Response to the NSABB Document "Preliminary Draft Findings & Recommendations"

September 20, 2022

Dear NSABB members,

We are writing in response to the NSABB document *Preliminary Draft Findings & Recommendations* posted on the National Institutes of Health (NIH) website. In early July 2022, we and 29 other signatories (the 'Signatory Group') submitted a document titled *Recommendations to Strengthen the US Government's Enhanced Potential Pandemic Pathogen Framework and Dual Use Research of Concern Policies* to the NSABB, NIH, and White House.

The purpose of this letter is to commend several recommendations made in the draft NSABB document and to express serious concern about remaining gaps and shortcomings the Signatory Group believes should be specifically addressed in the final NSABB findings and recommendations.

We commend the NSABB for its recommendations to the US government (USG) to:

- ***Modify the definitions of potential pandemic pathogens (PPP) and enhanced potential pandemic pathogen (ePPP)*** to include transmissible pathogens that have low or moderate virulence or low case fatality rate (CFR) as well as less transmissible pathogens that have higher CFR (thus expanding the definition of what is included in the ePPP Framework).
- ***End the exclusion for surveillance and vaccine-related work.***
- ***Articulate specific roles, responsibilities, and expectations for all institutions*** involved in the proposed research, including requiring local entities conduct ePPP reviews before submitting for USG review and requiring the same level of oversight throughout the course of the research (not only at the start).
- ***Develop more specific information in articulating biosafety and biosecurity standards.***
- ***Develop principles and guidelines*** applicable to substantiating the claims that:
    1. There are no feasible, scientifically sound alternative methods of obtaining the benefits sought in the research in a manner that poses less risk;
    2. Unnecessary risks have been eliminated and an overall assessment of remaining risks finds that they are justified by the potential benefits to society.
- ***Share a summary of key determinants and decisions*** resulting from USG review.
- ***Consider developing similar frameworks for pathogens*** that could pose severe threats to human health or food security via impact on animals and/or plants.

Despite these important recommendations in the NSABB's *Preliminary Draft Findings & Recommendations*, we are seriously concerned the document does not yet address a number of the most important recommendations from our July document, particularly 1b, 1c, 2c, and 3g. These recommendations can be summarized as:

- ***Broaden the ePPP Framework*** to incorporate the oversight of research that could enhance the virulence or transmissibility of any pathogen to produce an ePPP
- ***Within the ePPP Framework, establish oversight of sequence information*** about ePPPs, the risks related to computational methods for designing PPPs, and biosafety measures related to the synthesis of ePPPs, which would address the information hazards that are created as part of this work

- ***Distinguish between practical benefits and unsupported claims*** of benefit
- ***Improve transparency throughout the approval process*** by using a model such as Registered Reports to allow for the public to see risk-benefit assessments and any dissenting views prior to the research commencing.

In addition to the above, other critical shortcomings in current USG Policy that are not yet addressed in the NSABB's *Preliminary Draft Findings & Recommendations* are listed in our submitted recommendations as 2a, 2d, 3a-f, 4a-c, and 5. These can be summarized as:

- ***Articulate the risks that must be considered*** in the ePPP Framework process
- ***Define the process for the "responsible communication of results"***
- ***Expand the stakeholders*** involved in the review and approval processes, and recuse those whose agency is funding or participating in the ePPP research
- ***Implement robust institutional health surveillance***
- ***Establish guidance regarding how to assess agents*** created during ePPP research
- ***Broaden the ePPP Framework to apply to non-federally funded research***
- ***Require all USG agencies to implement*** the ePPP Framework
- ***Strengthen USG outreach to other governments*** to catalyze ePPP Framework and Dual Use Policy development
- ***Expand the types of experiments*** included in USG Dual Use Policy.

The recommendations noted above are highly important elements of a strong and clear governance framework for ePPP research and dual use research of concern (DURC) experiments. Incorporating these recommendations into the final NSABB document will help ***diminish the risk*** that US science could inadvertently initiate epidemics or pandemics while ***minimizing disruption*** of scientific work that does not pose this risk; ***clarify the scope and decision-making*** process; and ***increase transparency*** around US policy and decision-making on these issues.

We remain very hopeful that as the NSABB considers the current draft and this additional feedback, these concerns (more fully articulated in the July 2022 recommendations document endorsed by 34 signatories) will be addressed in the final NSABB recommendations to the USG. We are greatly appreciative of the NSABB's careful consideration of these issues and value the importance of the constructive impact they will have on US policy.

Sincerely,

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