

BONNIE CULLISON
Legislative District 19
Montgomery County

Health and Government
Operations Committee



The Maryland House of Delegates
6 Bladen Street, Room 312
Annapolis, Maryland 21401
410-841-3883 · 301-858-3883
800-492-7122 Ext. 3883
Fax 410-841-3882 · 301-858-3882
Bonnie.Cullison@house.state.md.us

Chair, Insurance and Pharmaceuticals
Subcommittee

THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

**Testimony in Support of HB 626 Animal Testing and Research –
Human-Relevant Research Funding and Animal Testing and Research Licensure**

Good afternoon, Chairman Peña-Melnyk, Vice Chair Kelly and honorable members of the committee. Thank you for this opportunity to present **HB 626 Animal Testing and Research - Human-Relevant Research Funding and Animal Testing and Research Licensure**. This bill creates a fund to spur the development of human-relevant research driving the development of emerging research technologies that do not use animals. The fund is modeled after the Stem Cell Research Fund, administered by TEDCO, and includes a license fee on institutions that engage in animal testing.

Maryland should be proud of its work on two fronts: to invest in its biotech industries and research institutions, and to create strong animal welfare protections. Specifically, I am referencing the Center for Alternatives to Animal Testing at JHU and the emerging biotech center at UMD. HB 626 will ensure that Maryland stays a leader as new, non-animal testing methods move to the forefront. We are already seeing the impact that human relevant technologies have on advancing human health and discovering cutting edge solutions that animal testing could never have revealed (SEE ADDENDUM). Testing on animals is not even necessarily accurate-- 90% of drugs found safe on animals ultimately fail in human trials. Investing in these emerging technologies will take Maryland to the next level in our research, our biotech, and our lifesaving interventions.

Maryland has already established that we want to be a humane state. Legislature in 2021 passed a law ending the testing of new cosmetics on animals. The removal of 4,000 dogs last summer from a center that bred for research shone a spotlight on the inhumane treatment animals in research too often face. While those 4,000 dogs were able to start new lives in loving homes, more than 60,000 dogs are used in laboratory testing each year across the country – not to mention the countless other animals. We move away from animal testing by investing in innovative research that is humane.

We are working with stakeholders on amendments as to the funding mechanism, to have institutions that test on covered animals, animals under the protection of the federal Animal Welfare Act, to make contributions to the fund. That would not require new reporting or oversight, as those institutions already must receive USDA licenses, and report the number of animals they test on. It would also strike the penalty provisions in the current bill.

HB 626 is a revenue-neutral way to move Maryland towards the future we want – one with solutions to the hardest medical questions, and one that is less reliant on outdated animal testing. There is broad stakeholder agreement with the amendments, and I respectfully request your favorable consideration.

