SB761_FAVORABLE_American Anti Vivisection Society.
Uploaded by: Crystal Schaeffer
Position: FAV

SM American Anti-Vivisection Society

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March 7, 2024

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

Re: Testimony in SUPPORT of S.B. 761, 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. 761, a bill that outlines a comprehensive approach to address the use of alternatives and other important issues surrounding animal use in research and testing in 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 assessing 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 a chance to model state interests at the intersection of science and animals, and build on legislation passed last year (H.B. 626/S.B. 560) that established a fund to develop non-animal alternative methods, aligning with public expectations. On behalf of our members and supporters, including those in Maryland, I submit this testimony in SUPPORT of S.B. 761, with a focus on three key areas.

Licensing and Reporting
Licensing and subsequent required reporting will protect the public interest and provide much-needed accountability. We know from our interactions with the public that Americans care about animals used in research and testing, and support government regulatory bodies' roles to ensure that animals are

protected and laboratories are held accountable if animals are suffering. Unfortunately, current oversight has not been effective since the only mechanism is via the federal Animal Welfare Act (AWA), which excludes an estimated 93% of animals actually used in labs because it contains exemptions. States have a legitimate interest, and S.B. 761 will offer an important layer of accountability and protection for animals.

There are 32 laboratory facilities in Maryland registered with the U.S. Department of Agriculture (USDA), which enforces 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. 761 would require private facilities to be licensed and to report their animal use.

S.B. 761's reporting requirements will provide the public and non-governmental organizations with more information about animal use in research and testing in Maryland, the assurance 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 will help give a view into the use of animals in research and testing in Maryland, providing state government and legislators with clear information about what is occurring within its borders.

Prioritizing Non-Animal Methods

An important component of S.B. 761 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 (FDA) has reported that approximately 90 percent of new drugs, green-lighted in animal studies, fail in human clinical trials. Even within the same species, 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 has announced funding to establish research centers to accelerate the translational use of this new technology. Additionally, the FDA Modernization Act 2.0 gives the FDA authority 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 act and report on their use of 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. Because there has been a lag in the uptake of alternative methods, it will be important to spur more interest in using alternatives. Excellent resources and training are available, including 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. Motivating a shift towards alternatives use could also accelerate innovation at testing facilities in Maryland.

Special Consideration for Dogs and Cats
AAVS strongly believes that all animals used in research and testing need and 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, because those are the animals they know the best. That concern was amplified following national media coverage of the serious welfare issues uncovered at the Envigo dog breeding facility in Virginia in recent years, causing the close of that location.

Dogs are often used in toxicity studies to test the safety of drugs and industrial chemicals. Most dogs used in research are bred in laboratories or by private companies that sell strictly to labs. Dogs can be bred to be pathogen-free or genetically manipulated in an attempt to simulate human disease.

Animal testing is generally recognized to be costly and time-consuming, and increasingly, producing test results that are 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 the evolution of 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. 761 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, Energy, and the Environment Committee to give S.B. 761 a favorable report.

Sincerely,

Crystal Schaeffer
Director of Outreach
American Anti-Vivisection Society
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SB0761_Favorable_Rise for Animals.pdf
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Position: FAV

Rise for Animals.

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March 7, 2024

Education, Energy, and the Environment Committee
Maryland General Assembly
2 West
Miller Senate Office Building
Annapolis, Maryland 21401
Submitted electronically

RE: *Testimony in Support of SB0761 - Testing Facilities That Use Animals - Licensing and Regulation*

Chair Feldman, Vice Chair Kagan, and members of the Committee:

As a national, nonprofit organization that advocates for the abolition of animal experimentation and the adoption of human-relevant research methodologies, Rise for Animals is writing in support of Maryland Senate Bill 761 (hereinafter, "the Bill").

I. Rise for Animals supports and applauds the Bill's call for the use of human-relevant, non-animal research methods, though Rise for Animals remains concerned that the implicit, unfounded characterization of animal research as the scientific "gold standard" will inhibit progress.

The abolition of animal experimentation is necessary for the health and well-being of both humans and millions upon millions of non-human animals. Unfortunately, to this end, the Bill's requirement that non-animal methods be deemed "equivalent or better" (to or than animal methods) in generating scientific information pertaining to product safety is critically misguided.[1]

Firstly, though research utilizing non-human animals *does* typically generate scientific information, it *does not* typically proffer *human-relevant* scientific information, which should be specified, narrowly defined, and required. The absence of such a requirement can be expected to stymy transitional progress – indeed, "[t]he major obstacle for the development of new non-animal models is the prevailing over-reliance on the value of animal-based procedures as an information source…."[2]

Secondly, regardless of the availability of non-animal methods, non-human animal experimentation is *not* predictive of human response; and, as such, animal experimentation should be discontinued *regardless* of whether an "equivalent or better" method is already available.[3] Stated differently, we should not wait "to abandon a test that does not work until we can find one that does"[4], and this remains true even in the face of researchers' claim that they must use a "living system" – non-human animals provide "the wrong living system[s] and no matter how many

animals are used, they will never provide an appropriate model for humans."[5] By ways of evidentiary example only:

- Non-human models "have a predictive value below 50%, making them less informative than a coin flip and rendering them of no practical use in predicting human outcomes".[6]

- Up to 89% of preclinical, non-human animal research is unreliable.[7]

- Major assessments by pharmaceutical companies have found that "animal-based research studies" are reproducible only 11-25% of the time.[8]

Finally, the use of non-human animals as means for human ends is unethical *regardless* of the realization of human-relevant findings, such that, as a matter of ethical integrity (even if not also scientific reliability), the practice should be abolished full-stop.

II. Rise for Animals supports the prohibition on non-federally-required animal use for toxicity testing, though Rise for Animals laments that the Bill's scope arbitrarily restricts this prohibition *both* to toxicity testing *and* to dogs and cats.

Animal research is roundly unethical and demonstrably non-predictive for humans, and toxicity testing is but one form of such research.[9] It follows that a prohibition on *all* non-federally-required animal use would be far superior to and more effective at ushering in scientific progress than the Bill's current scope vis-a-vis this provision.

