SB495 FAV Humane Rescue Alliance - Hovermale.pdf
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Position: FAV

HUMANE RESCUE ALLIANCE

Animals. People. Community.

March 2, 2023

Education, Energy, and the Environment Committee
Maryland Senate
11 Bladen St
Annapolis, MD 21401

RE: **Support for SB 495 Research Facilities and Testing Facilities That Use Animals - Licensing and Regulation**

Dear Chairman Feldman, Vice Chair Kagan, and Honorable Members of the Education, Energy, and the Environment Committee:

On behalf of the Humane Rescue Alliance and our thousands of supporters in Maryland, thank you for the opportunity to submit testimony in support of SB 495, legislation to implement protections for animals in laboratories and pushing for the use of available alternative methods.

The Humane Rescue Alliance honors more than 150 years of commitment to protecting animals, supporting families, and advocating for positive change to create a world where all animals can thrive. We are the largest animal services provider in the Mid-Atlantic region, touching the lives of over 100,000 animals annually through adoption, community veterinary care and other support services, and lost pet reunification. Last year, we helped over 4,000 Maryland families find their new animal companions.

There is no discernable difference between the dogs and cats we care for in our sheltering facilities and the ones used in laboratories for research. Until the day that humane methods have fully replaced animals in scientific research, we have an obligation to reduce the number of animals used in experiments and ease the suffering of those in laboratories. SB 495 is a comprehensive bill that works to do this by implementing protections for animals in laboratories and pushing for the use of available alternative methods by:

- Mandating that laboratories use non-animal methods whenever possible.
- Prohibiting the use of dogs or cats to assess the safety of products such as pesticides and food additives when not required by federal law.
- Banning cruel laboratory practices such as devocalizing dogs, obtaining dogs and cats from animal shelters, and conducting euthanasia in an inhumane manner.
- Requiring animal laboratories to obtain a state license and report on how the animals at their facilities are used.
- Requiring that USDA-registered laboratories be inspected regularly to ensure that animals are being properly cared for.
- Requiring laboratories that use animals in biomedical research experiments to provide a justification for why animals must be used.

These provisions codify the value of the Three Rs (3Rs) that the research community espouses when using animals in experiments: (1) Replacing animals with non-animal methods; (2) Reducing the number of animals used; and (3) Refining methods to minimize animal suffering.

SB 495 represents an acknowledgment of our responsibility to animals used in research and supports non-animal research methods that can often more closely mimic how the human body responds to drugs and treatments, providing countless possibilities to improve our understanding and treatment of human conditions humanely.

For these reasons, we respectfully request a favorable report for SB 495.

Thank you for your consideration of this important legislation.

Emily Hovermale
Director of Government Affairs

SB0495_Favorable_RiseforAnimals.pdf
Uploaded by: Lindsey Soffes
Position: FAV

Rise for Animals.

6 Liberty Square PMB 91098, Boston, MA 02109 riseforanimals.org

March 2, 2023

Senator Brian J. Feldman, Chair
Education, Energy, and the Environment Committee
Maryland General Assembly
2 West
Miller State Office Building
Anapolis, Maryland 21401

Re: Senate Bill 495, *Research Facilities and Testing Facilities That Use Animals*

Dear Mr. Chair and members of the Senate Education, Energy, and Environment Committee:

This testimony in support of Maryland Senate Bill 495, *Research Facilities and Testing Facilities That Use Animals - Licensing and Regulation*, is submitted on behalf of Rise for Animals (formerly the New England Anti-Vivisection Society), a national non-profit organization that champions the interests of both humans and animals by opposing animal experimentation.

Rise for Animals strongly urges you to support Maryland Senate Bill 495 and requests your paid attention to three of the Bill's myriad strengths:

★ Firstly, **Senate Bill 495 would ban research and testing facilities from performing a devocalization surgery on or utilizing for experimentation a devocalized dog or cat.**

Senate Bill 495 would protect research animals from a physically and emotionally detrimental surgical procedure that serves no medical benefit for either the subjects of animal research and testing or the claimed beneficiaries of research and testing (i.e., humans). Devocalization – the surgical destruction of an animal's ability to use his or her vocal cords – is performed almost exclusively to serve menial human interests (effectively, human convenience), which the American Veterinary Medical Association defines to include reductions in animal noise and associated human annoyance. And, because significant and prolonged vocalization is most commonly symptomatic of serious, underlying animal welfare issues (such as boredom, social isolation, and anxiety – all conditions that frequently accompany life as a research subject), laboratories that are allowed to rely on devocalized animals are, effectively, empowered both to ignore stark evidence of poor animal welfare *and* to further compromise the well-being of their charges; to be sure, devocalization surgery is an invasive procedure that commonly precedes various, serious, painful post-operative consequences *and* that directly increases an animal's stress and frustration by stymying his or her ability to perform a fundamental behavior.

Further, expliciting prohibiting research and testing facilities from devocalizing animals or using devocalized animals conforms with previous decisions made by Maryland's legislature, including – more generally – Maryland Criminal Code §§ 10-601, 10-602 (which define animal "cruelty" to include the causing of "unnecessary or unjustifiable physical pain or suffering" and makes clear the General Assembly's intent to protect from cruelty both animals "corporately or institutionally owned" and those "used in scientific or medical activities") and – more specifically – the passage of Maryland Criminal Code § 10-625 (which, effectively, bans elective devocalization).

Rise for Animals.

6 Liberty Square PMB 91098, Boston, MA 02109 riseforanimals.org

★ Secondly, **Senate Bill 495 would ban research and testing facilities from obtaining dogs and cats from Class B dealers and animal shelters.**

Senate Bill 495 would serve to protect Maryland's companion animals by paying homage to a primary motivation for the enactment of landmark federal legislation: societal opposition to the practices of Class B dealers – in, for example, stealing companion dogs for sale to laboratories – and "pound seizure" – by which animal shelters transferred unclaimed dogs and cats to research and testing facilities for experimentation – was a primary driver of the passage of the federal Animal Welfare Act's earliest incarnation (the Laboratory Animal Welfare Act of 1966). Concerns about these practices remain cogent today and counsel in favor of Maryland's increased regulation of Class B dealers and prohibition on research and testing facilities sourcing research subjects from Maryland's homeless companion animal population.

