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
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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,

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