Answers to Additional Questions for the Record

Questions from House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Responses from Dr. Rocco Casagrande, PhD, Executive Chair, Gryphon Scientific

Question from: The Honorable Frank Pallone, Jr.
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?

Cuts right now to any agency that funds research in the life sciences, especially cuts to the preeminent life sciences funder in the US—the NIH, would be particularly harmful to the economy of the US, its independence and the health of its people.

Regarding the economy: the life sciences are already the basis of a critical sector of the US economy, called the "bioeconomy", which spans commercialization of discoveries in agriculture, materials, fuels, industrial processes and medicine. The bioeconomy is today an important sector of the US economy and is perhaps one of the most dynamic engines of economic growth in the US. Direct revenues from the bioeconomy contributed more than $500 billion to the US economy with an annual growth rate of more than 20%.[1] The continued growth of the bioeconomy is dependent on innovation deriving from research in the life sciences, of which the NIH is a critical funder. Cutting funding for any critical life sciences grant-maker right now would imperil the growth of one of the most dynamic sectors of the US economy. Moreover, the bioeconomy of China is close behind that of the US, and China continues to invest heavily in research in the life sciences, suggesting that withdrawing support of research now would greatly strengthen China's relative position. Scientific leadership can lead to long-lasting economic dominance because of the reliance of the bioeconomy on patents, and the protection they offer against derivative technologies. For this reasons, cuts in life-science funding now can lead to Chinese dominance of the sector for the decades to come.

The US failing to invest in its bioeconomy would allow China to become the world leader in biomedicines, which would imperil the independence of the US. If Chinese companies become the only providers of next-generation treatments (cures for cancer, personalized medicine, preventatives for infectious diseases), China could use that dominance to exert pressure on US policies. For example, given the close ties between the Communist Party of China and the private sector, China could threaten exports of critical and uniquely effective biomedicines as part of a broader strategy to influence US decision-making.

Failure to invest in the life sciences would undermine the explosive growth in the development of next-generation treatments and cures for diseases that are just beginning to make dramatic

[1] Bioeconomy Capital, 2023, accessed at http://www.bioeconomycapital.com/bioeconomy-dashboard

improvements in the quality of life for Americans. Biotech treatments, based on engineered immune cells, are curing cancer in more and more Americans every year. Cures for many genetic disorders are just now showing promise in the clinic. The unprecedentedly rapid deployment of the SARS-CoV-2 vaccine was the result of a decade-long investment in biomedicine. Undermining investments in biomedicine at the NIH threatens to stop the engine of innovation and halt further discoveries that could improve the health and well-being of millions of Americans in the next decade and better prepare the US to mitigate the next pandemic.

The Honorable Jan Schakowsky
Last year's Consolidated Appropriations Act included a provision directing HHS to support research into the safe conduct of biomedical research. How will investments in biosafety research – like those that Congress made last year – help bring us closer to understanding what can effectively reduce risks?

Research in biosafety can effectively reduce risks arising from laboratory accidents in several ways.

Firstly, research is needed to determine how accidents occur, the factors that lead to accidents and the measures that most effectively mitigate the accidents. Unlike every other human endeavor with significant risks (such as aviation and nuclear power), the life sciences do not have a robust history of safety research, so these data are currently completely lacking. This research can identify experiments that should be altered to reduce risks, training requirements to boost safe work practices and equipment that should be emplaced to prevent releases. For example, in recent work our group published, we determined that snap-cap tubes in the lab create splashes more often than previously thought, suggesting that they should be substituted for screw-cap tubes when scientists are manipulating the most hazardous materials (a change that would cost a few dollars per experiment).

Secondly, biosafety research is needed to make smart investments in biosafety. Currently, because data is lacking, biosafety has traditionally added more and more measures, equipment and training to reduce risk, because the efficacy of any particular mitigation is unknown. Undoubtedly, some of these measures do not meaningfully reduce risk and are wasting funding and the time of researchers. By gathering data on what measures truly mitigate accident risks, laboratories can spend only on the measures, equipment and training that are valuable, and eliminate those that are merely theater. In this way, funding in biosafety could have a significant Return on Investment by making the entire pathogen research community more efficient.

Lastly, safety research data will help boost compliance with safety guidelines. Scientists are focused on data and want to know "why" various measures (some of which are onerous) must be followed to improve safety. Historically, compliance has been difficult to achieve when the scientists themselves are skeptical about the value of the safety measure. Biosafety research can generate the data to objectively demonstrate that costly safety measures are truly necessary. For example, a longstanding biosafety principle suggests that workers decontaminate their workspace every time they have completed their work but many scientists think that they know when they spill a tiny

amount of hazardous substance while working and are therefore resistant to decontaminating their workspace unless they know they had a spill. Our research has demonstrated that even experienced scientists are unaware of about half the spills they make, proving the value of this longstanding recommendation to the researchers themselves.

The Honorable Kathy Castor
The Republicans' proposed Default on America Act may require a 22% cut to the National Institutes of Health's budget as well as significant cuts to the HHS Office of the Inspector General. Can you explain why funding NIH and its oversight mechanisms are important and how cuts of that magnitude could undermine our biosafety goals in the United States and across the world?

In the response to Rep. Pallone above, I described how cuts to the NIH in general would be disastrous, and particularly right now.

Regarding biosafety oversight, because biosafety standards are general, robust oversight from funding agencies is necessary to ensure that grantees are performing research safely and responsibly. Part of a granting agency's job is to ensure that the proposed research can be conducted safely in the laboratory designated and that the work itself doesn't highlight scientific advancements that can be misused by those seeking to do harm with engineered viruses or bacteria. The grant-making agency can suggest changes to the experimental design or the substitution of less hazardous strains to reduce risks. Ideally, the granting agency is a partner to the research institution who can collaboratively craft a research protocol that is safe yet scientifically innovative.