Further, *no* sentient beings should be exploited in the name of human science, *including but certainly not limited to* dogs and cats. Problematically, by restricting its scope to dogs and cats, the Bill fails to affect *almost all* animal research: of the estimated 111 million animals used in U.S. research each year, dogs and cats together comprise far less than 1% of the victims.[10] Indeed, more than 99% of the animals exploited in U.S. laboratories are mice and rats, for whom the U.S. remains one of the only Western nations to deny *any* legal protections[11] and who are, for purposes of ethical inquiry, the same as dogs and cats in all ways that matter – scientific research *itself* has made clear that, *just like dogs and cats*, mice and rats "have their own specific internal life and qualia" and "are not just different versions of humans."[12]

Animals other than dogs and cats are favored frequently by researchers *not* because they are less sentient or less physically, emotionally, and psychologically harmed by scientific exploitation, and *not* because they are more predictive of human response; rather, they are used because they are "cheaper"[13], "easier to breed"[14], unregulated by law, and/or not held in high regard by humans for reasons entirely devoid of any scientific or other objective justification.[15]

III. With the above caveats, Rise for Animals supports the thrust of the Bill *while* maintaining that the Bill should apply to all animal research facilities within the state.

The restriction of the Bill's scope to private research facilities is regrettable and overwhelming of the Bill's supposed intent, both because this restriction undercuts an even-handed, consistent demand for industry-wide progress and because this restriction curtails the Bill's reach to a *minority* of modern animal research endeavors. To be sure, the private research sector generally relies *less* on animals than the public research sector[16], such that the Bill's limited application to the former impedes its ability to impact *most* animal research in Maryland.

In conclusion, Rise for Animals reiterates its general support for the presumed motivations underlying Maryland Senate Bill 761 (e.g., the transition to human-relevant research) while asking this Committee to consider seriously the myriad ways in which the Bill, as currently contemplated, falls short of actually honoring such motivations. Beyond (and, to some degree, in summation of) the aforementioned concerns, Rise for Animals asks this Committee to consider that the Bill's current iteration fails to meaningfully address the current "culture of science", a deeply entrenched culture that remains erroneously and self-servingly fixated on animal research and, therefore, must be forced to evolve if we are ever "going to stop performing experiments on animals"[17] and truly start performing ethical, human-relevant science for the good of all.

With gratitude for your consideration,

/s/ Lindsey Soffes

Lindsey Soffes, Program Officer
Rise for Animals

Endnotes

1. Akhtar, A. (2012). *Animals and Public Health: Why Treating Animals Better Is Critical to Human Welfare*. Palgrave Macmillan ("Another major hurdle to the development and use of non-animal testing methods is that government regulations tend to require far more validation than was ever required, if at all, for the animal experimental methods, most of which have never been validated themselves. This creates a double standard that allows the acceptance of most animal experimental methods as the 'gold standards' (based on tradition, rather than proven efficacy), providing a disincentive to the development of alternative methods."); Archibald, K., Coleman, R., & Drake, T. (2019). Replacing Animal Tests to Improve Safety for Humans. In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 341-375). essay, Brill ("New technologies are assessed on how well they can predict the "gold standard" animal data, thus ensuring that they cannot succeed if the drug affects animals differently from humans, which we now know is very often the case."); Blattner, C. (2019). Rethinking the 3Rs: From Whitewashing to Rights. In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 168-193). essay, Brill ("The gold standard in animal experimentation is the animal model, which poses ethical problems, has never been validated as a research method, and is strongly criticized for lacking sufficient predictive value to draw inferences. Despite these apparent flaws and the structural deficiencies of the animal model . . . a non-animal model not only needs to be as 'effective' as the animal model, but (unlike the animal model) it actually needs to work...."); Pounds, P. (2023). *Rat Trap: The capture of medicine by animal research - and how to break free*. MATADOR .("Some feel that the bar is set too high for validating human-focused technologies, with the quest for perfection causing delays and bottlenecks. Others believe that new approaches should be validated against animal data, which is obviously problematic since animal methods themselves have never been validated and are far from the gold standard, as we know. Furthermore, data from human biology-based methods would not be expected to agree with data generated from animal studies."); *id.* (describing the "view of animal studies as the gold standard" as "inappropriate" and detrimental to "scientists using human-based methodologies").

2. Hartung, T. (2019). Research and Testing Without Animals: Where Are We Now and Where Are We Heading? In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 244-272). essay, Brill.

3. Greek, R., & Kramer, L. (2019). How to Evaluate the Science of Non-human Animal Use in Biomedical Research and Testing: A Proposed Format for Debate. In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 65-87). essay, Brill; *see* Archibald, K., Coleman, R., & Drake, T. (2019.).

4. Blattner, C. (2019).; *see* Greek, R. (2019). The Scientific Problems with Using Non-Human Animals to Predict Human Responses to Drugs and Disease. In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 391-416). essay, Brill ("Given that non-human animal models have unacceptably low predictive value for human responses . . . the use of animal models in drug development and disease research could be abandoned immediately for the same reasons that society has abandoned wrong or harmful medical practices such as phrenology, bloodletting, and trephination–they were simply ineffective."); *see also* Gluck, J. (2019). Afterword: Evidence Over Interests. In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 689-691) ("The tendency of scientists to confer authority to 'established' theories and methods have been the central factor in the delay of medical progress, and so it is now with much of the work in animal research."); Keen, J. (2019). Wasted Money in United States Biomedical and Agricultural Animal Research. In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 244-272). essay, Brill ("Failed animal models are the root cause of disappointing and diminishing returns on biomedical investments.").

5. Ram, R. (2019). Extrapolation of Animal Research Data to Humans: An Analysis of the Evidence. In K. Hermann & K. Jayne (Eds.), *Animal Experimentation: Working towards a paradigm change* (pp. 341-375). essay, Brill; *see* Greek, R. (2019). (" . . . it is outside the realm of science to use one complex system in expectation of its having predictive value for another, when the perturbation affects higher levels of organization").

6. Greek, R., & Kramer, L. (2019) (stating that, "[w]hen human health is involved low predictive value means anything below 90-95%" and that "[b]ased on evolved complex systems, evolution, and empirical data, animal models, overall, do not and cannot have a numeric predictive value above about 50%; and, hence, for all practical purposes, they have no predictive value."); *id.* ("The paradigm of animal modeling is not scientifically viable for predicting human response to drugs and diseases, and, thus, animal models should not be used to predict human responses to drugs and disease."); *id.* (noting that no species "regardless of genetic similarity, will ever be similar enough to another to serve as a valid predictive model. That is, according to science, the observation of a drug response in one species is uninformative about the drug response in another species.").

