

Responses to Additional Questions for the Record

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The Honorable Morgan Griffith

1. Are there any established protocols in biosafety level labs to safely destroy pandemic potential viruses or bacteria in the event of an emergency or natural disaster?

a. If there are no current protocols in place, what are some potential protocols or regulations that can be put into place to ensure a safe destruction of any pandemic potential viruses or bacteria in the case of an emergency or natural disaster?

ANSWER

The Biosafety in Microbiological and Biomedical Laboratories (BMBL) is the foundation for biosafety practices in the United States.¹ The BMBL provides guidance, not regulations, for how laboratories should be designed and operated safely. The BMBL does recommend that all labs have a safety manual that includes an emergency response plan for how to deal with a wide range of emergencies, including both natural and human-made events, and regular emergency response drills for lab employees. Labs that work with live animals are supposed to have a plan for the disposition of animals in the event of an emergency. However, the BMBL does not prescribe the contents of emergency response plans, such as procedures for safely destroying potential pandemic pathogens or how to safely dispose of live animals or carcasses. Such details are left up to the discretion of each laboratory.

For labs that possess Select Agents, there are more detailed requirements for what the lab's incident response plan should include and how often the lab should conduct drills and exercises.² In addition, the CDC and USDA, which are jointly responsible for implementing the

¹ Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition, June 2020, https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

² Federal Select Agent Program, "Incident Response Plan: Regulatory Requirements," August 27, 2021, <https://www.selectagents.gov/compliance/guidance/incident-response/regulatory.htm>; Federal Select Agent Program, "Drills and Exercises Guidance," January 29, 2021, <https://www.selectagents.gov/compliance/guidance/drills/index.htm>

Federal Select Agent Program, have provided guidance to registered labs for how to comply with this portion of the Select Agent Regulations.³ However, neither the Select Agent Regulations nor the accompanying guidance specifies that labs must include procedures for the safe destruction of Select Agents in the event of an emergency in their incident response plan. While specific labs may have such procedures in place, they are not required.

It would be advisable for both the BMBML and the Federal Select Agent Program to update their incident response plan requirements and guidance to include protocols for the safe disposal of pathogens, animals, and carcasses in the event of an emergency that could compromise the lab's safety or security. The Federal Select Agent Program should also review existing incident response plans to assess whether such protocols are included and if any best practices could be shared with the rest of the high containment laboratory community.

2. Your Global Biolabs Report identified 57 biosafety level 3 plus or biosafety level 3 enhanced labs in 28 countries. As you noted, these labs do gain-of-function experiments involving high-path avian influenza and other serious pathogens. I am worried that the BSL-3+ level isn't an adequate substitute and that there is a temptation for researchers to try to do things in BSL-3+ that they should really be doing in BSL-4.

a. Do you believe standards are needed to ensure proper safety in biosafety level 3+ labs?

ANSWER

It is important to note that while BSL-3 enhanced labs have been used to conduct so-called "gain of function" experiments that generate engineered pathogens with enhanced virulence and/or transmissibility, not all such labs conduct such experiments. In addition, this type of research has also been carried out at lower levels of biosafety since there are no international, and frequently no national, standard for the biocontainment level that research with potential pandemic pathogens should be conducted under. In contrast, Canada has decided that research with mammal-transmissible H5N1 influenza should be conducted only in a BSL-4 lab.⁴

The proliferation of labs claiming to be BSL-3 enhanced raises several concerns. First, there is no internationally agreed definition of what BSL-3 enhanced means, allowing different countries to adopt different standards. Second, most countries do not have national regulations or standards for BSL-3 enhanced, allowing different labs within the same country to have differing interpretations about what types of pathogens or experiments should be conducted at BSL-3 enhanced. Third, there has been little to no research performed to demonstrate that these enhancements provide an adequate level of additional safety commensurate with the higher risk

