THE HUMANE SOCIETY OF THE UNITED STATES

Testimony in Support of SB 560
Presented to the Senate Finance Committee
March 3, 2023
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The Humane Society of the United States

Dear Chair Griffith, Vice-Chair Klausmeier, and members of the Senate Finance 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 560. This legislation creates a Human Relevant Research Fund to provide grants to public and private institutions in the state of Maryland to advance non-animal research techniques. The funding for SB 560 is achieved through a mandatory contribution by institutions using animals for research and testing (as amended). This important legislation will provide a necessary investment in 21st century science and will speed the transition from traditional animal methods toward research and development of modern technologies that are based on human biology.

The promise of human relevant research

The world is continuously moving toward a future dominated by sophisticated methods that use human cells, tissues and organs, 3D printing, robotics, computer models and other technologies to create experiments that do not rely on animals. While animal experiments were developed decades ago and will always have severe limitations, advanced non-animal methods represent the very latest techniques that science has to offer, provide countless possibilities to improve our understanding and treatment of human diseases and will only continue to improve over time. Non-animal methods also have several advantages over outdated animal experiments: they more closely mimic how the human body responds to drugs, chemicals and treatments; they are more efficient and often less expensive; and they are more humane. Ultimately, moving away from animal experiments is better for both humans and animals.

Passage of SB 560 would demonstrate that Maryland is making a concerted effort to shift funding and technological development toward more non-animal alternatives. Examples of alternative approaches include:

- "Organs-on-chips" 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.
- Sophisticated computer models use existing information to predict how a drug or chemical might affect a human.
- Cells from a cancer patient's tumor are used to test different drugs and dosages to get exactly the right treatment for that specific individual, rather than testing the drugs on animals.
- Specialized computers use human cells to print 3D tissues that are used to test drugs.

- Skin cells from patients, such as those with Alzheimer's disease, are turned into other types of cells (brain, heart, lung, etc.) in the laboratory and used to test new treatments.
- Sophisticated computer programming, combined with 3D imaging, is used to develop highly accurate 3D models of human organs, such as the heart. Researchers then input real-world data from healthy people and those with heart disease to make the model hearts "beat" and test how they might respond to new drugs.
- Human cells or synthetic alternatives can replace horseshoe crab blood in tests to determine whether bacterial contaminants are present in vaccines or injectable drugs.

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[1] after having completed extensive animal studies. These failures are due to unexpected toxicity in human patients or lack of efficacy, sometimes resulting in hospitalizations or even death. 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.

Animal tests are not only inaccurate, but also incredibly cruel. In traditional animal tests, dogs, rabbits, non-human primates, mice and rats have substances forced down their throats or into their lungs, dripped into their eyes, or smeared onto their skin. Thousands of animals may be used for a single test, and they can suffer for months or years before being killed. Mice, rats, and birds who have been purpose-bred for research make up the majority of animals used in research and testing, and yet they are excluded from even the most minimal protections of the Animal Welfare Act.

Impact of laws and regulatory agency actions

In 2016, Congress revised the Toxic Substances Control Act, which included a provision directing the Environmental Protection Agency (EPA) to reduce and replace the use of animals in chemical testing. Since that time, EPA has been at the forefront of efforts to assess modern non-animal test methods for chemical and pesticide safety including the creation of a New Approach Methods Workplan that was updated in 2021, where the agency declared that "reducing the use of vertebrate animals for toxicity testing is a priority."[2] This forward-thinking workplan provides an updated roadmap for ensuring the agency's success in this reduction goal.