ADDENDUM

Research Examples

1. Using blood cells from patients with Schwarzman Diamond syndrome (an inherited disease that affects blood cell development in the bone marrow), researchers created a "bone marrow on a chip" and used this to reveal defects in specific cell types that matched the clinical picture (and was not seen in animal models of this condition). This gave an entirely new insight into the condition. (Massachusetts)
2. Researchers have applied stretch forces to a lung on a chip model to mimic the movements of breathing. When they added a compound used for cancer treatment, they recreated the lung edema (where fluid leaks into the lungs) often observed in people - but this edema was not seen in the absence of the stretch forces, showing that this breathing movement is important. The study then used a novel drug to stop the edema - suggesting that this model could be used in studies predicting drug activity. (Massachusetts)
3. Multi-organ chip models, where different organ chips are linked together to allow communication between them, have been applied to understand drug mechanisms. Researchers have connected a liver chip with a heart chip and found that interaction with the liver metabolized the drug, producing a component that was damaging to the heart. These observations explained what had been seen in animal tests (which are required before drug approval) and show that integrated organ chips could be used as early indicators of toxicity and therefore reduce animal use in drug testing. (Florida)
4. In a similar study to the one above, organ chip developers carried out an extensive analysis of the capacity of the human liver chip to predict liver toxicity, using drugs with a known profile (ie those that had proven toxic or safe on humans). This study revealed that the chips were highly predictive of the effects seen in humans and the authors of this study suggested that liver chips be used in the drug development pipeline to reveal potentially damaging liver effects before drugs are developed further - saving time and money. (Massachusetts)
5. Researchers used skin cells from patients with Rett syndrome (an autism spectrum disorder) to create nerve cells that still displayed symptoms of the condition. They tested drugs on the RTT-nerve cultures and found a compound that corrected the nerve activity. This compound was tested in clinical trials, where it was safe and well tolerated and seemed to help some of the behavioral issues associated with the condition. (California)
6. A nerve chip was connected to a muscle chip to create a neuro-muscular junction for modelling neuropathies (a group of rare diseases that affect nerve conduction and movement). Researchers added patient blood samples to the chip to show that an element in the blood was damaging the nerves. They went on to show that a previously approved drug (approved for a different disease) could prevent this and may help reduce disease symptoms/progression. These data were accepted by the FDA and the treatment has recently been advanced to clinical trial for patients with the neuropathy. (Florida)
7. Researchers have developed a kidney chip, and used this to show the mechanism through which cysts are created in polycystic kidney disease - understanding this process could help researchers to work out how to treat this (Washington)
8. In Maryland specifically, there are a couple of projects that are using organ chip approaches, one of these looks at the gut-brain axis, so is using human cells to make these organ chips (brain and gut) - the aim is to better understand neurodegenerative diseases. One is looking at kidney disease, developing organ chips of different regions of the kidney for drug screening.
9. Johns Hopkins also have some projects looking at cardiac function - some of these tissue models are going to the International Space Station to look at the effects of microgravity and one project is using stem cells to make heart models, and nerve models. The researchers will look at these interactions, again to better understand cardiac diseases and act as a platform for screening drugs.

Institutions Testing on Animals

Account Name	Mailing City	Total Used + Held 2021
Frostburg State University	FROSTBURG	0
LOYOLA UNIVERSITY MARYLAND	BALTIMORE	0
MEDIMMUNE LLC	GAITHERSBURG	0
TOWSON UNIVERSITY	TOWSON	4
Elixirgen Therapeutics, Inc.	Baltimore	10
INTEGRATED BIOTHERAPEUTICS INC	ROCKVILLE	11
VRL MARYLAND LLC	GAITHERSBURG	17
COMMUNITY COLLEGE OF BALTIMORE COUNTY	BALTIMORE	44
WASHINGTON BIOTECHNOLOGY INC	SIMPSONVILLE	48
THOMAS D MORRIS INC	REISTERSTOWN	80
BIOMEDICAL RESEARCH INSTITUTE	ROCKVILLE	323
UNIVERSITY OF MARYLAND COLLEGE PARK	COLLEGE PARK	556
NOBLE LIFE SCIENCES, INC.	SYKESVILLE	561
UNIVERSITY OF MARYLAND BALTIMORE	BALTIMORE	951
BASI GAITHERSBURG	DARNESTOWN	1181
SIGMOVIR BIOSYSTEMS INC	ROCKVILLE	3208
BIO RELIANCE CORPORATION	ROCKVILLE	3262
Johns Hopkins University	Baltimore	4104
BIOQUAL INC	ROCKVILLE	11364
<i>Total COVERED Animals 2021</i>		25724

NOTE: Covered animals are those protected under the Animal Welfare Act, including dogs, cats, rabbits, guinea pigs, hamsters, gerbils, nonhuman primates, marine mammals, captive wildlife, and domestic livestock species used in nonagricultural research and teaching. It does not include the millions of rats, mice, fish, invertebrates, or other animals tested on annually.

Examples of Non-Animal Alternative Methods

- “Organs-on-chips” are tiny 3D chips created from human cells that look and function like miniature human organs. The 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 what might happen in the whole body.
- Sophisticated computer models use existing information (instead of carrying out more animal tests) to predict how a medicine or chemical, such as drain cleaner or lawn fertilizer, 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 then test how they might respond to new drugs.

Examples of Companies in Maryland Already Doing this Research

Institute for In Vitro Sciences	Gaithersburg, MD	Non Animal Testing, Alternative Test Methods, In Vitro Toxicology, IIVS IIVS at SOT 2019	In vitro assays.
Mimetas	Gaithersburg, MD	Human Tissue Models for Better Therapies (mimetas.com)	Organ on a chip.
Propagenix	Gaithersburg, MD	Programs (propagenix.com)	3D organoids.
3Dnamics	Baltimore, MD	3Dnamics	3D organoid models.