³ Centers for Disease Control and Prevention and U.S. Department of Agriculture, *Incident Response Plan Guidance*, August 2021, https://www.selectagents.gov/compliance/guidance/incident-response/docs/Incident_Response_Plan.pdf

⁴ Public Health Agency of Canada, "Biosafety Advisory: Efficiently Transmissible Engineered Influenza A H5N1 Viruses," February 1, 2012, <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/biosafety-directives-advisories-notifications/biosafety-advisory-efficiently-transmissible-engineered-influenza-a-h5n1-viruses.html>

research conducted in these labs. This is especially important since these labs are being used to conduct research with engineered pathogens that was not envisioned when this biosafety level was first developed by the U.S. Department of Agriculture in the late 1990s. While there have been a number of reviews of laboratory biosafety in the United States, none of them have specifically examined the scientific and empirical basis for the BSL-3 enhanced category or the extent to which these safety enhancements provide adequate safeguards for the research performed in these labs.⁵ I strongly urge that such a review be conducted by the Federal government with the full participation of the high containment laboratory research and biosafety communities.

The Honorable Frank Pallone, Jr.

1. How could a 22% cut to the National Institutes of Health's budget affect your field, as well as the broader landscape of scientific research and innovation?

ANSWER

The National Institutes of Health is the single largest funder of biomedical research in the world. This research is vital to advancing our understanding of human health, the myriad threats to public health, and how to reduce these threats through vaccines, therapeutics, antidotes, diagnostics, non-pharmaceutical interventions, and public policy. The value of this research was demonstrated during the pandemic when the United States was able to successfully develop multiple COVID vaccines based on mRNA technology in less than a year. A 22% cut to the NIH budget would be devastating to the biomedical research enterprise with long-lasting and far-reaching negative effects. Speaking narrowly on the topic of biosafety and biosecurity, a funding cut of this magnitude would likely lead to the closure of some high containment labs. Other labs would find their ability to invest in biosafety and biosecurity reduced. Finally, it would not be possible to fund new initiatives, such as applied biosafety research, in such an austere fiscal environment.

The Honorable Jan Schakowsky

1. You recently wrote in the New York Times that many of your ideas for improving biosafety were consistent with the Biden Administration's national biodefense strategy.

⁵ *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*, July 2009, <https://www.phe.gov/s3/law/boards-committees/biosafety-taskforce/Documents/transfedbiocontainmentrpt092009.pdf>; *Report of the Federal Experts Security Advisory Panel*, December 2014, <https://www.phe.gov/s3/Documents/fesap.pdf>; National Science and Technology Council, *Fast Track Action Committee Report: Biosafety and Biosecurity*, January 2017, <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/NSTC/ftac-bio-report.pdf>; and National Science and Technology Council, *Evidence-Based Laboratory Biorisk Management Science and Technology Roadmap*, April 2022, https://www.whitehouse.gov/wp-content/uploads/2022/04/04-2022-NSTC-ST-Biorisk-Research-Roadmap_FINAL.pdf

What are some of the ideas in the Administration's strategy that you see as most important to implement?

ANSWER

The Biden Administration's National Biodefense Strategy explicitly identified laboratory accidents, alongside biological weapons and bioterrorism, as the major biorisks facing the United States.⁶ One of the main goals of the strategy is to "strengthen biosafety and biosecurity practices and oversight to prevent bioincidents and reduce biological risks associated with life sciences research and development and advances in biotechnology."⁷ To achieve this goal, the strategy emphasizes three objectives that comprise ten specific action items. The first objective is to ensure that biological laboratories in the United States or funded by the U.S. government are "implementing and maintaining effective, transparent, rigorous, and comprehensive oversight, training, and monitoring programs for biosafety, biosecurity, and responsible and ethical conduct in science."⁸ A recent analysis of high-level biosafety and biosecurity reviews conducted during the Obama Administration found that more than half of their recommendations had still not been fully implemented.⁹ The Government Accountability Office (GAO) has identified the lack of a single regulatory agency responsible for biosafety and biosecurity as a key gap in national oversight of high containment laboratories.¹⁰ The most effective way to strengthen oversight of life sciences research would be to create an independent agency responsible for biosafety and biosecurity in U.S. labs.¹¹ Such an agency, modeled on the National Transportation Safety Board (NTSB), National Highway Traffic Safety Administration (NHTSA), Nuclear Regulatory Commission (NRC), or Federal Aviation Administration (FAA), would be able to promulgate national regulations and standards, provide guidance and training to stakeholders, and fund applied research to advance the science of biosafety and biosecurity.

