Beyond Gain of Function: Evaluating HHS Oversight of Research with Potential Pandemic Pathogens

Prepared Statement for the *Virtual Meeting and Listening Session on USG Oversight Framework for Research Involving Enhanced Potential Pandemic Pathogens (ePPPs)*
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Thank you for the opportunity to provide feedback on the formulation and implementation of the Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (the HHS P3CO Framework).[1]

In my remarks, I will discuss some positive aspects of the HHS P3CO Framework, offer my analysis of the gaps and weaknesses in this framework, describe shortcomings in the implementation of this Framework by the National Institute of Health (NIH), and finally provide recommendations for strengthening oversight of this class of research.[2]

Positive Aspects of the HHS P3CO Framework

The first positive aspect of the Framework is that it does not use the term "gain of function." The introduction of this term into the discussions on dual-use research in 2011-2012 triggered a long and unproductive debate about how to define this category of research. Carving out "gain of function" as somehow distinct or separate from dual-use research muddied the debate and continues to cause confusion today.

Second, the HHS P3CO Framework does a good job describing the principles and processes through which the department-wide committee at HHS will make funding decisions regarding research that involves enhanced potential pandemic pathogens (ePPPs). The requirement that the

[1] Department of Health and Human Services, *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, 2017, https://www.phe.gov/s3/dualuse/documents/p3co.pdf

[2] This statement in based, in part on, Lynn C. Klotz and Gregory D. Koblentz, "New Pathogen Research Rules: Gain of Function, Loss of Clarity," *Bulletin of the Atomic Scientists*, February 26, 2018, https://thebulletin.org/2018/02/new-pathogen-research-rules-gain-of-function-loss-of-clarity/

department-level review be conducted by a multidisciplinary group of experts is important as is the option to include voting and non-voting members from within HHS as well as other federal agencies. In addition, the inclusion of seven categories of dual-use experiments that the department-led review must also consider usefully expands, beyond increases in virulence and transmissibility, the range of potential risks that will be subject to review by HHS. This list of seven experiments are the same as those included in the 2012 and 2014 US government policies for dual-use research of concern—but those policies are only applied to research with 15 Tier 1 pathogens and toxins.

A third positive aspect of this policy is that it takes a risk-based approach that is not based on a list of specific pathogens, but instead focuses on the attributes of the modified organism. While the identity of starting organisms is central to existing US government oversight of dual-use research of concern, the HHS P3CO Framework emphasizes the importance of an organisms' properties once the experiment is over. This more comprehensive approach to dual-use research is a welcome change and should be more broadly reflected in how the United States conducts oversight of dual-use research.

Weaknesses in HHS P3CO Framework

However, the HHS P3CO Framework as currently formulated has a number of weaknesses and gaps. I will highlight four here: it applies only to HHS, it excludes privately funded research, it provides an inadequate description of the process and criteria used by the funding agency to determine if a research proposal is covered by the P3CO Framework, and it includes insufficient mechanisms for transparency.

Oversight of Potential Pandemic Pathogens Applies only to HHS

The first gap in the HHS P3CO Framework is that this policy only applies to research funded by HHS. This narrow scope contrasts with government-wide dual-use research oversight policy that the United States adopted in 2012. Key provisions in the HHS P3CO policy are already almost identical to those in the 2017 Office of Science and Technology Policy (OSTP) P3CO guidance.[3] There does not appear to be a compelling reason that every federal agency should need its own set of rules to oversee research involving potential pandemic pathogens. There are several agencies other than HHS, such as the USDA, the Department of Defense, Department of Homeland Security, and the Department of Energy, that conduct or sponsor virology research that could involve potential pandemic pathogens. Indeed, we know of one case where research with ePPPs was proposed to Defense Advanced Research Projects Agency

[3] Office of Science Technology and Policy, *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO),* January 9, 2017, https://www.phe.gov/s3/dualuse/documents/p3co-finalguidancestatement.pdf

(DARPA) but was rejected, due in part to concerns about dual-use issues.[4] Therefore, there is a need for oversight of research with potential pandemic pathogens to be standardized across the Federal government.