7. Keen, J. (2019).

8. Hartung, T. (2019).

9. Miller, R. J. (2023). *The Rise and Fall of Animal Experimentation: Empathy, Science, and the Future of Research*. Oxford University Press. (" . . . it is rather ridiculous to imagine, even in principle, that toxicological studies using animals would reliably predict adverse effects in humans . . . tossing a coin is a much cheaper way of going about things, and certainly much less cruel to animals.")

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.* ("Something that is not usually discussed but will be obvious is that most of the main animals on the list like rats, mice, worms, and flies are things that humans generally have an aversion to...."); *see also* Carbone, L. (2004). *What animals want: Expertise and advocacy in laboratory animal welfare policy.* Oxford University Press. ("[P]eople work with gradations and hierarchies of moral concern. Species may even be split within some of these hierarchies, depending on the individual's history, as in the case of pound versus purpose-bred dogs, or wild mice (vermin) versus laboratory mice (excluded from the [AWA]) versus wild mice in laboratory experiments (included under the [AWA])."

16. Keen, J. (2019).

17. Miller, R. J. (2023).

Testing Facilities That Use Animals – Licensing an

Uploaded by: Lisa Radov

Position: FAV

MARYLAND VOTES FOR ANIMALS

PO BOX 10411
BALTIMORE, MD 21209

March 8, 2024

To: Senate Education, Energy, and the Environment Committee
From: Lisa Radov, President and Chair, Maryland Votes for Animals, Inc.
Re: Testing Facilities That Use Animals – Licensing and Regulation – SB 761 – 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 Testing Facilities That Use Animals – Licensing and Regulation – SB 761.

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 761 and ask the committee to give this bill a favorable report.

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Uploaded by: Mathew Goldstein
Position: FAV

Secular Maryland https://secularmaryland.dorik.io secularmaryland@tutanota.com

March 08, 2024

SB 761 - FAV

Testing Facilities That Use Animals - Licensing and Regulation

Dear Chair Brian J. Feldman, Vice-Chair Cheryl C. Kagan, and Members of the Education, Energy, and the Environment Committee,

The $100 dollar maximum penalty for anyone who irresponsibly abandons their domesticated animal is too small to be effective in many contexts. This bill increases the maximum penalty to $1,000 and ninety days imprisonment. Additionally, this bill introduces a requirement that a tracking chip be installed by future dog owners. Secular Maryland recognizes that other social animals are like us and accordingly supports improving our animal welfare laws in general and this bill in particular.

Respectfully,
Mathew Goldstein
3838 Early Glow Ln
Bowie, MD 20716p

S0761_aakhtar_oral testimony.pdf
Uploaded by: Mikalah Singer
Position: FAV

CENTER FOR CONTEMPORARY SCIENCES

Oral Testimony of Dr. Aysha Akhtar
CEO and Co-founder
Center for Contemporary Sciences
Gaithersburg, MD USA
aysha@contemporarysciences.org

Submitted to the Maryland State Senate Education, Energy, and the Environment Committee hearing in support of SB0761, Testing Facilities That Use Animals – Licensing Regulation
Friday, March 8, 2024
9:00 AM EST

Good afternoon members of the Education, Energy, and Environment Committee. My name is Dr. Aysha Akhtar and I am the CEO and Co-founder of the Center for Contemporary Sciences, a Maryland based non-profit dedicated to unlocking the power of science to find solutions that improve the health and wellbeing of humans, animals, and the planet. I am a double-board certified neurologist and preventative health specialist, with a background in public health, and a U.S. veteran.

I am submitting testimony today in strong support of SB0761, Testing Facilities That Use Animals – Licensing Regulation, introduced by Senators Kramer, Lam, Lewis Young, and Waldstreicher. This legislation would do a number of things to protect animals used in research and support human-relevant testing methodologies including:

- Mandating 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, medical devices, vaccines, and chemical substances,
- Establishing requirements and prohibitions for the use and treatment of dogs and cats by testing facilities,
- Requiring all private 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,
- Creating a State Inspector position and inspection requirement and,
- Setting up an Animals in Research Fund with money collected from licensing fees to pay for the provisions of the bill.

The existing paradigm places animal experimentation at the center of research and testing despite a well noted lack of translatability between animal testing and human outcomes. More than 80 percent of all drugs and vaccines found safe and effective in animal tests fail during human clinical trials.[1]

A Personal Story

[1]Tagle DA. The NIH microphysiological systems program: developing in vitro tools for safety and efficacy in drug development. Curr Opin Pharmacol. 2019; 48:146-154. doi: 10.1016/j.coph.2019.09.007.

One of the hardest things I have had to do as a neurologist is to watch my own aunt, a strong, vibrant woman, deteriorate from Parkinson's disease until she died. I watched helplessly as she slowly lost control of her own body, a truly terrifying experience. Her arms pained continuously from the constant, uncontrollable tremors. Meanwhile, her legs often refused to move. By the end, she was unable to walk, stand, and perform the most basic of movements we expect from our bodies. Perhaps even more devastating, she lost her sense of self and her unique personality, humor and intelligence disappeared, to be replaced with a swirling chaos of dementia.

I tell you my aunt's story because there is not a single effective treatment for Parkinson's disease. Nor is there an effective treatment for Multiple Sclerosis, dementias, spinal cord injury, most cases of stroke, and just about every neurological disease. As best, we have treatments that help with some of the symptoms, but which do not truly impact the illness themselves.

Professional Story

In fact, there is no approved treatment for most diseases, neurological or otherwise. During my decade as a Medical Officer at the Food and Drug Administration (FDA) and in their Office of Counterterrorism and Emerging Threats, I studied the safety and effectiveness of new drugs and saw how promising drug after drug came through the pipeline only to fail in human clinical trials.

At some point, it became clear to me why there are so few effective treatments for human illnesses. Subtle differences between humans and other animals now significantly mislead the results of studies. I authored a study that showed that one of the most reasons why there are so few treatments for most illnesses is because animal tests do not predict human results.

Throughout my career, it has not just been the lack of treatments and cures that come out of using animal testing that has pushed me to support human-relevant testing methods, but the treatment of the animals being used in research. I have witness an experiment in which a cat's spinal cord was crushed and its movement on a treadmill being recorded. The cat had implanted electrodes forcibly implanted into her brain and she was struggling to keep upright, dragging her paralyzed legs on the treadmill. She repeatedly fell off the machine.

