emulate

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Testimony of

Jim Corbett, CEO Emulate, Inc.

Before the Maryland Health and Government Operations and Ways and Means

RE: Animal Testing and Research – Human-Relevant Research Funding and Animal Testing and Research Licensure

Dear Delegates, Cullison, Allen, Bagnall, Bridges, Charkoudian, Fennel, Fraser-Hidalgo, Lehman, R. Lewis, Lopez, Love, Patterson, Qi, Reznik, Ruth, Shetty, Solomon, and Stein

On behalf of Emulate, Inc., the leading provider of Organ-on-a-Chip technology, I offer this testimony in support of Maryland House Bill 626.

There is no doubt that animal models have contributed to major scientific advancements and to safe and effective drugs making it to market. However, these models have the difficult job of approximating the human body, and sometimes they get it wrong.

A growing body of evidence suggests that animal models are lacking in both sensitivity and specificity when it comes to predicting drug toxicity in humans.[1-3] A 2014 study analyzing the effects of 2,366 drugs in both animals and humans found that "tests on animals (specifically rat, mouse, and rabbit models) are highly inconsistent predictors of toxic responses in humans and are little better than what would result merely by chance."[4] A 2008 review found similar

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results, concluding that animal models predicting drug toxicity in humans may have sensitivity and specificity values below 70%.[2]

The costs of poor specificity and sensitivity are too often passed onto the patient. A review of 578 discontinued and withdrawn drugs in Europe and the United States showed that nearly half halted distribution due to post-approval toxicity.[5] Similarly, a 2012 analysis of 43 post-approval drugs with serious toxicity effects found that only 19% of them showed indications of toxicity in animal studies.[6]

In a recent study published in *Communications Medicine*, part of Nature Portfolio, researchers found the Emulate human Liver-Chip to have an 87% sensitivity and 100% specificity when differentiating hepatotoxic from non-hepatotoxic small molecules.[7] Importantly, all 22 hepatotoxic drugs included in the study had previously been classified as safe due to a lack of toxicity in animal models. Collectively, these compounds resulted in 208 patient fatalities and 10 liver transplants. Had the Emulate human Liver-Chip been used during the preclinical screening of these compounds, it's likely that many of these fatalities could have been avoided.

Animal models have played an undeniably significant role in the evolution of medicine and will continue to do so, but to make the drug development process safer, more efficient, and more humane, we must take a hard look at how we can leverage scientific advancements to continuously improve patient safety.

With the FDA Modernization Act 2.0 being signed into law by President Biden in December 2022, we applaud the state of Maryland for moving quickly to

identify creative ways to fund human-relevant research. The collective industries of New Approach Methods, Microphysiological Systems, and Organ-Chips will spur the next-generation of scientific advancements, leading to new education and career opportunities as well as boosting the economy of Maryland.

Sincerely,

Jim Corbett
Emulate, Inc. CEO

References

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