The strategy's second objective is to strengthen the responsible conduct of research in the life sciences by developing and promoting biosafety and biosecurity norms and oversight at the national and international levels.¹² To achieve this objective, the Biden Administration should adopt the National Science Advisory Board for Biosecurity (NSABB)'s March 2023 recommendations for reforming oversight of dual-use research.¹³ The Biden Administration

⁶ Joseph R. Biden, *National Biodefense Strategy and Implementation Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (Washington, DC: The White House, October 2022), 6. [hereafter Biden, *National Biodefense Strategy*]

⁷ Biden, *National Biodefense Strategy*, 11.

⁸ Biden, *National Biodefense Strategy*, viii.

⁹ Haines CA, Gronvall GK. "Improving U.S. Biosafety and Biosecurity: Revisiting Recommendations from the Federal Experts Security Advisory Panel and the Fast Track Action Committee on Select Agent Regulations," *Applied Biosafety* Vol. 28, No. 1 (2023):43-54.

¹⁰ Government Accountability Office (GAO), *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574, September 2009, <https://www.gao.gov/assets/gao-09-574.pdf>

¹¹ Ritterson R, Kingston L, Fleming AEJ, Lauer E, Dettmann RA, Casagrande R. "A Call for a National Agency for Biorisk Management," *Health Security* Vol. 22, No. 2 (2022): 1-5.

¹² Biden, *National Biodefense Strategy*, ix.

¹³ National Science Advisory Board for Biosecurity, *Proposed Biosecurity Oversight Framework for the Future of Science*, March 2023, <https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf>

should also work with Congress to extend this oversight to life sciences research conducted in the private sector.¹⁴ In addition, the Biden Administration could enhance biosecurity by requiring recipients of U.S. government grants for life sciences research to purchase synthetic DNA only from suppliers who screen orders for biosecurity purposes, such as members of the International Gene Synthesis Consortium (IGSC).¹⁵ Researchers at public universities in California, the largest recipient of life sciences funding from NIH, are already required to do so under a recent California state law.¹⁶ Adopting a similar policy at the Federal level would level the biosecurity playing field and create a strong incentive for more companies to join IGSC or implement equivalent biosecurity screening protocols in order to maintain their access to the U.S. market.

The third objective is to accelerate biosafety and biosecurity innovation “by supporting efforts to identify and address the research gaps needed to improve evidence-based laboratory biological risk management, both in the United States and globally, and share with international partners.”¹⁷ In a sign of the importance of this issue to the Biden Administration, the strategy charges the National Security Council (NSC) and Office of Science and Technology Policy (OSTP) with overseeing the development of a joint capability plan for biosafety and biosecurity innovation.¹⁸ In addition, in accordance with a September 2002 executive order on the bioeconomy, the Department of Health and Human Services (HHS) has established a Biosafety and Biosecurity Innovation Initiative to invest in applied biosafety research and innovations in biosecurity.¹⁹ The HHS plan for implementing this initiative is overdue.