It's difficult for us to imagine what the lives are like for these animals. We want to believe that these animals are being treated humanely, but I can tell you from personal experience that this is not the case. As soon as you walk into a laboratory, you can't help but notice the rows and rows of barren cages holding sad animals living under the glare of fluorescent bulbs. Their bodies are burned, mutilated and scarred. You can small the stench of blood, feces, and fear.

A Way Forward

Human-relevant testing methods are the future in medicine. Methods like bioprinted mini organs and human-body-on-a-chip are based on human data and human biology. Thus, unlike tests using different species these new methods are human-relevant. They are already outperforming animal testing in modeling human diseases and predicting human results. Last year Maryland passed HB626, which created a Human-Relevant Research Funding to provide grants to public and private institutions in Maryland to advance the discovery, creation, and use of human-relevant research techniques in the medical sciences.

Additionally, Maryland has already shown itself to be support humane legislation by passing a law to end the testing of new cosmetics on animals in 2021. SB0761 will not only help Maryland continue to pave the way for a new frontier in medicine, more effective research tools, and real hope for people suffering devastating illnesses by supporting human-relevant methods, but it will provide additional, much needed protections for those animals still used in testing.

Maryland established itself as a leader in the future of biotechnology and medicine by passing HB626. I and the Center for Contemporary Sciences favorably support SB0761 to help Maryland to remain a trailblazer in this space.

Sincerely,

Aysha Akhtar, MD, MPH
Co-founder and CEO
Center for Contemporary Sciences
9841 Washingtonian Blvd
Gaithersburg, MD 20878

SB0761_aakhtar_Written Testimony.pdf
Uploaded by: Mikalah Singer
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CENTER FOR CONTEMPORARY SCIENCES

Written Testimony of Dr. Aysha Akhtar
CEO and Co-founder
Center for Contemporary Sciences
Gaithersburg, MD USA
aysha@contemporarysciences.org

Submitted to the Maryland State Senate Education, Energy, and the Environment Committee hearing in support of SB0761, Testing Facilities That Use Animals – Licensing Regulation
Friday, March 8, 2024
9:00 AM EST

Good afternoon members of the Education, Energy, and Environment Committee. My name is Dr. Aysha Akhtar and I am the CEO and Co-founder of the Center for Contemporary Sciences, a Maryland based non-profit dedicated to unlocking the power of science to find solutions that improve the health and wellbeing of humans, animals, and the planet. I am a double-board certified neurologist and preventative health specialist, with a background in public health, and a U.S. veteran. I previously served as Deputy Director of the U.S. Army Traumatic Brain Injury Program developing the Army's brain injury prevention and treatment strategies for soldiers, and was a Medical Officer at the Food and Drug Administration for a decade, most recently in the Office of Counterterrorism and Emerging Threats, implementing studies on vaccine effectiveness and safety.

I am submitting testimony today in strong support of SB0761, Testing Facilities That Use Animals – Licensing Regulation, introduced by Senators Kramer, Lam, Lewis Young, and Waldstreicher. SB0761 would among others, (1) require each testing facility in the State to be licensed by the Department of Agriculture to use animals in research, education, or testing, (2) establish requirements and prohibitions for the use and treatment of dogs and cats by a testing facility, (3) establish a State Inspector of Animal Welfare in the Department to inspect certain testing facilities and require facilities to notify the Inspector of violations, (4) prohibit a testing facility from using traditional animal test methods under certain circumstances, (5) establish the Animals in Research Fund as a special, nonlapsing fund and require interest earnings of the Fund to be credited to the Fund. Additionally SB0761 would require a testing facilities that use live animals for research, education, or testing to report on the number of each species owned and used by the facility, number of dogs or cats released to animal rescue organizations, and both the number of alternative test methods and traditional animal test methods waivers used.

The existing paradigm places animal experimentation at the center of research and testing despite a well noted lack of translatability between animal testing and human outcomes. More than 80 percent of all drugs and vaccines found safe and effective in animal tests fail during human

clinical trials.[1] This failure rate can be attributed to the physiological and pathological differences between humans and non-human animals.[2] Even with attempts to improve the failure rate by changing animal study design protocols, which can be costly and time-consuming, there has yet to be a sufficient impact in translatability to humans.[3]

Human-relevant testing methods are the future in medicine. These are methods, such as human body-on-a-chip, bioprinted mini-organs, smart AI, and virtual humans that are rapidly becoming the go-to methods for biomedical research. Not only are these methods so advanced and sophisticated, but they are based on human data and human biology. Thus, unlike tests using different species these new methods are human-relevant. They are already outperforming animal testing in modeling human diseases and predicting human results.

SB0761 will not only help Maryland move away from ineffectual animal experimentation by supporting human-relevant methods and providing additional protections for those animals still used in testing, but will also provide the funding needed to support these changes. The establishment of the Animals in Research Fund will be used to support the State Inspector of Animal Welfare in the Department of Agriculture.

Maryland has already shown itself to be support humane legislation and human-relevant testing methods. In 2021, the legislature passed a law to end the testing of new cosmetics on animals and last year Maryland passed HB626 which created a Human-Relevant Research Funding to provide grants to public and private institutions in Maryland to advance the discovery, creation, and use of human-relevant research techniques in the medical sciences.

Maryland established itself as a leader in the future of biotechnology and medicine by passing HB626, and SB0761 will help Maryland to remain a trailblazer in this space. I and the Center for Contemporary Sciences favorably support SB0761 so that Maryland can continue to pave the way for a new frontier in medicine, more effective research tools, and real hope for people suffering devastating illnesses.

Thank you for considering this testimony. Please feel free to contact me at aysha@contemporarysciences.org if you need additional information.

Sincerely,

Aysha Akhtar, MD, MPH

[1]Tagle DA. The NIH microphysiological systems program: developing in vitro tools for safety and efficacy in drug development. Curr Opin Pharmacol. 2019; 48:146-154. doi: 10.1016/j.coph.2019.09.007.
[2] Ibid.
[3] Ibid.

