Rise for Animals.

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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

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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).