Privately Funded Research on Potential Pandemic Pathogens is Excluded

A second gap in the HHS P3CO Framework is that it excludes research on ePPPs that is privately funded. Given the increasing role of the private sector and philanthropies in funding life sciences research, this is a large and growing loophole.[5] The synthesis of horsepox virus by Canadian scientists, with funding from a US biotech company, illustrates how privately funded research can stray into the realm of dual-use research.[6] In addition, since the accidental or deliberate release of an enhanced potential pandemic pathogen could cause a major outbreak, if not a pandemic, there seems to be a compelling public health and safety rationale for regulating such research, regardless of the source of funding. Indeed, the National Science Advisory Board on Biosecurity (NSABB) recommended that oversight of research with potential pandemic pathogens be applied to all researchers, regardless of their source of funding.[7] The 2017 guidance issued by the Office of Science and Technology Policy called for a process to consider the adoption of this NSABB recommendation.[8] The time to re-examine this issue is now.

Inadequate Description of Process and Criteria for Use by Funding Agency to Review Research Proposals

The Framework's description of the process and criteria to be used by an HHS funding agency to determine if a research proposal should be forwarded to the department-level review is woefully inadequate. Under Section II (D) of the HHS P3CO Framework, the funding agency is responsible for determining if proposed intramural and extramural research is "reasonably anticipated to create, transfer, or use" an enhanced potential pandemic pathogen which is defined in Section II (A) and (B) as a pathogen that has been modified to become "likely highly

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[4] Sharon Lerner and Maia Hibbett, "Leaked Grant Proposal Details High-Risk Coronavirus Research," *The Intercept*, September 23, 2021, https://theintercept.com/2021/09/23/coronavirus-research-grant-darpa/

[5] Gregory D. Koblentz, "The Evolving Global Biosecurity Landscape," Prepared Statement Before the Bipartisan Commission on Biodefense, *The Biological Threat Expanse: Current and Future Challenges to National Biodefense*, Washington, DC, March 22, 2022, https://www.dropbox.com/s/8yfagmlwppbnzkd/Koblentz-Evolving%20Global%20Biosecurity%20Landscape.pdf?dl=0

[6] Gregory D. Koblentz, "A Critical Analysis of the Scientific and Commercial Rationales for the Synthesis of Horsepox Virus," *mSphere*, Vol. 3, No. 2 (March/April 2018), pp. 1-10, https://doi.org/10.1128/mSphere.00040-18

[7] National Science Advisory Board on Biosecurity, *Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research*, May 2016, https://osp.od.nih.gov/wp-content/uploads/2016/06/NSABB_Final_Report_Recommendations_Evaluation_Oversight_Proposed_Gain_of_Function_Research.pdf

[8] Office of Science Technology and Policy, *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO),* January 9, 2017, https://www.phe.gov/s3/dualuse/documents/p3co-finalguidancestatement.pdf

transmissible and likely capable of wide and uncontrollable spread in human populations" and "likely highly virulent and likely to cause significant morbidity and/or mortality in humans."[9]

As noted above, the process and criteria to be used by the department-level review group is well described in the HHS P3CO Framework. In contrast, the Framework does not provide any guidance to the funding agency about how to measure how "likely" a pathogen is to be highly transmissible, highly virulent, or highly pathogenic in human populations, or, for that matter, how to characterize the level of transmissibility, virulence, or pathogenicity. The word "likely" is too strong, as it implies a high probability or a high level of confidence in the estimated probability. "Possibly" would be a better qualifier as it implies some probability, but does not set the bar too high. This is particularly important since, absent a large outbreak, laboratory accident, or experimental infection of humans (which raises serious ethical and legal questions), it will not necessarily be possible to determine ahead of time how transmissible, virulent, or pathogenic a novel virus will be in humans. It is unclear from the Framework if it applies equally to *in vivo* and *in vitro* research. Finally, there is no guidance for judging when the standard of "reasonably anticipated" is met. This lack of detail and ambiguous terminology provides HHS funding agencies with excessive latitude in determining which research proposals fall under the scope of the P3CO Framework—in contrast to the well-delineated process and criteria that are used by department-level group to review the proposals that are referred to them.