Co-founder and CEO
Center for Contemporary Sciences
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SB761Support CrueltyFreeIntl.pdf
Uploaded by: Monica Engebretson
Position: FAV

March 1, 2024

Senate Committee on Education, Energy, and the Environment

RE: Support for SB 761 – 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 761.

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 761 will provide state accountability for the use of animal used in research and testing by requiring the facilities covered by the bill to obtain a license and annually report the number of animals used, the number of dogs and cats released for adoption, and data on their use of animal methods and non-animal alternatives. Finally, the bill creates a state inspection requirement for testing facilities in the state that will aid in ensuring that the minimal protections afforded to animals in laboratories under the federal Animal Welfare Act are being upheld. The state inspection requirement are 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 761 requires the use of alternatives that have been approved for use by the regulatory agencies responsible for regulating the product being tested.

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 tests that are still conducted in the US despite having valid non animal replacements. Such animal tests are long overdue for replacement. SB 761 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 761 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 expectations for the protection and reduction of animals used in research and testing. SB 761 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

2024-SB0761-FavAmend.pdf
Uploaded by: Nelda Fink
Position: FAV

SB0761 – Favorable with Amendment

Nelda Fink

MD District 32

Favorable.

Thank you for helping to protect the lives and wellbeing of God's creatures, ones we also refer to as pets.

I would only like to request this bill be amended to include costs for health care for the pet that has undergone testing and is now being adopted out. The testing facility should provide vet care for at least one year for any dog or cat that has been involved in the testing where the dog or cat has received any of the drugs, vaccines or substances being tested.

The testing is part of determining unknowns about a substance. Because the animal is receiving a substance that has unknowns, the long-term health effects of that substance may not be known either. Therefore to have a person (the final forever home adopter, not the rescue organization) adopt this pet and then suffer major vet expenses because of the results of testing is unconscionable, and is an improper shift of liability.

The vet care could be in the form of insurance for 1 – 2 years or something to that effect. The fact that the pet is coming from a testing facility also needs to be provided to the forever-home adopter.

Asking for a favorable report with this amendment.

Thank you.

Nelda Fink

SB0761_Favorable_Physicians Committee for Responsi
Uploaded by: Ryan Merkley
Position: FAV

PhysiciansCommittee
for Responsible Medicine
PCRM.ORG
5100 Wisconsin Ave. NW, Suite 400 • Washington, DC 20016 • Tel: 202-686-2210 • Fax: 202-686-2216 • pcrm@pcrm.org

March 7, 2024

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

RE: Support for Senate Bill 761

Dear Chair Feldman and Members of the Committee:

I am writing on behalf of the Physicians Committee for Responsible Medicine, a global nonprofit with 900,000 members and supporters, to urge you to support Senate Bill 761. This legislation would improve the safety of chemicals and drugs while sparing dogs, cats, and other animals the cruelest forms of experimentation.

Considering the failings of the federal government in this area, greater state oversight is badly needed. Under the federal Animal Welfare Act (AWA), no experiments are prohibited – including those that inflict pain. The AWA is primarily a husbandry statute that regulates the size of cages, cleanliness, and food and water. In addition, the U.S. Department of Agriculture, which is supposed to enforce the AWA, was cited by its own inspector general for closing investigations involving animal deaths and serious repeat violations and for unnecessarily reducing fines by an average of 86%.[1] In 2019, *The Washington Post* reported, "USDA inspectors documented 60 percent fewer violations at animal facilities in 2018 from the previous year…The drop in citations is one illustration of a shift – or what critics call a gutting – in USDA's oversight of animal industries."[2]

The federal government's failures are why, in recent years, several states have passed laws prohibiting certain types of experiments or increasing oversight of facilities that use animals. In 2022, Virginia signed into law five bills that regulate the use and sale of dogs "for experimental purposes."[3] Also in 2022, California passed a law that would prohibit the use of dogs in the testing of chemicals, toxic substances, and food additives.[4] In 2018, Virginia outlawed the use of state funds for carrying out painful experiments on dogs.[5] In 2023, legislators in Pennsylvania and Michigan introduced bills that would prohibit the use of public funds for painful experiments on dogs.[6,7]

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[1] USDA Office of Inspector General. (2014). Animal and Plant Health Inspection Service Oversight of Research Facilities Audit Report 33601-0001-41.
[2] Brulliard, K. (2019, Feb. 26). *The USDA Is Issuing Far Fewer Citations to Zoos, Labs and Breeders for Animal Welfare Violations.* The Washington Post.
[3] Jaquith, O. (2022, April 4). *Youngkin Signs 'Beagle Bills' for Animal Welfare Reform*. WRIC.
[4] Solis, N. (2022, Sept. 7). *California Bans Unnecessary Pesticide, Chemical Testing on Dogs and Cats*. Los Angeles Times.
[5] S.B. 28, 2018 Session, Va. Gen. Assembly.
[6] Jessop, L. (2023, June 23). *Lawmaker Urges Pennsylvania to Stop Funding Inhumane Animal Testing*. The Center Square.
[7] H.B. 4849. 2023 Session, Mich. Legislature.

In addition, about 95 percent of all animals used in laboratories are excluded from accurate federal reporting requirements. Simply put, in the United States, we have no idea how many animals are used in labs. (In comparison, the governments of other countries – including the United Kingdom, Canada, and the entire European Union – regularly collect and publish detailed information on how many animals are used in research and testing.) SB 761 would help alleviate that problem.

This bill would also help translate research and testing conducted in Maryland to patients by furthering the replacement of animals with human-relevant methods. According to the National Institutes of Health (NIH), drugs that prove safe in nonhuman animals fail in human clinical trials 95 percent of the time.[8] That immense failure is a big reason we are seeing an international effort to replace animals in drug testing. This may be achieved by using tissue chips – small, high-tech devices about the size of a thumb drive. They can be lined with human organ cells – from healthy or diseased donors – and they allow scientists to acquire data quickly without having to translate it from another species. Researchers at Harvard have developed patient-derived tissue chips to study kidney and lung dysfunction associated with kidney injury and respiratory disease. Scientists are even developing patients-on-a-chip – devices that use an individual patient's cells to model rare diseases and cancers.[9] The goal is to use these systems to develop patient-specific treatments.

