommendations without additional congressional direction. However, implementation of some recommendations might require new appropriations or authorities.

For example, while FSAP covers all research involving select biological agents and toxins regardless of the funding source, including research conducted at private institutions and companies, P3CO and DURC apply only to research that is funded by the U.S. government. Both the NSABB and GAO reports recommend that these policies be extended to cover privately funded research. Congress may consider whether agencies have the authority to make that change or whether additional authorities would be needed. Congress may also choose to examine agencies' ability to conduct oversight of research conducted at private institutions, companies, and international institutions. Other recommendations, such as the development of guidance documents and implementation plans and the provision of technical and financial support, might require additional appropriations.

Through its oversight of federal agencies, Congress may also monitor agency implementation of the GAO and NSABB recommendations.

For additional CRS analysis on enhanced potential pandemic pathogens, see CRS Report R47114, *Oversight of Gain of Function Research with Pathogens: Issues for Congress*, by Todd Kuiken.

Author Information

Todd Kuiken
Analyst in Science and Technology Policy

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