Senate Bill 495's prohibition on "pound seizure" would, additionally, align with and complement existing Maryland law, specifically Maryland Criminal Code § 10-617, which fails to identify transfer to a research or testing facility as an acceptable way for "animal control units" to "dispose" of unclaimed dogs or cats.

★ Thirdly, and finally, **Senate Bill 495 would require research facilities using animals for biomedical research to provide a justification to the State Inspector for their use**.

The lack of transparency (and, hence, accountability) endemic to the modern animal research industry has long and often been credited with both impeding human-relevant innovation and encouraging the infliction of ongoing, unnecessary harms upon animal subjects. Moreover, because it is generally agreed that the prevailing focus on animal research poses a primary hurdle to the development and utilization of human-relevant research methodologies, increased regulatory oversight is generally regarded as a necessary precondition to beneficial human-relevant innovation.

It follows that, by requiring researchers to justify their use of animals *and* to attest to the availability of non-animal methods, Senate Bill 495 stands poised to weaken the capacity for industry momentum and the entrenchment of animal research practices (the "this is how we've always done it" rationale) to forestall the development and acceptance of human-relevant technologies – it, thereby, stands poised to act in benefit of both human and animal welfare.

Rise for Animals is grateful for this Committee's consideration and urges this Committee to vote in favor of Maryland Senate Bill 495.

Sincerely, on behalf of Rise for Animals,

/s/ Lindsey Soffes

Lindsey Soffes
Program Officer

Research Facilities and Testing Facilities That Us

Uploaded by: Lisa Radov

Position: FAV

MARYLAND VOTES FOR ANIMALS

PO BOX 10411
BALTIMORE, MD 21209

March 2, 2023

To: Senate Education, Energy, and the Environment Committee
From: Lisa Radov, President and Chair, Maryland Votes for Animals, Inc.
Re: Research and Testing Facilities That Use Animals – Licensing and Regulation – SB 495 – Support

Chair Feldman, Vice Chair Kagan, members of the Education, Energy, and the Environment Committee, thank you for the opportunity to testify before you today. My name is Lisa Radov. I am the President and Chair of Maryland Votes for Animals. We champion humane legislation to improve the lives of animals in Maryland. Speaking for Maryland Votes for Animals, our Board of Directors, and our members across Maryland, I respectfully request that the Education, Energy, and the Environment Committee vote favorably for Research and Testing Facilities That Use Animals – Licensing and Regulation – SB 495.

This bill would establish comprehensive guidelines and oversight to protect animals used in research and require that non-animal methods of research must be used whenever possible. This bill would:

- Prohibit the use of dogs and cats when assessing the safety of chemicals such as pesticides and household cleaners unless required by federal law.
- Ban cruel laboratory practices such as devocalizing dogs, obtaining dogs and cats for research from animal shelters, and conducting euthanasia in an inhumane manner.
- Require laboratories to obtain a state license and report on how the animals at their facilities are being used. USDA-registered laboratories would be inspected regularly to ensure proper care of the animals used in experiments.
- Require biomedical research laboratories that use animals to provide justification for the need to use them in experiments.

Many of the requirements of this bill are already required by federal law but are not being enforced in our state. Under US Law and policies, scientists must consider alternative methods before using animals for toxicology research and testing:

- The Animal Welfare Act requires that facilities conducting animal research and testing approve proposed animal use and ensure that alternatives are used where appropriate.
- The Public Health Service Policy on Humane Care and Use of Laboratory Animals, which applies to NIH and other federal agencies under the U.S. Public Health Service, requires that research proposals justify animal use and the specific procedures.

The NIH Revitalization Act of 1993 directed the National Institutes of Health (NIH) to support research to replace, reduce, and refine animal use in biomedical research, and to develop and validate alternatives to animal use for acute and chronic safety testing.

Nine out of ten experimental drugs fail in clinical studies using animal subjects. The differences between the physiology, anatomy, and metabolism of humans and animals make it difficult to apply data derived from animal studies to human conditions. A good example of this is Lipitor, Pfizer's blockbuster drug for reducing cholesterol, which was not promising in early animal experiments. Fortunately, a research scientist requested that the drug be tested in a small group of healthy human volunteers. It was only then that its effectiveness was demonstrated.

We are transitioning from depending on animal testing to alternatives that yield better results and are more cost-effective such as testing cells and tissues in test tubes or cell cultures, 3D tissue culture - also referred to as organs-on-a-chip, computational and mathematical models, and stem cell research. As Maryland moves forward with these state-of-art alternatives for animal testing, we need the protections outlined in this bill. Laboratories in Maryland must be on record for the kind of research that they are doing and why they need to use animals. They should be held to the highest standards out of respect for their subjects - who never volunteered to participate in the studies and are not being compensated.

Maryland's lab animals are counting on you!

In closing, I would like to thank Senator Kramer for his sponsorship of SB 495 and ask the committee to give this bill a favorable report.

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Secular Maryland secularmaryland@tutanota.com

March 02, 2023

HB 495 - SUPPORT

Research Facilities and Testing Facilities That Use Animals - Licensing and Regulation

Dear Chair Feldman, Vice-Chair Kagan, and members of the Education, Health, and Environmental Affairs Committee,

Secular Maryland supports this bill which would confer better protection for animals against unnecessary reliance on animals for medical and product testing and research. This bill promotes the development and use of alternatives to animal testing. Current state law lacks consideration for the potential of animals to be harmed. Scientific research has revealed that humans are more similar to our non-human animal counterparts than some people may want to believe. The provisions in this bill strike a sensible balance between the potential harms and benefits from medical and product testing and research on animals. One concern with this bill is that information on testing with animals that must be reported may nevertheless need to be kept under wraps because of the potential for researchers to be threatened by extreme animal rights activists acting outside the law in an effort to shut down all animal testing.

