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Thank you. I am honored that you invited me to speak about such a timely and important topic as laboratory safety.

Overview:

Today, I am going to advocate for several improvements that are critically needed to ensure that the laboratories that study the most deadly and transmissible viruses remain safe. This research is essential to prevent and respond to pandemics of the future, however it is not without risks. The practice of mitigating such risks is called biosafety. Historically, biosafety has been perceived as consuming time and money that would otherwise be spent on critical research, but I am also going to argue that needed improvements in biosafety will not stifle research or draw away resources, but will help improve the efficiency of the research enterprise if implemented properly.

The critical improvements that I will talk about today can be grouped into six categories:

1. Oversight
2. Research
3. Standards
4. Workforce
5. Resources
6. Mission

Specifics:

Regarding oversight, biosafety authority in the US derives from a patchwork of regulations, laws and guidance given the pathogen researched or the source of funding. Currently, some pathogen research is conducted in the US without any federal oversight. Theoretically, a privately funded group could work on influenza virus in a makeshift laboratory and attempt to make a strain more deadly or more transmissible. If they are not using a select agent strain of flu and they are doing the research for peaceful purposes, there is no federal entity that could ensure that they are doing their work safely and securely, or prevent them from continuing if safety or security is lacking. The US needs a unified biosafety system that can provide oversight for research on all dangerous pathogens (Risk Group 2+) regardless of the funding source or affiliation of the researchers.

Unlike other high-risk endeavors like aviation and nuclear power, biosafety does not have a robust research history because there has been nearly no funding for research in biosafety over the past several decades. We currently lack data on how accidents occur or the factors that can effectively mitigate accidents. Historically, biosafety improvements have always added on to existing equipment, procedures or administration because there were no data suggesting which specific improvements were particularly effective vs others available. Investments in biosafety research can determine exactly what measures effectively reduce risk, and which are simply theater, enabling the efficient use of research dollars across the United States. Using new evidence to eliminate wasteful measures would also make laboratories more sustainable, as money need not be spent maintaining equipment with little value. Biosafety research can also directly inform laboratory practices on the choice of equipment and procedures that are inherently safer, improving safety in the near term. Data generated by biosafety research can also boost compliance with safer but inconvenient practices, because scientists are naturally skeptical and data-focused. [For more information on the need for biosafety research see Ritterson and Casagrande, "Basic Scholarship in Biosafety is Critically Needed to Reduce Risk of Laboratory Accidents",

submitted along with this written testimony because the manuscript is openly available due to the courtesy of the American Society for Microbiology.]

Although there are general standards regarding safe practices for research, more standards are needed to cement and communicate best practices and ensure that the laboratories doing the least don't have an advantage over those taking more measures to be safe. For example, standards are needed to define how many biosafety professionals are needed to support research facilities of various sizes and complexities and what type of training is needed to work in containment. Developing these standards, and templates for training, would save all research facilities from developing their own.

The biosafety workforce is rapidly aging and experiencing burnout due to adopting extra duties to keep campuses and workplaces safe during the COVID pandemic. Fellowships, curricula and training is needed to recruit scientists into the safety workforce and ready them for a career.

Biosafety has been historically under-resourced for various reasons. In most institutions, biosafety staff are paid out of overhead costs, instead of directly from research dollars, meaning that the safety workforce draws resources out of the institution instead of paying for itself. As a colleague of mine has aptly said, biosafety has a "soft money, soft jobs" problem. Allowing the maintenance of safe labs as a direct cost on grants would help ensure biosafety is adequately supported. Moreover, in order to be properly implemented, any additional requirement put on the biosafety workforce (such as those recommended recently by the NSABB) should be accompanied by an increase in funding to ensure that existing biosafety professionals don't have to do more with the same resources, which itself could hamper safety.

Regarding mission, currently, there is no federal agency that is in charge of biosafety, funding biosafety research, promulgating specific biosafety standards, fostering the biosafety workforce or providing oversight to all pathogen laboratories regardless of their funding source or specific pathogen

investigated. To fix this issue, either an existing or a new federal agency must be given the comprehensive mission of improving biosafety. [For more information on the need for a single federal entity with unified biosafety authority see Ritterson, et al “A Call for a National Agency for Biorisk Management”, submitted along with this written testimony with permission from the publisher.]

[For more information on other concepts to improve biosafety see Dettmann et al, “Concepts to Bolster Biorisk Management ”, submitted along with this written testimony with permission from the publisher.]

Some have argued that additional oversight of biosafety of the type I described would stifle research. This position is belied by the fact that countries that have already implemented similar systems have equally robust pathogen research communities and bioeconomies. Specifically, Canada, Switzerland, Germany and the UK all have comprehensive oversight of pathogen laboratories. Switzerland’s cell-based biotechnology industry rivals that of the entire US. Both Switzerland and Canada have more laboratories that can study the world’s most dangerous pathogens per capita than the US. These suggestions would simply enable the US to catch up to its peers.

The resources needed to sponsor research, develop standards, foster the workforce is small compared to the resources spent on pathogen research itself. An annual budget of \$60M would provide sufficient funding to support this work (this sum is approximately 1% of NIAID’s 6BN annual budget). Moreover, this funding would have a large return on investment as it would lead to the identification of the biosafety measures that are truly valuable (allowing others to fall by the wayside), save every research institution from developing its own standards and training and alleviate difficulties of finding properly trained biosafety staff.

To close the oversight gaps I mentioned and adequately fund biosafety professionals to take on greater responsibilities would require more funding though the funding is clearly justified by the risks. The pandemic, which plausibly could have been caused by a laboratory accident, cost more American lives

than all wars in my lifetime and harmed the economy more than any other single event. Investments on the scale of a single major weapons program would transform biosafety in the US and more cost effectively mitigate a major risk facing the US. The right answer isn't to draw funds away from pathogen research, which is essential for creating treatments and cures to address the next pandemic, but to consider investments on the scale used to address other threats to the US.