The failings are also seen in disease research. Ninety-two percent of cancer studies in animals fail to successfully translate to human clinical trials.[10] And in a landmark 2013 study, researchers from Stanford University, Harvard University, and elsewhere found that when it comes to serious inflammatory conditions such as sepsis, burns, and trauma, results from mice cannot be applied to humans because of their vastly different genetic responses.[11] Even the director of the NIH acknowledged the time and resources wasted on sepsis experiments on mice, calling the catastrophe – in which 150 drugs successfully treated sepsis in mice but failed in human trials – a "heartbreaking loss of decades of research and billions of dollars."[12]

Clearly, patients deserve better. But we can make progress for them – and animals – by making SB 761 into law. We urge you to advance this bill out of your committee.

Thank you for your time and your work on behalf of the people of Maryland.

Sincerely,

Ryan Merkley
Director of Research Advocacy
Phone: 202-527-7336
Email: rmerkley@pcrm.org

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[8] National Center for Advancing Translational Sciences. (2015, Oct. 8). *Request for Information (RFI): Soliciting Input for the National Center for Advancing Translational Sciences (NCATS) Strategic Planning Process*.
[9] https://wyss.harvard.edu/technology/human-organs-on-chips/
[10] Mak, I.W., Evaniew, N. & Ghert, M. (2014). Lost in Translation: Animal Models and Clinical Trials in Cancer Treatment. *American Journal of Translational Research*, 6(2).
[11] Junhee, S. et al. (2013). Genomic Responses in Mouse Models Poorly Mimic Human Inflammatory Diseases. *PNAS*, 110(9).
[12] Collins, F. (2013, Feb. 19). *Of Mice, Men, and Medicine*. NIH Director's Blog.

SB 761_Favorable_Sherman McFarland.pdf
Uploaded by: Sherman McFarland
Position: FAV

JOHNS HOPKINS
ENVIRONMENTAL HEALTH
& ENGINEERING

Bill: SB 761
Committee: Senate Education, Energy, and the Environment
Position: Support
Date: March 8, 2024

Hello, my name is Sherman McFarland. I am a Postdoctoral Fellow at the Johns Hopkins University School of Public Health, and I have a Juris Doctor from the UC-Davis School of Law. I am testifying in support of SB 761 because it prohibits testing facilities from using dogs and cats to test the safety or efficacy of chemical substances, drugs, vaccines, ingredients, products, and product formulations, unless required by federal law. SB 761 should also reduce the use of animals in experiments because, under the language of the bill, testing facilities may not use a traditional animal test method if the agency responsible for regulating the specific product or activity for which a test method is being used has approved an alternative, non-animal test method.

Furthermore, SB 761 prohibits testing facilities from using, either for research or testing, a dog or cat obtained from an auction, flea market, or animal shelter, or from a person that did not breed and raise the dog or cat. Testing facilities are also prohibited from using dogs sold by Class B dealers licensed under the federal Animal Welfare Act, and from using dogs or cats that have undergone a devocalization surgery. Furthermore, SB 761 prevents testing facilities from performing a devocalization surgery on a dog or a cat.

In addition, SB 761 requires that, every year, each testing facility that uses live animals for research, education, or testing shall report the following to the Maryland Secretary of Agriculture: (1) the number of each species of vertebrate animal owned and used by the facility; (2) the number of dogs and cats released to animal rescue organizations; (3) the type and number of alternative test methods and traditional animal test methods used; (4) the purpose of any tests performed using alternative test methods or traditional animal test methods; and (5) the number of traditional animal test method waivers and canine or feline toxicological experiment waivers used. This reporting requirement should enable the enforcement of SB 761's requirements and goals.

Moreover, SB 761 allows the Maryland Department of Agriculture to enter into an agreement with an animal welfare organization, local animal control agency, or other similar entity to conduct the inspections that the State Inspector of Animal Welfare must perform under the language of the bill.

In conclusion, I believe that this bill will spare the suffering of animals in Maryland. Dogs and cats will be spared from being experimented on for drug, vaccine, ingredient, product, product formulation, and chemical substance safety and efficacy tests, unless required by federal

law. Dogs and cats will also be spared from devocalization surgeries. In addition, SB 761 advances the use of alternative, non-animal test methods, and is designed to ensure animal welfare. SB 761 represents a humane step forward for Maryland, and I encourage the legislature to pass it on behalf of the welfare of animals in this state.

Thank you very much for allowing me to testify in support of SB 761 today. If you have any questions about my testimony, or need more information, please contact me via email at smcfar13@jh.edu

Please be aware that I am submitting this testimony in my individual capacity and that the views expressed do not necessarily reflect the official policy or position of Johns Hopkins University or the Johns Hopkins University Bloomberg School of Public Health.

SB 761_FAVORABLE_HSUS_03.07.24.pdf
Uploaded by: Vicki Katrinak
Position: FAV

THE HUMANE SOCIETY OF THE UNITED STATES

Testimony in Support of SB 761
Presented to the Senate Education, Energy, and the Environment Committee
March 8, 2024
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 761. 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 761:

- Mandates the use of non-animal methods by private facilities when they are available and provide equivalent or superior scientific information to assess the safety of products such as household cleaners, drugs, pesticides, cosmetics, vaccines, and chemical substances.

- Prohibits the use of dogs or cats at private facilities 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 private 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 private 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 private facilities using animals for research and testing in Maryland and additional inspections for USDA-registered private facilities that have received Animal Welfare Act violations to ensure proper care at research facilities.

- 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 761 seeks to ensure that private Maryland facilities are held to these basic principles.**

Alternatives Mandate

S.B. 761 requires private 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, 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]

Last session, Maryland became the first state in the nation to prioritize the development of human-relevant research, by establishing a dedicated fund to provide grants to scientists in the state developing these non-animal technologies. SB 761 will ensure that private 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), more than 500 dogs were used in a private Maryland research facility in 2022. SB 761 contains several provisions to provide additional protection for dogs and cats used in research and testing including prohibiting the use of

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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

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 private research facilities to proactively work to reduce and replace the use of these animals.

Dog tests do not ensure human safety and have scientific limitations that will never 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 761 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 private 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 761 prohibits private research facilities from performing devocalization surgery on dogs and cats or using a dog or cat that has received these procedures.

SB 761 also requires that dogs and cats in private 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 761 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 private 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

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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://canineraabiesblueprint.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

upbringing, and consequently have an uncertain medical history and temperament for living in an institutional setting. These circumstances make them poor candidates for experiments.