Respectfully,
Mathew Goldstein
3838 Early Glow Ln
Bowie, MD

SB495SupportCrueltyFreeIntl.pdf
Uploaded by: Monica Engebretson
Position: FAV

March 1, 2023

Senate Committee on Education, Energy, and the Environment

RE: Support for SB 495 – An Act Concerning Research Facilities and Testing Facilities That Use Animals - Licensing and Regulation

Dear Committee members,

On behalf of Cruelty Free International, a leading organization working to promote the use of modern non-animal testing methods around the world, I write in support of SB 495.

This bill will help ensure that animals are not used in outdated unnecessary tests when valid non-animal methods are available for ensuring the safety of cosmetics, household products, medicines, vaccines, and pesticides. The bill also prohibits certain particularly cruel and problematic practices such as devocalization and the acquisition of dogs and cats from shelters for laboratory use. Crucially, SB 495 will provide state accountability for the use of animal used in research and testing by requiring all facilities using animals in research and testing to get a license and annually report the number of animals used, the number of dogs and cats adopted into homes after their time in research has ended, and for product testing facilities to provide data on their use of animal methods and non-animal alternatives. Finally, the bill creates a State Inspector position and inspection requirement for USDA registered facilities to ensure proper care at research facilities and this position is paid for through new licensing fees provided in the bill.

Mandating alternatives

Historically, animals have been used in painful tests to assess the safety of many products and medicines used by people. However, in the past 35 years, due to innovations in science, animal tests are increasingly being replaced with non-animal approaches. Modern alternatives are required to go through a rigorous process to demonstrate that they are as or more effective than the animal tests they replace. SB 495 requires the use of alternatives that have been approved for use by regulatory agencies or validated for use by bodies such as the U.S. Inter-Agency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), or the Organization for Economic Co-operation and Development (OECD) which publishes international test guidelines relevant for safety testing of chemicals.

It may be commonly assumed that once a non-animal alternative test is available the animal tests no longer occur, or at least rarely. The reality is that such animal tests can persist and even increase long after the adoption of suitable alternative methods. For example, Cruelty Free International has created a list of 10 regulatory animal test that are still conducted in the US despite having valid non animal replacements. This list includes the rabbit pyrogen, skin and eye irritation and skin sensitization tests as well as antibody production and various batch safety tests. Such animal tests are long overdue for replacement. SB 495 will identify and what, if any, outdated tests are still being used in Maryland and help to complete the replacement process once and for all, for both scientific and ethical reasons.

Post research placement of dogs and cats.

In the past ten years laws governing post-research placement for dogs (and sometimes cats) have been passed by fifteen US states and federal legislation has been introduced on this issue. However, information on law compliance and the number of animals released for adoption in these states is lacking. Cruelty Free International conducted a review of state laboratory laws and concluded that without specific reporting requirements and publicly available information about research facilities, their adoption policies and availability of adoptable animals, it could be difficult if not impossible, to enforce such laws or to measure their life-saving impact. SB 496 would address this issue by requiring that laboratories in the state report the number of dogs and cats adopted into homes after their time in research has ended.

State Accountability

According to our analysis the most recent data available from the USDA (2021 statistics) Maryland used 42, 850 animals in laboratories in 2021 including 25 cats, 378 dogs, 3,705 rabbits and 8, 657 monkeys. The total number of animals used in testing in Maryland is likely significantly higher than reported by the USDA, because many animals used in research [rats, mice, birds, reptiles and farmed animals used under certain circumstances] are not regulated under the Animal Welfare Act (AWA) and are therefore not counted or afforded the minimal protections provided by the AWA.

Adequate enforcement of the AWA by the USDA is of considerable concern. A recent article in National Geographic exposed a long history of weak enforcement and a shocking lack of consequences faced by laboratories for even the most serious animal welfare violations under the Act.[1] The article pointed out that even laboratories that receive millions of taxpayer dollars for research, and those with billions in revenues, face penalties so small that the facilities likely consider them merely a cost of doing business. Weak enforcement of the AWA runs counter to long-standing public concern for animals used in laboratories. Indeed, the original AWA was passed in 1966 following massive public outcry over the use of animals in laboratories.

It has become clear that individual states must play a greater role in overseeing activities involving the use of animals in research and testing to meet public expectation for the protection and reduction of animals used in research and testing. SB 495 will help achieve this.

Again, I urge your support.

Sincerely

Monica Engebretson
Head of Public Affairs N. America
Cruelty Free International

Monica.Engebretson@crueltyfreeinternational.org

[1] https://www.nationalgeographic.com/animals/article/toothless-and-paltry-critics-slam-usda-fines-for-animal-welfare-violations

SB 495_SUPPORT_American Anti-Vivisection Society.p
Uploaded by: Sue Leary
Position: FAV

March 1, 2023

The Honorable Brian J. Feldman
Senate Education, Energy, and the Environment Committee
2 West
Miller Senate Office Building
Annapolis, Maryland 21401

Re: Testimony in SUPPORT of S.B. 495, Research Facilities and Testing Facilities That Use Animals - Licensing and Regulation

Dear Chairman Feldman, Vice-Chair Kagan, and Members of the Senate Education, Energy, and the Environment Committee,

Thank you for the opportunity to submit written testimony for S.B. 495, a bill that outlines a comprehensive approach to address several important issues surrounding the use of animals in research and testing in the state of Maryland. Founded in 1883, the American Anti-Vivisection Society (AAVS) is the first non-profit animal advocacy and educational organization in the United States dedicated to ending the use of animals in research, testing, and education. AAVS works with individuals, students and parents, educators, grassroots groups, corporate and government decision makers, and members of the scientific community. We also receive frequent inquiries and communications about the use of animals in research and testing, and we know that Americans are concerned and care about what happens to animals behind closed laboratory doors.