The Biden Administration could take several steps immediately to incentivize innovation in biosafety and biosecurity. First, the terms and conditions for grants from NIH and other funders of life sciences research could be modified to create line items for biosafety and biosecurity expenses that could be charged to grants. This would end the practice of research institutions having to pay for biosafety and biosecurity out of overhead which creates a perverse incentive for these institutions to minimize these expenses. Second, NIH, or ideally a new independent biorisk management agency, could create a grant program dedicated to applied research in biosafety and biosecurity to encourage this type of research, increase empirical knowledge, and contribute to the development of new science-based biosafety and biosecurity policies. There have been concerted efforts to identify knowledge gaps that need to be filled to improve the theory and practice of biosafety and biosecurity.²⁰ These efforts, however, have not been

¹⁴ Gerald L. Epstein, “Private-sector Research Could Pose a Pandemic Risk. Here’s What to Do About It,” *Bulletin of the Atomic Scientists*, February 16, 2023, <https://thebulletin.org/2023/02/private-sector-research-could-pose-a-pandemic-risk-heres-what-to-do-about-it/>

¹⁵ Gregory D. Koblenz, “The De Novo Synthesis of Horsepox Virus: Implications for Biosecurity and Recommendations for Preventing the Reemergence of Smallpox,” *Health Security*, Vol. 15, No. 5 (August 2017): 1-9.

¹⁶ UC Riverside, “Guidance on Purchasing Gene Synthesis Equipment or Products in Compliance with AB 1963,” April 26, 2023, <https://training.ucr.edu/gene>

¹⁷ Biden, *National Biodefense Strategy*, ix.

¹⁸ Biden, *National Biodefense Strategy* ix.

¹⁹ Department of Health and Human Services, “Fact Sheet: HHS Takes Action on Executive Order Launching a National Biotechnology and Biomanufacturing Initiative,” September 14, 2022, <https://www.hhs.gov/about/news/2022/09/14/fact-sheet-hhs-takes-action-executive-order-launching-national-biotechnology-biomanufacturing-initiative.html>

²⁰ National Science and Technology Council, “Evidence-Based Laboratory Biorisk Management Science and Technology Roadmap”; and Stuart D. Blacksell, et al., “The Biosafety Research Road Map: The Search for

accompanied by funding to conduct the research necessary to fill these knowledge gaps and enable the development of science-based biosafety and biosecurity policies and practices.²¹

Finally, a cross-cutting theme across all of these objectives is the need to strengthen biosafety, biosecurity, and dual-use research oversight in other nations. There are several international initiatives already underway in this space that make important contributions to this objective. However, to achieve greater results, they need increased funding, greater authority, and enhanced coordination. The United States should take a leadership role in redesigning the architecture of global biorisk management. The centerpiece of this architecture should be an international mechanism to audit laboratory compliance with international standards for biosafety and biosecurity.²² This international audit mechanism would increase the confidence of local communities and neighboring countries that high consequence biological research laboratories are operating safely, securely, and responsibly.

Evidence to Support Practices in Human and Veterinary Laboratories,” *Applied Biosafety*, Vol 28, No. 2 (2023): 64-71.

²¹ Rocco Casagrande, “Federal Funding for Biosafety Research Is Critically Needed,” CSIS Brief, August 2019, https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/190802_Casagrande_Biosafety_WEB.pdf; and Ryan Ritterson and Rocco Casagrande, “Basic Scholarship in Biosafety Is Critically Needed To Reduce Risk of Laboratory Accidents,” *mSphere* Vol. 2, No. 2 (March/April 2017): e00010-17.

²² Filippa Lentzos and Gregory D. Koblenz, *Global BioLabs Report 2023* (London, United Kingdom and Arlington, VA: King’s College London and George Mason University, 2023), <https://www.kcl.ac.uk/warstudies/assets/global-biolabs-report-2023.pdf>; and Gregory D. Koblenz and Filippa Lentzos, “A Plan B to Strengthen Biosafety and Biosecurity,” *Think Global Health*, November 15, 2022, <https://www.thinkglobalhealth.org/article/plan-b-strengthen-biosafety-and-biosecurity>