

Testimony for the Record
Submitted to the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
“Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety”

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Chairman Griffith, Vice Chair Lesko, Ranking Member Castor and members of the Subcommittee, thank you for inviting me to participate in today’s hearing and thank you for devoting your time and effort to topic that is important to our nation’s public health and capability to respond to current and future infectious disease threats. A focus of my professional career has been to understand how viruses infect and cause disease in humans, not only during pandemics but during annual seasonal outbreaks. The public health implications of research in this area are great, as our ability to find methods to reduce infectious disease burden are critical to maintain the health of the US population.

Personal Background

My name is Andrew Pekosz and I am a virologist who has been doing basic research into respiratory viruses including influenza virus, SARS-CoV, SARS-CoV-2, bunyaviruses and hantaviruses for over 30 years. That research has been done at either BSL1, BSL2 or BSL3 levels of containment,

depending on the agent I was working on and the type of experiment. I co-direct the Johns Hopkins Center of Excellence in Influenza Research and Response (JH CEIRR) and direct the Center for Emerging Viruses and Infectious Diseases (CEVID) in addition to being a part of several multi-investigator initiatives, all of which are focused on understanding how respiratory viruses infect humans and are able to continue to spread and cause disease even with the availability of vaccines and antivirals. In addition to my research interests, I have served on numerous review or advisory boards at the institution, state and national level that have been focused on establishing guidelines and biosafety recommendations that would allow critical research to move forward under the most appropriate biosafety conditions.

I would like to state for the record that the opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

Summary Statement

Investigations into the origins of the COVID-19 pandemic have brought increased scrutiny of laboratory biosafety practices and the likelihood that research efforts aimed at microbes that pose a public health concern may inadvertently lead to an epidemic or pandemic. It is important to understand that research on microbes is currently regulated in diverse and complementary ways that continue to be updated and improved upon as technology and methodologies change. Periodic review of biosafety policies, guidelines and definitions of research of concern is welcome and needed to ensure the highest level of safety is being followed while also maintaining the robust and critical response capabilities to a new infectious disease. Clear language defining research of concern, coupled with transparent and open descriptions of review criteria and processes are needed and welcomed by most scientists. For the United States to maintain its position as a world leader in research in infectious diseases, vaccines and antivirals, specific and detailed guidance that will not hinder the vast majority of critical research efforts is needed and I am honored to contribute to that discussion through my testimony at this subcommittee meeting.

Critical issues regarding Biosafety and “Gain of Function” research

Gain of Function is a term that has little utility because it is too broad, ill defined and has historically been applied to research with virtually any microbe. For the rest of this document, I will use the term “research of concern” to focus on experiments that are focused on pathogens that pose a clear, potential public health threat and that are aimed at modifying key features of that pathogen, such as its ability to cause disease, spread in a population, evade antimicrobial drugs or population immunity. My definition runs close to that currently used by the U.S. Government Potential Pandemic Pathogen Care and Oversight (PC3O) and Dual Use Research of Concern (DURC) Policies. It is important to note that research of concern is governed by a number of regulatory groups dependent upon the type of research being proposed.

Basic laboratory research requires institutional approval and training at the BSL1, BSL2, BSL3 and BSL4 levels. Research involving animal models requires additional training and approvals from animal welfare committees. Research involving human subjects involves additional training and approvals from Institutional Research Boards. The trainings need to be documented and refreshed on a regular basis. In addition, all microbes and work with toxic or harmful chemicals requires additional approvals from institutional safety committees that involve clear descriptions of the methods used and safety considerations given. All of these levels of biosafety assessments, trainings and reviews are present to ensure that important research can go forward with the most appropriate and relevant degree of safety.

NSABB guidelines are broad and subject to a wide range of interpretation.

A recent meeting of the National Science Advisory Board for Biosecurity (NSABB) put forth a list of recommendations for improving the oversight and transparency of research of concern. While the intent of the committee was to provide constructive recommendations that would update and

clarify guidelines for research of concern, the language used in the proposal was broad and vague which has led to more confusion rather than clarity with respect to an understanding of what research falls under the proposed increased review and approval processes. Precise, clear definitions of the agents and types of research that fall under the research of concern umbrella are provided in the current P3CO and DURC guidelines. The NSABB recommendations need to be reviewed with an eye to providing more detail and guidance about the specific subsets of research that should be targeted for additional oversight and regulation.

Close loopholes and increase transparency

Regularly assessment of how effective regulatory policies are and whether there are clear needs to update them are necessary. Most scientists would agree that the current process of reviewing research of concern can be more transparent and open. Identifying precisely when research proposals are being reviewed and by what entities is clearly something that can be improved going forward. The fact that the funding source dictates whether a research proposal should undergo increased scrutiny for research of concern makes little sense and is not a policy that most institutions utilize when it comes to biosafety regulations. The biosafety guidelines I utilize are the same, irrespective of the funds used to support the research. These and other points have been discussed by virologists openly and represent areas where we can quickly and significantly improve biosafety.

Closing statement

The US is the global leader in infectious diseases research, vaccine development, and antimicrobial agent development. There is an opportunity for the US to cement that position and serve as the model for how research into pathogens that threaten the human population now or potentially in the future, can be done. That research will better prepare us to deal with the inevitable next pandemic. This subcommittee has the opportunity to be an important part of national and global

plan that will strengthen, or public health preparedness and I am grateful that you have taken the time to consider my thoughts on this topic.