Based on the traditional assumption that animals respond the same way that humans do when exposed to certain products, unknown numbers of animals are subject to tests that assess the safety of cosmetic, personal care, household products, chemicals, medical devices, and their component ingredients. Exposed to substances that can cause a variety of reactions, including burning, vomiting, and seizures, animals are forced to endure enormous suffering, often with little pain relief. Animals in labs are also kept in sterile, stressful environments that cause them to develop abnormal physiological and behavioral responses, which, despite increasing recognition that such conditions can affect research data, is tolerated because the animals have no voice, and there is no incentive to change. The Maryland legislature has an opportunity to model innovative ways to conduct animal research that are aligned with the interests of the public.

On behalf of our members and supporters, including those in Maryland, I submit this testimony in SUPPORT of S.B. 495, with a focus on three key areas.

Licensing and Reporting
Licensing and subsequent required reporting will protect the public interest, provide a level of accountability, and, in the case of animal laboratories, set some sort of minimal standards to protect animal wellbeing. We know from our interactions with the public that Americans care about animals used in research and testing, especially dogs and cats, and rely on government regulatory bodies, such as the U.S. Department of Agriculture (USDA) to ensure that animals are protected and laboratories held accountable if animal lives are endangered. The USDA oversight has not been effective in preventing violations of the federal Animal Welfare Act (AWA), generally limiting penalties and fines, so S.B. 495 will offer another important layer of accountability and protection for animals.

There are 34 laboratory facilities in Maryland registered with the USDA, as required by the AWA. However, there are likely more animal labs operating without USDA oversight because they use vertebrate animals not covered by the AWA, like mice, rats, and fish. S.B. 495 would require all these facilities to be licensed and to report their animal use, regardless of AWA coverage.

It's generally acknowledged in the scientific community that approximately 90 percent of all animals used in research and testing are mice, followed by rats and fish, yet, because they are not covered by the AWA, scientists are not required to consider alternatives and their numbers are not reported. S.B. 495 will provide some much-needed oversight for facilities using these animals, and its reporting requirements will provide the public more information about animal use in research and testing in Maryland, knowing that alternatives to their use were considered and that those violating the law will face penalties.

Additionally, preparing an annual report containing all required data submission will help give a view into the use of animals in research and testing and will be a great resource for the public and organizations like AAVS.

Prioritizing Non-Animal Methods
An important component of S.B. 495 is the requirement to use "alternative test methods" instead of animals in toxicological testing, or if an alternative is not available, to use the fewest number of animals possible and cause the least amount of suffering. There are several reasons to advocate for the use of alternatives instead of animals in research and testing, including concerns over animal welfare, reliability of the science, and the availability of non-animal testing methods.

Besides the obvious welfare implications, differences between animals and humans also cast doubt on the validity of any results obtained using animals. As a result, animal-based testing methods continue to fail legitimate human needs, while new discoveries in the field of alternatives have led to new and improved techniques that do not involve live animals. For example, the Food and Drug Administration has reported that approximately 90 percent of new drugs that have shown to be safe in animal studies, fail in human clinical trials. Even within the same species, similar disparities can be found among different sexes,

breeds, age and weight ranges. However, alternatives can use human cells and tissues, producing study data that is directly applicable to human conditions.

Researchers have made tremendous progress developing alternatives in recent years and we are just beginning to reap some of the exciting scientific rewards. For example, recognizing the promise of microphysiological systems (including Organs-on-chips or organelles) for drug development, the National Institutes of Health recently announced funding to establish research centers to accelerate the translational use of this new technology. Additionally, recent federal legislation has cleared the way for the Food and Drug Administration to consider new drug applications without requiring animal testing, relying instead on human-relevant, non-animal methods, which again indicates the accelerating importance of these technologies.

Requiring facilities to report how animals will be used in research and testing and a justification for their use, along with potential alternatives to replace animals, not only helps with keeping facilities accountable, but it will also provide a way to measure upward trends in alternatives use and how many lives are saved by their use instead of animals.

Because scientists tend to be traditional and hold steadfast to the use of animals in research and testing, it will be important to include incentives, such increased funding, to spur more interest in using alternatives. It would also be prudent to encourage researchers to participate in the Animal Welfare Information Center's free training (https://www.nal.usda.gov/about-us/events/awic-workshop) on the use of alternatives and alternatives searches. A motivated shift towards alternatives use could also give a booster to testing facilities in Maryland, including those already operating there.

Special Consideration for Dogs and Cats

AAVS strongly believes that all animals used in research and testing are entitled to humane care and treatment and beyond what is provided under the federal Animal Welfare Act. However, we recognize that the public has a special concern for dogs and cats, which has been amplified following national media coverage of the serious welfare issues uncovered at the Envigo dog breeding facility in Virginia and the Inotiv testing labs in Indiana.

Dogs are often used in biomedical research investigating heart and lung disease, cancer, and orthopedics. They are also used in toxicity studies to test the safety of drugs and industrial chemicals, but are rarely used to assess the safety of personal care and household products. Most dogs used in research are purpose-bred in laboratories or by private companies that sell strictly to labs. Dogs can be bred to be pathogen-free or genetically manipulated to be a model of human disease.

Cats are frequently used in neurology research to study spinal cord injury, as well as problems related to vision, sleep, and hearing, and continue to be used because so much is known about their neurological functions. This type of research is extremely invasive, and almost always results in the euthanasia of the cats after they are subjected to grueling vivisection procedures. They can also be used to study Parkinson's disease, cancer, genetic disorders, and other human conditions and ailments

Animal testing is generally recognized to be costly, time-consuming, and unreliable, and much of the research is neither appropriate nor applicable to humans. Fortunately, people do not have to choose between inflicting pain and suffering on animals and establishing the safety of products.