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 761 will give a more complete picture of how many animals are actually being used in Maryland by requiring private research facilities to obtain a license and report annually on their use of all vertebrates.

SB 761 creates a new position, the State Inspector of Animal Welfare within the Maryland Department of Agriculture. The State Inspector must inspect each private facility before receiving a license and inspect once per year each private facility with a current license or once every two years for USDA-licensed facilities. It also requires private facilities to report any violations of the AWA and corresponding regulations within 30 days, triggering an additional inspection within 30 days after notification. SB 761 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 private research facilities, which were cited more than 20 times in the last five years for violations of the AWA. 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, 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.

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, therefore that more than 90% of human drugs fail during clinical trials[11] 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 761 encourages private research facilities to move away from outdated animal testing and instead use more human-relevant non-animal methods.

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

Strong public support

A YouGov Blue poll conducted last year 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 761 create a mandate for private Maryland facilities to follow these decades-old principles including the important transition toward better, more human relevant alternatives to animal methods. HSUS urges a favorable report on SB 761.

Sincerely,

Vicki Katrinak

Vicki Katrinak,
Director, Animal Research and Testing
The Humane Society of the United States
1255 23rd St. NW, Suite 450
Washington, DC 20037

MD SB 761.pdf
Uploaded by: Amanda Hagan
Position: UNF

March 8, 2024

The Honorable Senator Brian J. Feldman
Chair, Education, Energy & the Environment Committee
2 West Wing, Miller Senate Office Building
11 Bladen Street
Annapolis, Maryland 21401

Dear Chair Feldman:

On behalf of the Animal Health Institute (AHI), we respectfully oppose SB 761, which adds unnecessary reporting requirements for testing facilities. AHI is the U.S. trade association for research-based manufacturers of animal health products – the medicines that keep pets and livestock healthy.

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 R's 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 is working with each of the federal agencies that approves/reviews 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. For example, the animal health industry has worked with U.S. Department of Agriculture (USDA) 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 (FDA) to reduce the need for research animals. The Environmental Protection Agency (EPA) has stated a commitment to the 3 R's 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 making products for use in animals, those products must also be tested on the target animal. The use of animals is required by the regulatory agencies which approve animal health products, including the FDA, EPA, and USDA. While we continue to work on reducing the need for animal testing, some amount will always be required by federal agencies because we are making products to improve the health and welfare of animals.

The Federal Animal Welfare Act governs, among other animals, dogs and cats used in research. The Animal Welfare Act contains 164 pages of USDA regulations governing animal use along with an additional 424 pages that comprise the USDA's Animal Welfare Guide, which is used by the USDA's Animal and Plant Health Inspection Service to inspect facilities which use animals in research. The Animal Welfare Act and USDA regulations require registration and licensing of entities using animals in research, inspections of facilities, and generally govern all aspects of humane care.

USDA requires facilities to submit an annual report that includes the number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes; as well as how many animals were used in different categories of research.

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As these reports are already publicly available on USDA's website, it is unclear what problem or goal the legislation attempts to address. The bill would institute an unnecessary administrative burden for testing facilities with no beneficial effect.

We urge the subcommittee to recommend a "no" vote on SB 761. Thank you for your consideration.

Sincerely,

Mandy Hagan
Director, State Government Affairs

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Position: UNF

National Association for BIOMEDICAL RESEARCH

March 7, 2024

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

Dear Chair Feldman:

The National Association for Biomedical Research (NABR) opposes SB761- Testing Facilities That Use Animals – Licensing and Regulation.

For more than 45 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 320 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.

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, which is to inspect all licensed facilities each year, a responsibility it can delegate to animal rights 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. In addition, it includes provisions regarding the adoption of dogs and cats used for research and creates duplicative and onerous reporting requirements. There are significant criminal penalties associated with violations of the bill.

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 unnecessarily 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 for the 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 AAALAC International. AAALAC International is the primary accrediting body for animal research programs in the United States and elsewhere.

This legislation would slow 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 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 SB761 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

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SB761_BIOQUAL_UNF.pdf
Uploaded by: Timothy Hampton
Position: UNF

March 7th, 2024

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

BIOQUAL Inc. urges an unfavorable report on SB 761 – 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, 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. In addition, it includes provisions regarding the adoption of dogs and cats used for research and creates duplicative and onerous reporting requirements. There are significant criminal penalties associated with violations of the bill.

BIOQUAL Inc. (BIOQUAL), a Maryland based Contract Research Organization founded in 1981, has long been engaged in development of in-vivo testing programs and has been extensively involved in research efforts to develop vaccines and therapies against emerging diseases including AIDS, Hepatitis, Influenza, Zika, Chikungunya and many others. Most recently, the company has played a vital role in COVID-19 research and in the development of successful vaccines and therapies against the SARS-CoV-2 pandemic. The use of animals in this research was essential to the rapid development of the COVID-19 vaccines that are estimated to have saved millions of lives worldwide (ref. Lancet Infect Dis 2022; 22: 1293-302, June 23, 2022; https://doi.org/10.1016/S1473-3099(22)00320-6).

Animal models are a necessary component of BIOQUAL's mission to provide innovative research support for improved global health. BIOQUAL is a USDA Registered Class R Research Facility, holds an Assurance with the Office of Laboratory Animal Welfare (OLAW), and is an Accredited institution with the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Further, to ensure ethical and human treatment, BIOQUAL is committed to:

- Having a duly constituted Institutional Animal Care and Use Committee (IACUC) that is qualified through the experience and expertise of its members to ensure that all research and teaching protocols using live vertebrate animals are designed and performed in a humane manner that complies with all applicable laws, policies, and guidelines.
- Fostering a culture of recognition and appreciation for the role of animals in research for all staff.
- Incorporating the 3Rs of animal research (Replacement, Reduction, and Refinement) to constantly seek to improve our program of animal care, and
- Maintaining the highest standards of animal care and use through a collaborative approach involving veterinarians, scientists, and animal support staff.

BIOQUAL, Inc.

The proposed bill places undue burden and bureaucracy on research operations, adding layers of administrative work and increases to operational costs that will hinder the development of such vaccines and treatments. The proposed structure duplicates existing federal oversight, undermines the institutional animal care and use committee's authority and responsibility for expert evaluation of proposed research, and generates onerous administrative burden.

SB761 duplicates existing federal oversight.

