

Testimony on
SB 441 “Enacting the biological laboratory accident transparency act”
Senate Committee on Public Health and Welfare
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Written Only

Chairman Hilderbrand and Member of the Senate Committee on Public Health and Welfare: Protecting American agriculture and food from global biothreats while safeguarding the public from zoonotic animal diseases, foodborne pathogens, and other infectious diseases are recognized as vital to U.S. homeland security. Kansas State University (K-State) is internationally recognized for its long-standing expertise in zoonotic, emerging and reemerging infectious diseases, and livestock medicine, and has been an important contributor to responding to and mitigating these pervasive threats through our research to characterize, prevent, detect, and respond to biological threats of natural, accidental, or deliberate origin.

At the same time, K-State recognizes that maintenance of the public trust is essential for conducting high-containment biological research. K-State has a strong record of compliance with federal and state reporting obligations and enjoys an open and transparent relationship with not only the local community and first responders, but also state and federal regulators.

We provide some comments for consideration below.

- 1. Increasing the Regulatory Burden:** As currently written, SB 441 would apply to institutions and organizations that have substantial control of or run a high-risk biological laboratory. Per Section 2(a)(1), the bill defines a “high risk laboratory” as a commercial or research facility that engages in research involving human pathogens or grows or manipulates any pathogens listed in the National Institute of Allergy and Infectious Disease (NIAID) pathogen priority list. As SB 441 does not specify NIAID list Category A, B and/or C, as written, all categories of pathogens would be included, including everything from pathogens requiring BSL-4 containment, such as Ebola and Marburg viruses, to pathogens only requiring BSL-2 containment, such as *salmonella spp*, rabies virus, and many influenza viruses. Laboratories working with foodborne or waterborne pathogens, as well as diagnostic and teaching laboratories, are not usually considered to be “high risk laboratories,” but due to the overarching definition of what is considered high risk, these laboratories could also fall under the definition provided in this bill, resulting in potentially hundreds of BSL-2 laboratories falling under the reporting requirements.

These overarching and confusing reporting requirements will significantly increase the regulatory burden for researchers, laboratories, and research institutions and, without careful and comprehensive review, would likely impede research productivity and innovation without providing any meaningful oversight. In 2012, the Federal

Demonstration Partnership survey found that investigators of federally funded research spent, on average, 42 percent of their time meeting requirements, including administrative and compliance requirements, rather than on actively conducting research.¹ Furthermore, the National Science Foundation Task Force on Administrative Burden has stated: “The Board shares the concern that some administrative tasks may unnecessarily by consuming valuable time that our nation’s scientists, engineers, and educators could otherwise devote to the federally sponsored research that underpins our national security, prosperity, health, and welfare,”² further underscoring the potential regulatory and administrative burden of SB 441.

2. **Unclear and Inconsistent Definitions.** Per Section 2(a)(1), a high-risk laboratory could be defined as a BSL-1 or BSL-2 laboratory, a diagnostic laboratory, or others if they are working with any pathogens on the NIAID pathogen list. In contradiction, Section 3(a)(2)(c) states that institutions and organizations may (*emphasis added*) publicly report any laboratory accident or near-miss accident that occurs at BSL-1 or BSL-2 or an animal biosafety level 1 or 2 laboratory. The inconsistent and confusing definitions of which laboratories or research organizations would be subject to the requirements of the bill result in lack of clarity and lead to significant confusion.
3. **Lack of Oversight, Reporting Clarity, or Enforcement.** The reporting requirements are confusing and lack a clearly defined reporting and enforcement structure. Section 3(a)(1) requires institutions and organizations to publicly report any laboratory accident or near-miss accident that occurs in any high-risk biological laboratory in a summary format, report a list of accidents or near-miss events in the immediately preceding 10 years prior to July 1, 2022, be updated with events not later than one week after they occur, and linked on their website, but SB 441 does not identify to whom this report should be made, how often, or whether the reporting is anonymous. SB 441 lacks any clear guidance on which laboratories would be required to report this information, whom they would report to, when they would report this information, and which agency would enforce these requirements, if any, nor does it provide any funding or support for this duplicative regulatory burden.
4. **Duplication of Efforts.** There have been multiple, complementary, and sometimes overlapping efforts, to report accidents and near-miss accidents and incidents at high-containment laboratories. K-State is currently required to report a variety of different items to federal regulators, including the Federal Select Agent Program (FSAP) and the NIH Office of Biotechnology Affairs, state regulators, including the Kansas Department of Agriculture and the Kansas Department of Health and Environment, and our own internal oversight bodies, including the Institutional Biosafety Committee and the Institutional Animal Care and Use Committee. In addition, interested public parties could obtain data on theft, loss, or release from public FSAP reports; FSAP has clear guidance and regulatory authority to collect this data. Furthermore, Section 3(a)(4), explicitly states “reporting

¹ Federal Demonstration Partnership (FDP), “2012 Faculty Workload Survey: Executive Summary,” April 2014. Available at: https://thefdp.org/default/assets/File/Documents/fws_2012_exec_summary.pdf

² https://www.nsf.gov/nsb/committees/archive/task_force/tskforce_ab.jsp

made under this section shall not replace or exclude any other reporting required for public health or any other legal purpose.”

While oversight of biological research is essential for ensuring compliance, safety, and security when working with NIAID pathogens and other infectious agents, the unintended consequences of additional, unnecessary reporting places significant burden on institutions and individual researchers. As K-State already reports many of the incidents referenced in SB 441 to state and federal regulators, we support initiatives to reduce, streamline, and harmonize regulations, rather than duplicating existing efforts.

5. **Increasing Risk of Noncompliance and Nonconformance.** K-State recognizes the significant value of reporting accidents or near-misses. Reporting a near-miss can ensure that future incidents, accidents, and injuries are avoided and, in many cases, reporting and investigating near-misses can highlight otherwise overlooked hazards and gaps in a biosafety program that could lead to potentially significant problems in the future. Fostering a culture of voluntarily reporting benefits everyone in an organization. However, reporting near-miss accidents publicly could result in the reporting being regarded as punitive in nature, potentially encouraging individuals and researchers to not report the accident internally. In addition, without providing significant context to the near-miss accident, public misperceptions of risks could result in misunderstanding and fear related to the incidents. K-State has and indeed encourages a transparent and open communicative relationship with researchers working with infectious diseases, and this system works because they can trust that they will not be publicly shamed for a minor or incidental accident.
6. **Decreasing the Public Trust.** Publishing specific information related to laboratory accidents, without appropriate context and explanation of the risks and consequences, or lack thereof, will only serve to create a sense of danger that does not exist. In addition, the value of publishing information related to potential near-miss accidents, especially those from non-high containment laboratories, is limited at best without the addition of significant contextual information. As previously mentioned, the FSAP already issues an annual report that includes key observations related to inspection findings and compliance with the select agent regulations, as well as reported thefts, losses, and releases of select agents or toxins at regulated laboratories.

We would like to sincerely thank you for the opportunity to submit this testimony.



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