For more information about animal testing and alternatives, please refer to our 2019 issue of the *AV Magazine*, "Chemical Testing on Animals: Driving Change" at https://issuu.com/aavs/docs/av-mag_2019_issue1.

S.B. 495 offers reasonable solutions to offer dogs, cats, and other animals utilized in research facilities protection from inhumane treatment. AAVS strongly supports this legislation and urges the Senate Education, Health, and the Environment Committee to give S.B. 495 a ***favorable report***.

Sincerely,

Crystal Schaeffer
Director of Outreach
American Anti-Vivisection Society
www.aavs.org

SB 495_FAVORABLE_HSUS.pdf
Uploaded by: Vicki Katrinak
Position: FAV

THE HUMANE SOCIETY OF THE UNITED STATES

Testimony in Support of SB 495
Presented to the Senate Education, Energy, and the Environment Committee
March 2, 2023
By Vicki Katrinak, Director, Animal Testing and Research
The Humane Society of the United States

Dear Chair Feldman, Vice-Chair Kagan, and members of the Senate Education, Energy and the Environment Committee,

I appreciate the opportunity to submit this written testimony on behalf of the Humane Society of the United States (HSUS) and our Maryland members and supporters urging a favorable report of SB 495. This legislation creates a comprehensive framework to address opportunities for limiting unnecessary animal testing and providing protection for animals currently being used in research. Specifically, SB 495:

- Mandates the use of non-animal methods when they are available and provide equivalent or superior scientific information to assess the safety of products such as household cleaners, drugs, pesticides, cosmetics, medical devices, vaccines, and chemical substances.
- Prohibits the use of dogs or cats to assess the safety of products like pesticides and food additives when not federally required. Also requires drug developers to request a meeting with FDA prior to conducting a dog test.
- Bans certain cruel research practices such as devocalization and obtaining dogs and cats from shelters and mandates humane euthanasia.
- Requires all facilities using animals in research and testing to get a license and annually report the number of animals used, the number of dogs and cats adopted into homes after their time in research has ended, and for product testing facilities to provide data on their use of animal methods and non-animal alternatives.
- Creates a State Inspector position and inspection requirement for all facilities using animals for research and testing in Maryland and additional inspections for USDA-registered facilities that have received Animal Welfare Act violations to ensure proper care at research facilities.
- Calls for research facilities using animals for biomedical research to provide a justification to the State Inspector for their use.
- Sets up an Animals in Research Fund with money collected from licensing fees to pay for the provisions of the bill.

For centuries, animals have been used as stand-ins for humans to assess the safety of products and study diseases. However, there are severe ethical and scientific limitations with the continued use of animals. Maryland should address these considerations until the time when animals can be eliminated from research and testing entirely. The animal research community has long espoused the value of the Three Rs (3Rs) for animal use: (1) Replacement of animals with non-animal methods; (2) Reduction in the number of animals used; and (3) Refinement of test methods to minimize animal suffering. These

principles for ethical treatment of animals in research were originally described in 1959 by scientists, W.M.S. Russell and R.L. Burch.[1] **SB 495 seeks to ensure that Maryland facilities are held to these basic principles.**

Alternatives Mandate

S.B. 495 requires manufacturers and contract testing facilities to use test methods that replace animal testing when they are available and provide information of equivalent or better scientific quality and relevance. It also requires reporting on the use of traditional animal methods and alternatives. This provision applies to products such as cosmetics, household cleaners, drugs, medical devices, pesticides, and industrial chemicals. The provision does not prohibit the use of animal tests to comply with specific requirements of state or federal agencies.

While animal testing will always have limitations, non-animal testing strategies can more closely mimic how the human body responds to drugs and chemical substances. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods provides a list of more than 100 methods or guidance documents that completely replace or reduce animal use that are accepted by U.S. agencies on its website.[2] As just one example from this list, comprehensive studies have shown that non-animal approaches to test chemicals for the likelihood of causing skin allergies are more reliable predictors of human outcomes than the typical animal test methods."[3]

Unlike traditional animal test methods, sophisticated non-animal approaches to toxicity testing will only continue to improve. The future of non-animal science includes "Organs-on-chips," which are tiny 3D chips created from human cells that look and function like miniature human organs. Organs-on-chips are used to determine how human systems respond to different drugs or chemicals and to find out exactly what happens during infection or disease. Several organs, representing heart, liver, lungs or kidneys, for example, can be linked together through a "microfluidic" circulatory system to create an integrated "human-on-a-chip" model that lets researchers assess multi-organ responses.[4]

SB 495 will ensure that companies in Maryland are utilizing these new non-animal testing strategies as soon as they are approved for use.

Additional protection for dogs and cats

According to the United States Department of Agriculture (USDA), 378 dogs and 25 cats were used in Maryland research facilities in 2021. SB 495 contains several provisions to provide additional protection for dogs and cats used in research and testing including prohibiting the use of dogs and cats in certain toxicity testing, preventing devocalization, requiring humane euthanasia, and clarifying that pound seizure is prohibited in the state. It also requires research facilities to proactively work to reduce and replace the use of these animals.

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[1] Russell, W.M.S. and Burch, R.L., (1959). *The Principles of Humane Experimental Technique*, Methuen, London.
[2] NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) *Alternative Methods Accepted by U.S. Agencies.* (2023, Feb 23). Retrieved from: https://ntp.niehs.nih.gov/whatwestudy/niceatm/accept-methods/index.html
[3] Kleinstreuer NC *et al.*, Non-animal methods to predict skin sensitization (II): an assessment of defined approaches. 2018 Critical Reviews in Toxicology, 48:5, 359-374, doi: 10.1080/10408444.2018.1429386
[4] National Center for Advancing Translational Sciences. *Meet Chip.* (2022, March 18). Retrieved from: https://ncats.nih.gov/tissuechip/chip

Dog tests do not ensure human safety and have scientific limitations that never will improve. Comprehensive scientific analysis reveals that dogs are "highly inconsistent predictors of toxic responses in humans" and suggests that predictions of toxicity based on canine data are little better than those obtained through tossing a coin. The study concludes that "the preclinical testing of pharmaceuticals in dogs cannot currently be justified on scientific or ethical grounds."[5] The lack of scientific justification for toxicity testing on dogs to predict human impacts deems such tests unnecessary. SB 495 prohibits the use of dogs for toxicity testing that are not specifically required by federal law including for chemicals and food additives. It also establishes a process for companies to ensure that dog use is deemed necessary by the Food and Drug Administration (FDA) for drug testing before granting permission for their use.