Insufficient Transparency

The HHS P3CO Framework does not satisfy the guidance from OSTP which called on agencies "to the maximum extent possible" to "provide transparency to the public regarding funded projects involving the creation, transfer, or use of enhanced [potential pandemic pathogens]."[10] Instead, the HHS P3CO Framework provides only for occasional transparency about the process itself, not the results of that process. According to the HHS P3CO Framework, HHS "will periodically ask the National Science Advisory Board for Biosecurity to review the process described herein."[11] This approach to transparency is not timely nor tied to specific reviews of proposed or funded projects. In addition, there are no guarantees that the NSABB's review will be made available to the public. Furthermore, since the NSABB is advisory only, it has no authority to require HHS to revise its P3CO Framework, modify its process for implementing the Framework, or revisit or reverse a funding decision. Although the HHS P3CO

[9] Department of Health and Human Services, *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, 2017, https://www.phe.gov/s3/dualuse/documents/p3co.pdf

[10] Office of Science Technology and Policy, *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO),* January 9, 2017, https://www.phe.gov/s3/dualuse/documents/p3co-finalguidancestatement.pdf

[11] Department of Health and Human Services, *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, 2017, https://www.phe.gov/s3/dualuse/documents/p3co.pdf

Framework recognizes the importance of transparency for maintaining public trust in science, it does not go far enough in providing the requisite level of transparency to achieve that objective.

Shortcomings in Implementation

Implementation of the HHS P3CO Framework by NIH has suffered from three shortcomings: the lack of guidance on how NIH will implement the Framework, inadequate review of research proposals by NIH as exemplified by its handling of the grant to the EcoHealth Alliance, and a lack of transparency on how NIH has implemented the Framework.

Lack of Guidance on Implementation

HHS funding agencies, namely NIH, have failed to develop clear guidance on how it will implement the HHS P3CO Framework. On its website dedicated to "Research Involving Enhanced Potential Pandemic Pathogens," NIH does not include any information on its process for reviewing proposals under the Framework and determining which are "reasonably anticipated" to involve ePPP and therefore need to be referred to the HHS P3CO Review Group.[12]

The only public description of NIH's process for implementing the HHS P3CO Framework is provided in a July 2021 letter from NIH Director Francis Collins to Senator Charles Grassley:

"At NIH, following the completion of peer review by an SRG [Scientific Review Group composed of outside scientists who perform the first part of NIH's two-part scientific peer review process], if an SRG identifies research that may create, transfer, or use ePPPs as described above, the Scientific Review Officer records this as an administrative note. NIH Institute or Center program officials with scientific expertise in infectious diseases then review all proposed research found to be scientifically meritorious that is being considered for funding to determine if the research meets the scope of the HHS P3CO Framework. In the case of NIAID, if NIAID program officials determine that the proposed research may meet the scope of the HHS P3CO Framework, the proposed research is further evaluated by a group within NIAID, including members of NIAID leadership, with broader infectious diseases expertise. When evaluating proposed research to determine if it meets the scope of the HHS P3CO Framework, details of the experiment(s) and pathogen(s) are considered in the context of the state of the science in that field. All proposed research determined by this group to fall within the scope of the HHS P3CO Framework is referred by NIAID to HHS."[13]

[12] https://www.nih.gov/news-events/research-involving-potential-pandemic-pathogens.
[13] Letter from NIH Director Francis Collins to Senator Charles Grassley, July 28, 2021, https://www.grassley.senate.gov/imo/media/doc/national_institutes_of_health_to_grassley_-_covid_origins_grant_oversight.pdf

This brief description leaves several questions unanswered. What guidance, if any, is provided to the non-Federal scientists who comprise the Scientific Review Groups to enable them to determine if research proposals they are evaluating could be "reasonably anticipated to create, transfer, or use" an ePPP? What guidance, if any, is provided to NIH program officials and leadership about how to evaluate whether proposed research could be "reasonably anticipated to create, transfer, or use" an ePPP? How does the National Institute for Allergies and Infectious Diseases (NIAID) determine which program officials and members of the institute's leadership are appropriate reviewers of such proposals? Why are only officials with expertise in infectious diseases used in the review process and not a multidisciplinary approach that includes individuals with expertise in biosafety and biosecurity? If an NIAID official with infectious disease expertise determines that the proposed research may involve an enhanced potential pandemic pathogen, why does NIAID require a second internal review instead of referring that proposal directly to the HHS P3CO Review Group? How is the composition of this second-level review within NIAID determined and what criteria, standards, and process are used by this group to "reasonably anticipate" if a research proposal would result in the creation, transfer, or use of an ePPP? What does it mean that high-level internal review at NIAID considers the research proposal in "the context of the state of the science in that field"? Such a criteria is not part of the HHS P3CO Framework. What official or office is responsible for overseeing implementation of the HHS P3CO within NIH and each institute and generating and maintaining relevant documentation?