Research institutions are subject to the Animal Welfare Act and Regulations (AWAR) and compliance with the PHS Policy. Through the extensive requirements and guidance provided through these bodies, institutions communicate regularly with federal oversight representatives - including unannounced annual inspection by the USDA. Additionally, through accreditation with AAALAC, institutions must have robust policies in place to ensure animal health and welfare is prioritized and maintained. Further, through the internal IACUC, institutions must comply with the following responsibilities:

- Review, at least semiannually, the institution's program for the humane care and use of animals;
- Inspect, at least semiannually, the institution's animal facilities (including satellite facilities);
- Prepare reports to the Institutional Official (IO) of the IACUC evaluations;
- Review animal welfare concerns;
- Make recommendations to the IO on any aspect of the animal program, facilities, or personnel training;
- Review and approve activities related to the care and use of animals;
- Review and approve, proposed significant changes to the use of animals in ongoing activities; and
- Be authorized to suspend an activity involving animals.

The proposed bill duplicates many of these processes, such as annual/bi-annual inspection by the State Department of Agriculture, and annual reporting of animal use. BIOQUAL takes the responsibilities of the 3Rs principles seriously and supports such measures, but this bill provides very little in the direction of creating meaningful improvements to the actual welfare of animals.

Undermining IACUC Authority and Responsibility

Furthermore, this proposed legislation undermines the authority and responsibility of Institutional Animal Care and Use Committees (IACUCs). This duplication of oversight not only adds to the bureaucratic burden but also dilutes the expertise and effectiveness of established IACUCs in evaluating and approving research protocols involving animal subjects. By requiring researchers to justify the use of animals directly to the state body, the bill diminishes the role of IACUCs, which are comprised of experienced professionals dedicated to ensuring the ethical treatment of animals in research. This erosion of IACUC authority undermines the rigorous evaluation process that has long been established to safeguard animal welfare and scientific integrity within research institutions. Consequently, SB761 poses a significant threat to the autonomy and effectiveness of IACUCs, jeopardizing the welfare of research animals and hindering scientific progress.

BIOQUAL, Inc.

This bill generates onerous administrative burden.

The bill requires the type, number, and purpose of all test methods conducted by a testing facility to be reported annually to the State Secretary of Agriculture. This is a massive step up in administrative burden from the current regulatory reporting requirements. To elucidate, a given research study may include 10 or more test methods, each often conducted at multiple times over the duration of the study. The scale of this reporting would reach into the hundreds of pages and FTE-hours to account for the level of detail required.

Impact

In conclusion, SB761 will create negative impact on research operations, undue administrative burden, duplication of existing federal oversight, and lacks meaningful improvements to animal welfare. As a company committed to ethical research and the development of vaccines and therapies, we believe that this bill would hinder scientific progress and innovation rather than enhance animal welfare or regulatory oversight. For these reasons, we urge an unfavorable report on Senate bill 761.

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Uploaded by: Laura Bogley
Position: INFO

Informational Statement SB761
Testing Facilities That Use Animals – Licensing and Regulation
Laura Bogley, JD
Director of Legislation, Maryland Right to Life

We Oppose Any Testing on Embryonic or Fetal Human Beings

On behalf of the Board of Directors of Maryland Right to Life, we urge your amendments of SB761 to prohibit the unethical use of human embryonic cells or fetal tissue for the purpose of biomedical or commercial research and testing. This bill would restrict some traditional animal testing methods, but does not specify whether the definition of "animal" includes human beings for the purposes of protection. Previously enacted legislation specifically excluded "human animals" from state protections.

We strongly oppose any policy that authorizes or expands the use of human embryonic or fetal cells or tissues, particularly those derived through abortion violence and federally prohibited human organ harvesting. We also object to "Human-Relevant" testing methods that are largely undefined but typically rely on the use of human cells, if those cells are derived from human beings in their embryonic or fetal state. The state of Maryland should authorize only ethical and humane testing methods that prioritize the state's interest in preserving human life.

Human Embryo Testing is Unethical

Embryonic stem-cell research is routinely touted by supporters as having the potential to cure a number of diseases and medical conditions. However, the procedure for obtaining embryonic stem cells is fraught with ethical and scientific pitfalls and, importantly, <u>such research has yet to yield an effective treatment for any disease or condition.</u>

Living human beings in embryonic stage are killed in embryonic stem-cell research and human cloning. Specifically, embryonic stem-cell research is done by taking a days-old embryo that has grown to the several hundred-cell stage, breaking it apart, and taking the cells from the embryo's inner mass. These unspecialized cells are then grown and used for research, including by implantation in animals and resulting animal-human hybrid abominations that disregard the dignity of each human life.

Embryonic Testing is Unsuccessful

More than 15 years after the first isolation of embryonic stem cells, there is not a single disease that these cells can cure, regardless of whether the embryonic cells are created through the fusion of a human sperm and egg or through cloning. In fact, Geron Corporation, the company that received governmental approval for the first clinical trials using stem cells derived from human embryos, discontinued "further stem cell work" after "a strategic review of the costs… timelines and clinical,

manufacturing and regulatory complexities associated with the company's research and clinical-stage assets."[1]

Conversely, there are proven, ethical alternatives to research using stem cells from human embryos. One important source is umbilical cord blood—a very rich source of stem cells. Another is adult stem cells, which can be obtained from various organs. For example, researchers know that bone marrow cells can form into fat, cartilage, and bone tissue. A third promising source is neural stem cells. These stem cells have been successfully isolated and cultured from living human neural tissue and even from adult cadavers.

Moreover, since 2007, research breakthroughs are opening the door for the "reprogramming" of adult stem cells into the embryonic state—without the use or destruction of human embryos.

In Conclusion

In sum, any alleged "therapeutic" purposes for destructive embryo research have proven to be speculative, while simultaneously crossing ethical boundaries and taking human life. **As such, states should prohibit this ethically problematic research that has proven completely unnecessary.**

For legislators and policy makers, it is vitally important that careful attention be exercised to avoid some types of research (especially in the area of cloning) that are ineffective or that create incentives for researchers to destroy preborn human life and increase the demand for aborted fetal tissue including late term, fully developed human organs.

For these reasons we urge your amendment to ensure that any testing methods licensed or funded by the State of Maryland are ethical and prohibit the use of cells or tissues obtained from embryonic or fetal human beings. The state instead should encourage the development of ethical alternatives.