

TO: The Honorable Brian Feldman, Chair
Senate Education, Energy, and the Environment Committee

FROM: Michael Huber, Director, State Affairs,
Johns Hopkins University & Medicine

DATE: March 2, 2023

RE: SB 495 – Research Facilities and Testing Facilities That Use Animals - Licensing and Regulation

Johns Hopkins University and Medicine urges an **unfavorable** report on **SB 495 – Research Facilities and Testing Facilities That Use Animals – Licensing and Regulation**.

This bill would require facilities that use animals in research, education, or testing to be licensed by the State Department of Agriculture. The bill requires an inspection and payment of a licensing fee before the State may issue such a license. It creates a State Inspector of Animal Welfare to inspect all licensed facilities each year, a responsibility that can be delegated to animal welfare organizations. It requires researchers to justify the use of animals to the State Inspector, addressing whether another suitable model is available, whether the research can be performed ethically on human subjects, and whether animals are necessary to accelerate responses to life-threatening or debilitating conditions. There are also significant criminal penalties associated with violations of the bill.

As the leading research institution in the State, Johns Hopkins University & Medicine takes seriously its mission to improve the health of the community and the world by setting the standard of excellence in medical education, research, and clinical care. The use of animals is essential to the success of our mission. Unfortunately, this bill will hobble that mission and negatively impact critical lifesaving research – including vaccine development and cancer treatments – happening at research institutions throughout the State in several ways. It is duplicative with existing federal law. It ignores critical, and effective internal policies. Accordingly, Johns Hopkins has several concerns with the legislation, which we have described below.

The legislation will harm our ability to perform research that is critical to our mission and that yields benefits for society.

Progress in developing alternatives to animal testing has been impressive and, but at present, biomedical research could not continue to provide breakthroughs in our understanding of human disease and development of treatments without the use of animals.

Almost every medical advancement – from COVID-19 vaccines, insulin therapy for diabetes, treatments for cardiovascular diseases, cancer therapy to organ transplants – are the direct result of research

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performed on animals. Simply put, modern medicine, as we understand it today, would not exist without research performed in animals.

This bill makes a distinction between “testing facilities” and “research facilities,” however the intended distinctions are not clear. The bill’s definition of “testing” overlaps significantly with elements inherent in biomedical research such as testing new vaccines and drug candidates for effectiveness. Because these categories are not well defined, and do not clearly align with the mission of a variety of institutions in the State of Maryland performing research that involves animals, it is very difficult to know how this bill would impact biomedical research should the bill pass.

For example, The State of Maryland played a key role in the development of COVID-19 vaccines. Starting 3 years ago, as COVID initially spread world-wide, institutions, including Johns Hopkins and the University of Maryland, and private companies, rapidly ramped up research to develop new ways to treat and prevent COVID-19. The vaccines and therapeutics developed by biomedical researchers during this time were tested on animals before human trials as an integral part of development. Many different kinds of institutions and facilities contributed to this effort, leading to widely available COVID-19 vaccines in an unexpectedly short time. These efforts were central to containing the COVID pandemic.

SB495 is duplicative with existing federal law and internal procedures, and thus unnecessary.

Research facilities are subject to extensive oversight by multiple federal agencies, including the National Institutes of Health and the U.S. Department of Agriculture (USDA), and we are committed to complying with all federal laws that govern the use of animals in research. There are many. Our facilities are subject to unannounced inspections by the USDA. Our programs are designed to assure compliance with the federal Animal Welfare Act and the “Public Health Service Policy on Humane Care and Use of Laboratory Animals.” Policies and protocols are in place, and strictly adhered to, that address animal housing and care, veterinary medical care, facilities management, training, and occupational health. Additionally, the Johns Hopkins Animal Care Program is voluntarily accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (“AAALAC”). AAALAC is the primary accrediting body for animal research programs in the United States and elsewhere.

Federal regulations require most institutions that use animals in research, education, and testing to establish an Institution Animal Care and Use Committee (IACUC). Johns Hopkins is one such institution. The IACUC has the following responsibilities under federal regulation:

- Review at least once every six months the institution's program for humane care and use of animals.
- Inspect at least once every six months all of the institution's animal facilities.
- Prepare reports of the IACUC evaluations and submit the reports to the Institutional Official. The reports must distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.
- Review concerns involving the care and use of animals at the institution.

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- Make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.
- Review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals.
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.
- Be authorized to suspend an activity involving animals.

Johns Hopkins recognizes and adheres to our ethical and legal obligations relating to the use of animals in medical research. We follow strict policies designed to assure that laboratory animals receive the highest quality care as well and adhere to the highest standards to protect the health and safety of people who work with and around animals. We take seriously our obligations to implement the Three Rs principle:

- **Replacement:** Wherever possible, use alternatives to animals, including computer models and animal-derived tissue and organs.
- **Reduction:** Employ methods that reduce the number of animals used as much as possible without sacrificing the integrity of the research.
- **Refinement:** Use approaches that minimize or eliminate pain and distress in animals.

All researchers at Johns Hopkins who are using animals must be approved with the IACUC. In order to obtain approval, they must demonstrate that there are no scientifically viable alternatives available, adhering to the Three Rs principles above.

The robust existing federal oversight and internal procedures obviate the need to establish a new state office. The duties of this office this bill would create, known as the State Inspector of Animal Welfare, overlap with regulation already provided by entities like USDA and IACUC. Adding another layer of oversight will be confusing for our researchers and their teams, will mean more time away from their labs and research, and generally make it harder to perform the research that is vital to our mission and provides significant benefit to our patients and to society.

For the reasons stated above, we urge an unfavorable report on **Senate Bill 495**.