The lack of guidance provided by NIH on how it implements the HHS P3CO Framework is in contrast with the detailed advice it has provided to government agencies and research institutions that conduct oversight of dual-use research of concern. Following the issuance of new policies on dual-use research oversight in 2012[14] and 2014[15], NIH published guidance, including tools and case studies, to assist with implementation of these policies.[16] While intended primarily for institutions that receive Federal funding to conduct dual-use research of concern, the guidance notes that Federal agencies that conduct such research could also benefit from using this guidance to implement their responsibilities for oversight of dual-use research. The NIH should take its own advice and provide clear guidance to the non-government scientists and NIH officials involved in the scientific peer review about the criteria for evaluating whether research proposals fall under the HHS P3CO Framework and delineate the process by which NIH entities evaluate such proposals and make the necessary determinations as required under the HHS P3CO Framework.

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[14] *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*, March 29, 2012, http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf

[15] *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, September 24, 2014, https://www.phe.gov/s3/dualuse/documents/durc-policy.pdf

[16] NIH, *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern*, September 2014, https://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf; and NIH, *Implementation of the USG Policy for Institutional Oversight of Life Sciences DURC: Illustrative Case Studies*, September 2014, https://www.phe.gov/s3/dualuse/Documents/12-case-studies-durc.pdf

Mishandling of the EcoHealth Alliance Proposal and Grant

Second, NIAID's handling of the EcoHealth Alliance research proposal and grant raises questions about the organization's overall implementation of the P3CO Framework. Under a grant awarded by NIAID in 2014, EcoHealth Alliance undertook a 5-year research project (renewed in 2019) that included inserting receptor-binding domains of newly identified bat coronaviruses into two viruses, a bat coronavirus (WIV-1) and MERS-CoV. These chimeric coronaviruses were then to be used for *in vitro* and *in vivo* experiments at the Wuhan Institute of Virology (WIV) to determine the risk of wild bat-related coronaviruses spilling over into human populations.[17] This grant was appropriately flagged by NIAID program officers as potentially involving research covered by the 2014 "gain of function" funding pause.[18] NIAID reviewed this grant under both the 2014 "gain of function" funding pause and under the 2017 HHS P3CO and determined the research was "not expected to generate viruses that would be more transmissible or more virulent in humans."[19] One basis for this determination was that "laboratory-generated viruses are often weaker than the viruses used to create them."[20] Nonetheless, NIAID included a requirement in the grant to EcoHealth Alliance "that if any of the chimeric viruses generated under the grant showed evidence of enhanced virus growth greater than ten times that of the original virus from which they were created, the grantee must immediately stop all experiments with these viruses and provide NIAID and the WIV Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes."[21] According to NIH Acting Director Lawrence Tabak, this grant condition was inserted "out of an abundance of caution."[22] If this condition was met, it would prompt a new review under the HHS P3CO Framework and potentially lead to the revision of research aims or the enactment of new biosafety measures.[23]

The modification of the terms and conditions of the grant to require EcoHealth Alliance to monitor the characteristics of the chimeric viruses, halt its research if viral growth exceeded a specified threshold, report such an occurrence to NIAID, and subject the research to further review under the HHS P3CO Framework indicates that NIAID officials were concerned that a chimeric virus created by this research might demonstrate enhanced virulence or transmissibility.

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[17] Letter from NIH Director Francis Collins to Senator Charles Grassley, July 28, 2021, https://www.grassley.senate.gov/imo/media/doc/national_institutes_of_health_to_grassley_-_covid_origins_grant_oversight.pdf; NIAID, "Notice of Award: Understanding the Risk of Bat Coronavirus Emergence," Grant Award No. 1RO1AI110964-01, My 27, 2014, https://www.documentcloud.org/documents/21055989-understanding-risk-bat-coronavirus-emergence-grant-notice; and EcoHealth Alliance, "Understanding the Risk of Bat Coronavirus Emergence: Annual Report Covering June 1 2018 through May 31, 2019," August 3, 2021, https://www.documentcloud.org/documents/21089573-priority-grants-for-foia-request-55058-first-look-institute-2_redacted

[18] Sharon Lerner and Mara Hvistendahl, "NIH Officials Worked with EcoHealth Alliance to Evade Restrictions on Coronavirus Experiments," *The Intercept*, November 3, 2021, https://theintercept.com/2021/11/03/coronavirus-research-ecohealth-nih-emails/

[19] Letter from Collins to Grassley.