Devocalization, or ventriculocordectomy, is the surgical removal of part or most of an animal's vocal cords. When performed on dogs or cats it prevents them from barking or meowing. Dogs and cats can suffer physical consequences as a result of devocalization including nerve damage, infection, chronic coughing, and aspiration pneumonia. Aside from such physical problems, devocalized dogs and cats have a decreased ability to communicate creating psychological harm.[6] SB 495 prohibits research facilities from performing devocalization surgery on dogs and cats or using a dog or cat that has received these procedures.

SB 495 also requires that dogs and cats in research facilities only be euthanized through the injection of sodium pentobarbital by, or under the supervision of, a licensed veterinarian. Sodium pentobarbital is considered the most humane method for euthanasia of dogs and cats[7] and is considered the preferred method for companion dogs and cats according to the American Veterinary Medical Association.[8]

In addition, SB 495 provides clarification that dogs and cats from random sources (of unknown origin, such as flea markets, auctions, or animal shelters) should never be used for research and testing in Maryland facilities. In 2013, the National Institutes of Health (NIH) released a policy that it will no longer fund research that involves dogs from random source Class B dealers.[9] A similar policy regarding cats was adopted in 2012.[10] From a scientific research point of view, random source dogs and cats used for experimentation have not had standardized care and upbringing, and consequently have an uncertain medical history and temperament for living in an institutional setting. These circumstances make them poor candidates for experiments.

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[5] Bailey et al., "An Analysis of the Use of Dogs in Predicting Human Toxicology and Drug Safety". (2013)

[6] Humane Society Veterinary Medical Association. *Devocalization Fact Sheet.* (n.d.) Retrieved from: https://www.hsvma.org/assets/pdfs/devocalization-facts.pdf

[7] World Society for the Protection of Animals. *Methods for the euthanasia of dogs and cats: comparison and recommendations.* (n.d.) Retrieved from: https://caninerabiesblueprint.org/IMG/pdf/Link72_Euthanasia_WSPA.pdf

[8] American Veterinary Medical Association. *AVMA Guidelines for the Euthanasia of Animals: 2020 Edition.* (2020). Retrieved from: https://www.avma.org/sites/default/files/2020-02/Guidelines-on-Euthanasia-2020.pdf

[9] National Institutes of Health. *Notice Regarding NIH Plan to Transition from Use of USDA Class B Dogs to Other Legal Sources.* NOT-OD-14-034. (2013, December 17). Retrieved from: https://grants.nih.gov/grants/guide/notice-files/not-od-14-034.html

[10] National Institutes of Health. Notice Regarding NIH plan to Transition from use of USDA Class B Cats to Other Legal Sources. NOT-OD-12-049. (2012, February 8). Retrieved from: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-049.html

Transparency and accountability

In the United States, the federal Animal Welfare Act (AWA) requires research facilities to annually report the number of animals used in research and testing. Unfortunately, the AWA specifically excludes birds, rats, and mice bred for use in research, which represent the vast majority of animals used in research and testing (up to 99%), meaning that research facilities are not required to report how many of these animals are being used. SB 495 will give a more complete picture of how many animals are actually being used in Maryland by requiring all research facilities to report annually on their animal use, obtain a license, and pay a fee that the Department determines is necessary to administer the law.

SB 495 creates a new position, the State Inspector of Animal Welfare within the Maryland Department of Agriculture. The State Inspector must inspect each facility before receiving a license and inspect once per year each facility with a current license. It also requires facilities to report any violations of the AWA and corresponding regulations within 30 days, triggering an additional inspection within 30 days after notification. SB 495 allows the department to enter into an agreement with an animal control facility to conduct inspections. These inspections will provide much-needed additional oversight of animal welfare at research facilities. Unfortunately, annual inspections conducted by the USDA are not sufficient to ensure that animals are being treated according to the minimum standards set by the AWA. Research facilities that are accredited by a third-party organization, such as the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), are not inspected by the USDA as thoroughly as facilities that are not accredited. Without thorough, consistent inspections for all registered facilities, violations could be missed. Additionally, enforcement of documented AWA violations by research facilities is not carried out by the USDA as often as it should be. The state-level inspections required by the provisions in this bill would provide more opportunities for violations to be documented and corrected.

Research facilities conducting biomedical research must also report to the State Inspector providing justification for their decision to use live animals. The criteria that research facilities must provide within their justification is whether another suitable non-animal method is available and could be used; whether research could be done ethically on human subjects; and whether the research is necessary to accelerate prevention, control, or treatment of potentially life-threatening or debilitating conditions. These criteria are similar to the principles established in the 2011 report from the Institute of Medicine (IOM), *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity.* In this report, the committee decided that chimpanzee use should only be conducted if it met certain criteria.[11] SB 495 encourages research facilities to consider the scientific and ethical implications of their continued use of animals and provides transparency on this process.