The Food and Drug Administration has also indicated a need to prioritize the development and acceptance of non-animal methods to assess the safety of products regulated by the agency including drugs, vaccines, medical devices, and food ingredients. As part of the federal omnibus signed into law at the end of 2022, Congress appropriated $5,000,000 to *Reduce Animal Testing through Alternative*

[1] National Center for Advancing Translational Sciences. *About New Therapeutic Uses.* (n.d.). Retrieved from: https://ncats.nih.gov/ntu/about

[2] U.S. Environmental Protection Agency. *New Approach Methods Work Plan*. (2021, December). Retrieved from: https://www.epa.gov/system/files/documents/2021-11/nams-work-plan_11_15_21_508-tagged.pdf

Methods, a full funding of the agency request submitted as part of President Biden's budget.[3] The agency requested this money in part to create of a cross-agency New Alternatives Methods Program in the Commissioner's office. In 2021, FDA launched its Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program with the goal of assuring qualification of drug development tools such as tissue chips and novel toxicology assays.[4]

The National Institutes of Health (NIH), the largest funder of animal research in the world, has also proclaimed the value of non-animal approaches for testing and research. The National Center for Advancing Translational Sciences (NCATS) — one of 27 Institutes and Centers at NIH — was established by Congress in 2011 with its stated mission to "support the creation of innovative methods and technologies to speed the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions."[5] One of NCATS first projects was developing a Tissue Chip for Drug Screening initiative in conjunction with FDA and Defense Advanced Research Projects Agency (DARPA).[6] While this NIH investment in human-relevant science is important, it represents just a small fraction of the total research rewards given by the agency.

In addition to efforts from Congress and federal agencies, states have also taken actions recently to address the need to end unnecessary animal testing. Since 2018, ten states (including Maryland) have passed laws to prohibit the sale of cosmetics that have been newly tested on animals. There are currently 42 countries that have passed laws to help bring about an end to animal testing for cosmetics and Congress has considered legislation in recent years to do the same throughout the United States. Even China, which once required animal testing for all cosmetics, has begun to accept non-animal test methods for these products.[7]

The message being sent is clear: science is moving away from outdated animal methods and toward human relevant approaches. **Maryland could become a leader in this biotechnological space by passing SB 560.**

Strong public support for investing in non-animal research methods

In a poll of Maryland voters in February 2023, seventy-nine percent of respondents supported investing in research and development techniques that don't require animal testing, with only 13 percent opposed. In addition, seventy-two percent support banning animal testing to determine product toxicity. Passage of SB 560 would align with the sentiment of Maryland voters.

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[3] U.S. Food and Drug Administration. *FDA Seeks $8.4 Billion to Further Investments in Critical Public Health Modernization, Core Food and Medical Product Safety Programs.* (2022, March 28). Retrieved from: https://www.fda.gov/news-events/press-announcements/fda-seeks-84-billion-further-investments-critical-public-health-modernization-core-food-and-medical

[4] U.S. Food and Drug Administration. *Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program.* (2021, February 10). Retrieved from: https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/innovative-science-and-technology-approaches-new-drugs-istand-pilot-program

[5] National Center for Advancing Translational Sciences. *NCATS History.* (2022, November 8). Retrieved from: https://ncats.nih.gov/about/center/history

[6] National Center for Advancing Translational Sciences. *About Tissue Chip.* (2022, September 15). Retrieved from: https://ncats.nih.gov/tissuechip/about

[7] Institute for In Vitro Sciences. *China's Acceptance of Certain Non-Animal Testing Methods for the Regulation of Cosmetics.* (2019, April 3). Retrieved from: https://iivs.org/2019/04/03/china-accepts-new-alternative-methods-for-cosmetics/

Importance of dedicated funding

HSUS appreciates the willingness of research institutions in Maryland to work with us on amendment language all parties can agree to. We support the agreement thus far, which would create a mandatory annual contribution by institutions using animals into the Human Relevant Research Fund.

As regulatory agencies and state, federal, and international law continue to push for the use of non-animal methods and the public opposition to the continued use of animals grows, Maryland should take the opportunity to invest in the development of the new technologies that will be used by the chemical, cosmetics, and drug industries to evaluate their products. Maryland, a leader in research and biotechnology, should be aligned with this global shift away from animal use and encourage further innovation and development of modern non-animal approaches. This will also provide young scientists in Maryland with opportunities in this sector, creating a foundation for the future. HSUS urges a favorable report of SB 560 to help advance human relevant alternatives to animal testing in Maryland.

Sincerely,

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