[20] Letter from Collins to Grassley.

[21] Letter from Collins to Grassley.

[22] Letter from NIH Acting Director Lawrence Tabak to Representative James Comer, October 20, 2021, https://int.nyt.com/data/documenttools/nih-eco-health-alliance-letter/512f5ee70ce9c67c/full.pdf

[23] Letter from Collins to Grassley; and Letter from Tabak to Comer.

NIAID's insistence that these conditions be inserted into the EcoHealth Alliance grant is a tacit admission that they recognized that such research could be "reasonably anticipated" to produce a pathogen with enhanced virulence or transmissibility. Therefore, the proper course of action that NIAID should have taken was to refer this proposal to the department-level HHS P3CO Review Group to assess the risks and benefits of the research and recommend to NIAID how it should proceed with the grant. Under the HHS P3CO Framework, it is the responsibility of this department-level review group, not NIAID, to "develop recommendations on acceptability for HHS funding, including suggestions for additional risk mitigation measures and/or terms and conditions of award, if funded."[24]

Despite inserting terms and conditions into the EcoHealth Alliance grant regarding experiments involving chimeric coronaviruses, NIAID failed to properly monitor the conduct and outcomes of this research. One of the experiments conducted by EcoHealth Alliance resulted in laboratory mice infected with one of the chimeric coronaviruses becoming sicker than those infected with the parent strain.[25] According to NIH Acting Director Tabak, "As sometimes occurs in science, this was an unexpected result of the research, as opposed to something that the researchers set out to do."[26] The reasonable anticipation of unexpected results resulting from scientific research is a key reason that greater oversight is required for experiments with potential pandemic pathogens. Even if the intent of a researcher is not to enhance the virulence or transmissibility of the pathogen, one can "reasonably anticipate" that modifying elements of the genotype associated with virulence or transmissibility could lead to an enhancement of those aspects of the phenotype.

Furthermore, EcoHealth Alliance did not halt its research as required since it reported in its fifth annual progress report that "we continued with *in vivo* infection experiments of diverse bat SARSr-CoVs on transgenic mice expressing human ACE2."[27] According to EcoHealth Alliance documents, the experiment with a chimeric coronavirus resulted in a viral load in mice 10,000 times (or 4-log) higher than that caused by the parent strain.[28] EcoHealth Alliance claims that this exceedance of the 1-log threshold did not trigger a research halt because the way that its researchers measured viral growth, using genome copies per gram, was not considered an accurate measure of viral titer which is usually measured using the concentration of infectious viruses by plague assay.[29] This explanation raises two important questions. First, if the grant required EcoHealth Alliance to monitor viral growth during *in vivo* experiments with chimeric coronaviruses, why did researchers fail to utilize the proper techniques to provide such

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[24] Department of Health and Human Services, *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, 2017, https://www.phe.gov/s3/dualuse/documents/p3co.pdf

[25] Letter from NIH Acting Director Lawrence Tabak to Representative James Comer, October 20, 2021, https://int.nyt.com/data/documenttools/nih-eco-health-alliance-letter/512f5ee70ce9c67c/full.pdf

[26] Letter from NIH Acting Director Lawrence Tabak to Representative James Comer, October 20, 2021, https://int.nyt.com/data/documenttools/nih-eco-health-alliance-letter/512f5ee70ce9c67c/full.pdf

[27] EcoHealth Alliance, "Understanding the Risk of Bat Coronavirus Emergence: Annual Report Covering June 1 2018 through May 31, 2019," August 3, 2021, 15.

[28] Sharon Lerner and Mara Hvistendahl, "NIH Officials Worked with EcoHealth Alliance to Evade Restrictions on Coronavirus Experiments," *The Intercept*, November 3, 2021

[29] Letter from Peter Daszak to Michael Laurer, October 21, 2021, https://www.documentcloud.org/documents/21097880-ecohealth-letter-contesting-claims

measurements? Second, why were NIAID program officials not aware of EcoHealth Alliance's failure to design their research protocol to ensure reliable measurement of viral growth as required by the grant?