Scientific Limitations of animal testing

The continued use of animal models for human disease or to assess the possible impact of substances on the human body carries serious scientific limitations. Different species can respond differently when exposed to the same drugs or chemicals. Consequently, results from animal tests may not be relevant to humans, under- or over-estimating real world health hazards. It should not be surprising,

[11] Institute of Medicine (US) and National Research Council (US) Committee on the Use of Chimpanzees in Biomedical and Behavioral Research. *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity.* Washington (DC): National Academies Press (US); 2011. Retrieved from: https://www.ncbi.nlm.nih.gov/books/NBK91445/ doi: 10.17226/13257

therefore that more than 90% of human drugs fail during clinical trials[12] after having completed extensive animal studies. These failures are due to unexpected toxicity in human patients or lack of efficacy. In addition, animals do not always develop the same diseases as humans, or the impact of the disease varies greatly by species. Often treatments that seem incredibly promising in animal models turn out to not be effective in treating human diseases. SB 495 encourages research facilities to move away from outdated animal testing and instead look at more human-relevant non-animal methods.

Strong public support

A YouGov Blue poll conducted last month demonstrates that Maryland voters strongly support efforts to limit animal use in research and testing and support the development of non-animal methods instead. Seventy-nine percent of Maryland voters support state investment in research and development techniques that don't require animal testing, with only 13 percent opposed. Sixty-nine percent support prohibiting animal testing for non-medical reasons, with 21 percent opposed. Seventy-two percent support banning animal testing to determine product toxicity with 22 percent opposed. Eighty percent of Maryland voters support requiring the disclosure of the number of animals used in animal testing and the purpose of the testing, a proposal only 12 percent of voters oppose. Finally, voters strongly support holding animal research institutions accountable with 82 percent supporting a proposal to bar institutions with a record of repeated violations of animal welfare laws from receiving state funds for continued research.

It is time for research facilities to adhere to the 3Rs principles that so many highlight in their commitment to animal welfare. The provisions of SB 495 create a mandate for Maryland facilities to adhere to these decades-old principles including the important transition toward better, more human relevant alternatives to animal methods. HSUS urges a favorable report on SB 495.

Sincerely,

Vicki Katrinak

Vicki Katrinak,
Director, Animal Research and Testing
The Humane Society of the United States
700 Professional Dr.
Gaithersburg, MD 20879

[12] National Center for Advancing Translational Sciences. *About New Therapeutic Uses.* (2022, March 23). Retrieved from: https://ncats.nih.gov/ntu/about

MD SB 495.pdf
Uploaded by: Amanda Hagan
Position: UNF

March 2, 2023

Senator Brian J. Feldman, Chair
Senate Education, Energy, and the Environment Committee
2 West
Miller Senate Office Building
Annapolis, Maryland 21401

Dear Chairman Feldman:

Thank you for the opportunity to comment on SB 495, relating to animal testing facilities. While we share the goal of incentivizing the use of non-traditional test methods to reduce the need for animal testing, we have some concerns about the necessity for and workability of this bill, and with the publication of information required by this legislation.

The Animal Health Institute (AHI) is the U.S. trade association for research-based manufacturers of animal health products – the medicines that keep pets and livestock healthy. Animal health companies work to provide veterinarians, food producers and pet owners with high-quality, effective and innovative products.

The use of animals in testing a broad range of human and animal products has long been a matter of public debate. For several decades, researchers, non-government organizations, industry and regulators have acknowledged the Principle of the 3 R's as guidance in this area. Specifically, the 3 Rs refer to:

- Replacing animal use in an experiment as long as adequate alternatives are available.
- Reducing the use of animal experiments and the number of laboratory animals used, while using only as many animals as are needed to obtain a statistically significant outcome.
- Refining the methods and treatment of the animals during the experiments.

The animal health industry is committed to the 3 R's principle and are working with each of the federal agencies that approves animal health products to increase the adoption of non-traditional test methods. Progress has been made with the U.S. animal health regulatory agencies, and opportunities exist to enhance this progress. The animal health industry has worked with U.S. Department of Agriculture on the adoption of in vitro testing methods to replace outdated animal testing methods to test for potency. The animal health industry has also worked collaboratively with the U.S. Food and Drug Administration to reduce the need for research animals. The Environmental Protection Agency has stated a commitment to the 3Rs principle.

The animal health industry, however, is unique among industries that use animals for research. In animal health, laboratory animals are used in the research and development process. But, since we are also making products for use in animals, those products must be tested on the target animal. The use of animals is required by the regulatory agencies which approve animal health products. While we continue to work on reducing the need for animal testing, some amount will always be required because we are making products to improve the health and welfare of animals.

We also have concerns about the data requirements and public disclosure of such data. These testing facilities are already licensed by the U.S. Department of Agriculture and subject to the data reporting requirements of the Animal Welfare Act. The requirements in this bill for licensing and reporting are duplicative and the requirement to share reported information publicly makes these facilities a target for the kinds of vandalism that has taken place in the past.

For these reasons, we urge the committee to reject this legislation.

Sincerely,

Mandy Hagan
Director, State Government Affairs

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UNIVERSITY SYSTEM of MARYLAND

SENATE EDUCATION, ENERGY AND THE ENVIRONMENT COMMITTEE
Senate Bill 495
Research Facilities and Testing Facilities That Use Animals - Licensing and Regulation
March 2, 2023
Unfavorable

Chair Feldman, Vice Chair Kagan, and committee members, thank you for the opportunity to share our position on Senate Bill 495. The bill establishes requirements for the use and treatment of dogs or cats by research facilities and prohibits the use of certain dogs and cats for research or testing purposes.

While we join the sponsor in his efforts to reduce animal testing and are supportive of the overall concept of developing alternatives to using nonhuman animals in medical and product testing and research we feel that this is rather sweeping legislation that would add a new state regulatory office and set of procedures for licensing and monitoring animal research facilities that is a huge overstep from the current USDA requirements.

All laboratory animal work at USM institutions must be approved by the Institutional Animal Care and Use Committee (IACUC) in accordance with the Animal Welfare Act, The Guide for the Care and Use of Laboratory Animals, and other federal regulations. Researchers consider all alternatives to procedures by employing appropriate, protocol specific search strategies, regardless of species. They are guided by the approach of the Three Rs which represents a practical method for implementation referring to replacement, refinement, and reduction when deciding to use animals in research and in designing humane animal research studies. In terms of justifying the use of an animal model, the principal investigator must submit to the IACUC whether other alternatives (e.g. cell culture, computer/modeling/simulation) to animal usage exist and why they are not feasible for this particular research protocol.

