ENERGY & COMMERCE
CHAIR RODGERS

MEMORANDUM
April 25, 2023

To: Members and Staff, Subcommittee on Oversight and Investigations

From: Majority Committee Staff

Re: Hearing on "Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety"

On Thursday, April 27, 2023, at 2:30 p.m. (ET) in 2322 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety."

I. WITNESSES

- Rocco Casagrande, PhD, Executive Chairman, Gryphon Scientific.
- Gregory Koblentz, PhD, Associate Professor & Director, Biodefense Graduate Programs, George Mason University.
- Andy Pekosz, PhD, Professor of Molecular Microbiology and Immunology, Johns Hopkins University, Bloomberg School of Public Health.
- Robert Hawley, PhD, Former of Chief of Safety and Radiation Protection Division, U.S. Army Medical Research Institute, Fort Detrick.

II. OVERVIEW

The ongoing debate over whether the COVID-19 pandemic was the result of a natural zoonotic spillover or a research-related event has brought increased attention to the global proliferation of high-containment laboratories and how research with potential pandemic pathogens is regulated. This hearing is intended to highlight the need for virus research to be conducted more safely by strengthening standards and obtaining more data about laboratory accidents. The witnesses are expected to testify about how to prevent or mitigate accidents and wrongdoing in high-containment laboratories. Witnesses will also testify on the mechanics of how laboratory accidents in high-containment laboratories occur, how they are reported to officials, and gaps in current regulations and practices.

III. BACKGROUND

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) have established four main levels of biosafety (BSL-1 to BSL-4) to guide laboratory researchers in the safe handling of biological agents with BSL-1 being the lowest level and BSL-

4 the highest. Generally, the term "high-containment laboratory" refers to BSL-3 and BSL-4 laboratories.

The last two decades have seen the global proliferation of high-containment laboratories (BSL-3 and BSL-4) conducting research on potential pandemic pathogens. In 2000, there were fewer than ten biosafety level 4 (BSL-4) laboratories in operation. At the beginning of 2023, there are at least 59 BSL-4 laboratories in operation, under construction, or planned.[1] BSL-4 laboratories are used for research involving "infectious agents or toxins that pose a high risk of aerosol-transmitted laboratory infections and life-threatening disease for which no vaccine or therapy is available."[2] BSL-4 pathogens include Ebola and Marburg.[3]

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Description	· No Containment · Defined organisms · Unlikely to cause disease	· Containment · Moderate Risk · Disease of varying severity	· High Containment · Aerosol Transmission · Serious/Potentially lethal disease	· Max Containment · "Exotic," High-Risk Agents · Life-threatening disease
Sample Organisms	E.Coli	Influenza, HIV, Lyme Disease	Tuberculosis	Ebola Virus
Pathogen Type	Agents that present minimal potential hazard to personnel & the environment.	Agents associated with human disease & pose moderate hazards to personnel & the environment.	Indigenous or exotic agents, agents that present a potential for aerosol trans-mission, & agents causing serious or potentially lethal disease.	Dangerous & exotic agents that pose a high risk of aerosol-transmitted lab-oratory infections & life-threatening disease.

Figure 1: Overview of Biosafety Levels. Source: https://consteril.com/biosafety-levels-difference/

The number of BSL-3 laboratories has expanded at an even greater rate than BSL-4 laboratories. The Center for Security and Emerging Technology at Georgetown University estimates that there are at least 434 research institutions with BSL-3 laboratory facilities worldwide.[4] Many of these institutions have multiple BSL-3 laboratories.[5] For example, the

[1] King's College London & George Mason University, *Global Biolabs Report 2023* (2023), https://static1.squarespace.com/static/62fa334a3a6fe8320f5dcf7e/t/6412d3120ee69a4f4efbec1f/1678955285754/KCL0680_BioLabs+Report_Digital.pdf.
[2] ADMINISTRATION FOR PREPAREDNESS & RESPONSE, U.S. DEP'T. OF HEALTH & HUMAN SERVICES, BIOSAFETY LEVELS (Nov. 13, 2015), https://www.phe.gov/s3/BioriskManagement/biosafety/Pages/Biosafety-Levels.aspx#:~:text=Biosafety%20Level%204%20(BSL%2D4,vaccine%20or%20therapy%20is%20available.
[3] CDC & NIH, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES 312-317 (6th ed. 2020).
[4] Caroline Schuerger, Sara Abdulla, & Anna Puglisi, *Data Brief: Mapping Biosafety Levl-3 Laboratories by Publications*, Cntr. For Security & Emerging Tech., Georgetown University (Aug. 2022), https://cset.georgetown.edu/wp-content/uploads/CSET-Mapping-Biosafety-Level-3-Laboratories-by-Publications.pdf.
[5] *Id.*

Government Accountability Office (GAO) found that, as of 2010, there were at least 1,495 BSL-3 laboratories in the United States alone.[6] BSL-3 laboratories study "infectious agents that may be transmitted through the air and cause potentially lethal infection through inhalation exposure."[7] BSL-3 pathogens include SARS-CoV-2 and *Bacillus anthracis*, the agent that causes anthrax.[8]

