U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses

phe.gov/s3/dualuse/Documents/gain-of-function.pdf downloaded 30 Dec 2021

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phe.gov - Mission Areas

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- **Barda** — About BARDA. The Biomedical Advanced Research and Development...

https://www.phe.gov › emergency › news › healthactions › phe › Pages › default.aspx

Public Health Emergency Declarations - phe.gov

The Secretary of the Department of Health and Human Services (HHS) may, under section 319 of the Public Health Service (PHS) Act determine that: a) a disease or disorder presents a public health emergency; or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

https://www.phe.gov › emergency › events › COVID19 › investigation-MCM › Sotrovimab ...

Important Update - phe.gov

State/Territory-Coordinated Distribution of Sotrovimab December 17, 2021. In late November, the federal government paused shipment of the monoclonal antibody therapeutic sotrovimab in order to help ensure a more balanced portfolio of monoclonal antibody products and to allow more time to assess data regarding the effectiveness of sotrovimab against the Omicron variant.

Office of the Assistant Secretary for Preparedness and Response

ASPR — ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

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The Office of the Assistant Secretary for Preparedness and Response within the United States Department of Health and Human Services that focuses on preparedness planning and response; building federal emergency medical operational capabilities; countermeasures research, advance development, and procurement; and grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters. **Wikipedia**

Formed: December, 2006

Headquarters: Hubert H. Humphrey Building, Washington, D.C.

executive: Dawn O'Connell, Assistant Secretary for Preparedness and Response

Share Feedback

October 17, 2014

This is bullshit. This type of research is not necessary in order to "define the fundamental nature of human-pathogen interactions" which are already sufficiently described in pathology books.

Furthermore, this statement is completely illogical: changing a virus does not help understand that virus, but only allows understanding of the changed version, which is obviously different from the natural version.

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Gain-of-function studies, or research that improves the ability of a pathogen to cause disease, help define the fundamental nature of human-pathogen interactions, thereby enabling assessment of the pandemic potential of emerging infectious agents, informing public health and preparedness efforts, and furthering medical countermeasure development. Gain-of-function studies may entail biosafety and biosecurity risks; therefore, the risks and benefits of gain-of-function research must be evaluated, both in the context of recent U.S. biosafety incidents and to keep pace with new technological developments, in order to determine which types of studies should go forward and under what conditions.

This is rhetoric to make "doing whatever we want" appear reasonable and well considered.

In light of recent concerns regarding biosafety and biosecurity, effective immediately, the U.S. Government (USG) will pause new USG funding for gain-of-function research on influenza, MERS or SARS viruses, as defined below. This research funding pause will be effective until a robust and broad deliberative process is completed that results in the adoption of a new USG gain-of-function research policy[1]. Restrictions on new funding will apply as follows:

This announcement that they are going to pause GOF-SARS funding is essentially the same as admitting that they were previously funding GOF-SARS research.

New USG funding will not be released for gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

In parallel, we will encourage the currently-funded USG and non-USG funded research community to join in adopting a voluntary pause on research that meets the stated definition.

The deliberative process that will ensue during the period of the research pause will explicitly evaluate the risks and potential benefits of gain-of-function research with potential pandemic pathogens. The presumptive benefits that are generally identified in pursuing this type of research are stated in terms of enhanced ability for earlier awareness of naturally emerging dangerous pandemic pathogens or in the development of medical products in anticipation of such emergence.

Again, this is stupid: making fake viruses is not necessary for the understanding of natural viruses. Further, notice how this "research" is already married to the drug industry for "development of medical products."

However the relative merits of gain-of-function experimental approaches must be compared ultimately to potentially safer approaches. The deliberative process will offer recommendations for risk mitigation, potential courses of action in light of this assessment, and propose methodologies for the objective and rigorous assessment of risks and potential benefits that might be applied to the approval and conduct of individual experiments or classes of experiments. Although the gain-of-function studies that fall within the scope of research subject to the funding pause will be a starting point for deliberations, the suitability of other types of gain-of-function studies will be discussed. It is feasible that the discussion could lead to suggestions of broadening the funding pause to include research with additional pathogens,

[1] An exception from the research pause may be obtained if the head of the USG funding agency determines that the research is urgently necessary to protect the public health or national security.

however, federal Departments and Agencies who fund, support, or perform research should be consulted prior to any additional pathogens being added to the scope of the funding pause.

The deliberative process is envisioned to be time-limited, to involve two distinct, but collaborating, entities, and to be structured to enable robust engagement with the life sciences community. As a first step, the National Science Advisory Board for Biosecurity (NSABB) will be asked to conduct the deliberative process described above and to draft a set of resulting recommendations for gain-of-function research that will be reviewed by the broader life sciences community. The NSABB will serve as the official federal advisory body for providing advice on oversight of this area of dual use research, in keeping with federal rules and regulations.

"life sciences community" = Drug companies

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As a second step, coincident with NSABB recommendations, the National Research Council (NRC) of the National Academies then will be asked to convene a scientific conference focused on the issues associated with gain-of-function research and will include the review and discussion of the NSABB draft recommendations. This NRC conference will provide a mechanism both to engage the life sciences community as well as solicit feedback on optimal approaches to ensure effective federal oversight of gain-of-function research. The life sciences community will be encouraged to provide input through both the NRC and NSABB deliberative processes.

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The NSABB, informed by NRC feedback, will deliver recommendations to the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the heads of all federal entities that conduct, support, or have an interest in life sciences research (including the Assistants to the President for Homeland Security and Counterterrorism and for Science and Technology). The final NSABB recommendations and the outcomes of the NRC conference will inform the development and adoption of a new U.S. Government policy governing the funding and conduct of gain-of-function research. Upon adoption of a federal gain-of-function policy, the U.S. Government will declare the end of the research funding pause.

Government will inform drug companies so that the drug companies will start making products/drugs/vaccines in anticipation

The life sciences community will be informed of progress at regular intervals. The estimated time-line is six months for completion of the two deliberative steps (culminating in delivery of the NSABB recommendations to the HHS Secretary) and three months for the development, approval, and publication of the policy, with the goal of completing the entire process in less than one year from declaration of the research funding pause.