Whether EcoHealth Alliance reported these results in a timely manner, as required by the grant, is a matter of dispute. According to NIH, "EcoHealth failed to report this finding right away, as was required by the terms of the grant."[30] According to EcoHealth Alliance, they did report the results of the experiment in their fourth annual progress report to NIAID and they did not receive any feedback from NIAID on the *in vivo* experiments with chimeric coronaviruses.[31] Overall, this episode illustrates a breakdown in NIAID's implementation of its oversight responsibilities.

Lack of Transparency

Finally, NIH has not provided a clear and complete account of how it has implemented the 2014 "gain of function" funding pause and the HHS P3CO Framework. The *Washington Post* identified 18 projects funded by NIH between 2012 to 2020 that appeared to include experiments that would enhance the virulence and/or the transmissibility of a pathogen, including eight that were approved for funding after 2017.[32] NIH, however, only forwarded three research proposals for review by the HHS P3CO Review Group since adoption of the HHS P3CO Framework.[33] In light of the shortcomings identified above in the review of the EcoHealth Alliance proposal and monitoring of their grant, it would be advisable for the HHS P3CO Review Group to review other research proposals which were flagged during the scientific peer review process as potentially involving research with enhanced potential pandemic pathogens but were determined by NIH not to fall under the scope of the HHS P3CO Framework.

The way in which the public has learned about NIH's implementation of its oversight responsibilities under the 2014 funding pause and the P3CO Framework does not inspire confidence in the NIH's commitment to transparency. The most useful information has been provided by NIH primarily in response to Congressional inquiries, FOIA requests, and lawsuits. Without a better understanding of the process and criteria used by NIH to judge whether proposed research can be "reasonably anticipated" to create a potential pandemic pathogen with enhanced virulence or transmissibility, and how it has applied these principles in practice, it will be difficult to both restore public confidence in this oversight and effectively strengthen such oversight in the future.

Recommendation

The HHS P3CO Framework should be replaced by a comprehensive, national approach to biorisk management that includes field and laboratory biosafety, laboratory biosecurity, and oversight of dual-use research, including research with enhanced potential pandemic pathogens.

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[30] Letter from NIH Acting Director Lawrence Tabak to Representative James Comer, October 20, 2021, https://int.nyt.com/data/documenttools/nih-eco-health-alliance-letter/512f5ee70ce9c67c/full.pdf

[31] Letter from Peter Daszak to Michael Laurer, October 21, 2021, https://www.documentcloud.org/documents/21097880-ecohealth-letter-contesting-claims

[32] David Willman and Madison Muller, "A Science in the Shadows," *Washington Post*, August 26, 2021, https://www.washingtonpost.com/nation/interactive/2021/a-science-in-the-shadows/

[33] https://www.nih.gov/news-events/research-involving-potential-pandemic-pathogens

The creation of a National Agency for Biorisk Management would be an important step in achieving that objective.[34] OSTP should conduct an independent review of biorisk management in the United States that solicits input from across the U.S. government and stakeholders outside of the government to create a national system for ensuring that life sciences research is conducted safely, securely, and responsibly, regardless of the source of funding. The Biden Administration recently requested $1.8 billion to enhance biosafety and biosecurity as part of its pandemic prevention and preparedness initiative.[35] Without new policies and new institutions, these investments will not leave us as safe and secure as we need to be in an era of growing global biorisks.[36]

[34] Ryan Ritterson, Linette Kingston, Adam E. J. Fleming, Erin Lauer, Robert A. Dettmann, and Rocco Casagrande, "A Call for a National Agency for Biorisk Management," *Health Security*, Vol. 20, No. 2 (2022), https://doi.org/10.1089/hs.2021.0163

[35] White House, "The Biden Administration's Historic Investment in Pandemic Preparedness and Biodefense in the FY 2023 President's Budget," March 28, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/28/fact-sheet-the-biden-administrations-historic-investment-in-pandemic-preparedness-and-biodefense-in-the-fy-2023-presidents-budget/; and White House, *American Pandemic Preparedness: Transforming Our Capabilities*, September 2021, https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf

[36] Koblentz, "The Evolving Global Biosecurity Landscape"; and Filippa Lentzos, Gregory D. Koblentz, and Joseph Rodgers, "The Urgent Need for an Overhaul of Global Biorisk Management," *CTC Sentinel*, Vol. 15, No. 4 (April 2022), pp. 23-29. https://ctc.westpoint.edu/the-urgent-need-for-an-overhaul-of-global-biorisk-management/