Concurrent with the expansion in the number of the high-containment laboratories, there have been research advancements in biology, virology, and other related fields that promise advancements in public health, but also present the real risk of accidents causing human infections and disease. Much of the research carried out in high-containment laboratories is inherently dual-use, thus presenting the risk of intentional misuse.[9] There are credible concerns that gain-of-function experiments involving potential pandemic pathogens could trigger a pandemic in the event of a failure in containment.[10]

The United States does not have a single entity responsible for regulating high-containment laboratories or risky research. Due to concerns about the risk inherent with gain-of-function experiments and following a spate of safety incidents at federal laboratories in 2014, the Obama White House paused funding for such experiments from 2014 to 2017.[11] Funding was resumed in 2017 with the White House Office of Science and Technology Policy (OSTP) issuing guidance for Department that funded gain-of-function research.[12] The Department of Health and Human Services (HHS) is the only agency to have issued its own framework for Proposed Research Involving Enhanced Potential Pandemic Pathogens ("P3CO Framework").[13] However, to date, only three experiments have been referred to the P3CO review committee subject to the P3CO Framework.[14] As a result, biosafety practices for gain-of-function experiments are largely managed by the research agency funding the grant under which the experiment has been proposed.

Beyond the P3CO Framework, the Federal Select Agent Program ("FSAP"), jointly run by the Centers for Disease Control and Prevention (CDC) and U.S. Department of Agriculture (USDA), is the other means by which experiments involving potential pandemic pathogens are

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[6] U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-466R, HIGH CONTAINMENT LABORATORIES (2013), https://www.gao.gov/assets/gao-13-466r.pdf.

[7] *Supra*, note 2.

[8] CDC & NIH, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES 149-150 (6th ed. 2020); *see also* CDC, *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)* (Dec. 13, 2021), https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html.

[9] Gregory D. Koblentz & Rocco Casagrande, *Biology is Dangerously Outpacing Policy*, N.Y. TIMES, Feb. 20, 2023, https://www.nytimes.com/2023/02/20/opinion/biology-is-dangerously-outpacing-policy.html.

[10] *Id.*

[11] OFF. OF SCI. & TECH POLICY, EXEC. OFF. OF THE PRESIDENT, DOING DILIGENCE TO ASSESS THE RISKS AND BENEFITS OF LIFE SCIENCES GAIN-OF-FUNCTION RESEARCH (Oct. 17, 2014), https://obamawhitehouse.archives.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-researcH.

[12] OFF. OF THE DIRECTOR, NIH, NIH LIFTS FUNDING PAUSE ON GAIN-OF-FUNCTION RESEARCH (Dec. 19, 2017), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research.

[13] CONG. RES. SERV., IN FOCUS: GLOBAL PANDEMICS: GAIN-OF-FUNCTION RESEARCH OF CONCERN (Nov. 21, 2022), https://crsreports.congress.gov/product/pdf/IF/IF12021.

[14] *Id.*

regulated.[15] The FSAP requires laboratories that handle select agents, defined as agents with the "potential to pose a severe threat to public health and safety," of humans and/or animals to register and submit to inspections.[16] Researchers or employees with access to select agents are also required to undergo special training and background checks.

The Consolidated Appropriations Act, 2023, included several provisions related to the issues presented. The bill codified the National Science Advisory Board for Biosecurity (NSABB), tasking NSABB with issuing U.S. government-wide guidance and recommendations related to biosafety and biosecurity oversight of biomedical research.[17] It also reauthorized certain aspects of the FSAP, as well as added provisions to ensure proper training of personnel and additional reporting requirements to Congress in the event of a release, loss, or theft of select agents at federal laboratories.

In addition, the Act required OSTP to establish a strategy for the maintenance and coordination of federally owned or funded BSL-3 and BSL-4 laboratories. It also required OSTP to conduct a full review of existing policies regarding the review and oversight of federally funded research related to potential pandemic pathogens and regularly update such policies to ensure consistent application across federal agencies. The Act prohibited HHS funding of research involving select agents or pathogens of pandemic potential conducted by foreign entities at facilities located in countries of concern until the OSTP policy review is complete and with appropriate notice to Congress.

IV. ISSUES

The following issues may be examined at the hearing:

- How are existing U.S. regulations and guidance working to protect against laboratory accidents or deliberate releases? Have these regulations kept pace with scientific developments?
- Why does the U.S. not have a single entity responsible for oversight of research involving potential pandemic pathogens?
- How does the current U.S. system compare to biosafety regulatory systems in other countries?
- Are there common factors or patterns in how laboratory accidents happen that can guide policy makers in crafting an effective regulatory regime?

V. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin or John Strom at (202) 225-3641.

[15] CDC & USDA, 2021 ANNUAL REPORT OF THE FEDERAL SELECT AGENT PROGRAM (2021), https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2021_508.pdf.
[16] *Id.*
[17] *Id.*