It is important to remember that animal-based research has resulted in groundbreaking discoveries that have helped to save or improve the lives of countless individuals in the United States and throughout the world. At UMB for example, they have carried out major life saving medical research using animal models including the development of aromatase inhibitors for the treatment of breast cancer. In addition, animal-based research carried out by Maryland's Shock Trauma has led to major advances in life saving procedures such as the use of hypothermia to improve the survival of non-trauma cardiac arrest patients. Last year, University of Maryland School of Medicine (UMSOM) faculty at the University of Maryland Medical Center (UMMC), together known as the University of Maryland Medicine were able to successfully transplant a modified pig heart into an adult human with end-stage heart disease. Recently, UMCP's researchers were able to develop an inhalable coronavirus vaccine making it safe for children and the immunocompromised after conducting animal trials. More broadly, animal-based research has resulted in treatments for asthma, dementia, epilepsy, diabetes, high blood pressure, and numerous other medical conditions. We continue to see the benefits of animal-based research in our everyday lives and the lives of animals.

We conduct animal research models in conjunction with federal research grants and contracts. We therefore adhere to all federal regulations relating to animal research, our facilities are inspected once a year, are subject to unannounced inspections by federal agencies, have internal protocol measures and oversight in place and provide an annual report to the USDA as a registered research facility.

As written, SB 495 does not clearly define the term animal and does not specifically rule out applicability to other species that are commonly used in animal research. That ambiguity is concerning since the universe of animal populations that might be used in studies is a very large one. The bill also creates another level of licensing requirement and inspection cycle within the Maryland State Department of Agriculture with a specific focus on dogs and cats and already existing species covered as well as requiring additional reporting which is duplicative of the USDA requirements and guidelines. It also uses federal reporting to trigger state inspections of facilities which may be outsourced to contractors who are not held to the same inspection standards as of federal agency.

While animal-based research is necessary for the development of lifesaving and life altering treatments for people and animals, USM holds firm to the belief that we have an ethical and moral responsibility to provide quality, compassionate and humane treatment of all our animals. We also recognize that our responsibility to our animals does not end when a research project concludes. We also have adoption policies in place, including those already related the dogs and cats under Maryland law, and continue to make every effort when an opportunity presents itself for adoption of our covered research animals.

About the University System of Maryland

The University System of Maryland (USM)—one system made up of twelve institutions, three regional centers, and a central office—awards eight out of every ten bachelor's degrees in the State of Maryland. The USM is governed by a Board of Regents, comprised of twenty-one members from diverse professional and personal backgrounds. The chancellor, Dr. Jay Perman, oversees and manages the operations of USM. However, each constituent institution is run by its own president who has authority over that university. Each of USM's 12 institutions has a distinct and unique approach to the mission of educating students and promoting the economic, intellectual, and cultural growth of its surrounding community. These institutions are located throughout the state, from western Maryland to the Eastern Shore, with the flagship campus in the Washington suburbs. The USM includes Historically Black Colleges and Universities, comprehensive institutions, research universities, and the country's largest public online institution.

USM Office of Government Relations - Patrick Hogan: phogan@usmd.edu

NABR MD SB495.pdf
Uploaded by: Brandon Morton
Position: UNF

National Association *for* Biomedical Research

March 1, 2023

The Honorable Senator Brian Feldman
Chair, Senate Education, Energy, and the Environment Committee
2 West Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401Dear Senator Griffith:

Dear Senator Feldman:

The National Association for Biomedical Research (NABR) opposes **SB495- Research Facilities and Testing Facilities That Use Animals – Licensing and Regulation.**

This bill would require research 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, which is to inspect all licensed facilities each year, a responsibility it can delegate 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 ae necessary to accelerate responses to life-threatening or debilitating conditions. There are significant criminal penalties associated with violations of the bill.

For more than 43 years, NABR has been the nation's only organization solely dedicated to advocating for sound public policy in support of ethical and essential laboratory animal research and the lifesaving discoveries they produce. NABR's diverse and unified membership includes more than 330 universities, medical and veterinary schools, teaching hospitals, pharmaceutical and biotechnology companies, patient groups and academic and professional societies that rely on humane and responsible use of research animals to advance global human and animal health.

Animal research remains vital to our mission to understand disease, discover targeted therapies, alleviate suffering, and improve and increase the quality of life. Biomedical research projects involving animals, governed by a strict structure of laws, regulations, and guidelines, continue to yield invaluable data in the process of discovering new therapies to treat, cure, and prevent disease.

NABR believes this legislation is duplicative of oversight that is already required at the federal level. Under current federal law, research facilities are subject to unannounced USDA inspections and must comply with the Animal Welfare Act as well as the Guide 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. Furthermore, most research institutions are also 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.

This legislation would also negatively impact breakthroughs in biomedical research. Cancer therapies, immunizations, organ transplants, reconstructive surgeries, and many other innovations have been brought to fruition through research conducted at our member institutions with the ethical and essential use of animal models. We support efforts to replace, reduce, and refine the use of animals in drug and

National Association *for* Biomedical Research

vaccine development. However, new drug and vaccine testing technologies to realize this vision at a broad scale and that meet regulatory acceptance are still many years away. We ask the committee to unfavorably report SB495 so research facilities can continue to create lifesaving treatments for diseases, discover targeted therapies, alleviate suffering, and improve and increase the quality of life for both humans and animals.

Sincerely,

Matthew R. Bailey
President

SB 495 - Johns Hopkins - Oppose.pdf
Uploaded by: Michael Huber
Position: UNF

JOHNS HOPKINS
UNIVERSITY & MEDICINE
Government and Community Affairs

SB495
Unfavorable

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

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.

- 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**.