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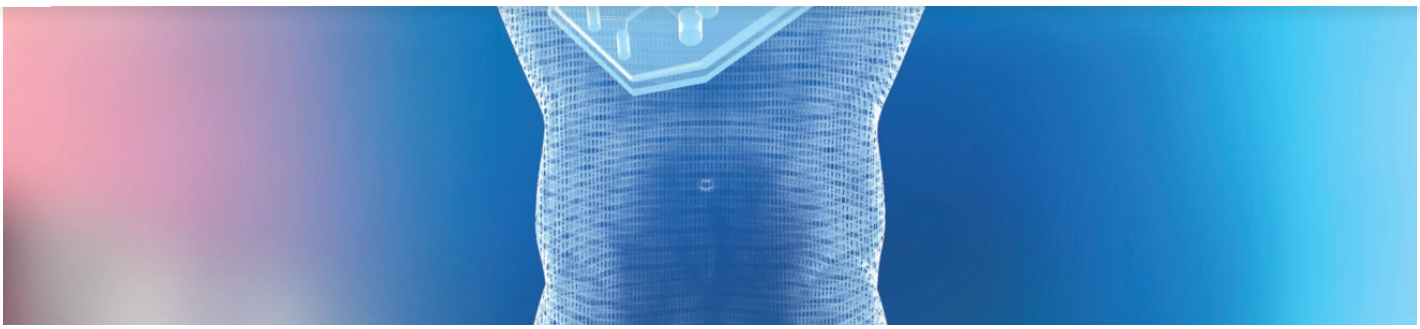
Time to humanize European health research with an action plan

Concrete targets and accountability needed to move beyond last century's animal model paradigm.



via Humane Society International

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European Commissioner for Transport Adina-Ioana Vălean recently declared before the European Parliament that "the Commission is convinced that animal testing should be phased out in Europe." MEPs agreed, suggesting that there exists a broad consensus among EU institutions about the scientific and ethical benefits of replacing the use of animals in safety science and health research.

However, during this exchange, sharp divergences emerged as to how this goal could be achieved.

MEP Katalin Cseh called for "a credible plan with measures and targets" to replace animal experiments, to which the Commission replied that it was "working towards this goal in particular by means of the directive on the protection animals in science" and that this made "additional strategy documents and actions redundant."

To this, MEP Tilly Metz responded that the 2010 EU Directive dealing with the protection of animals used for scientific purposes was "one of the strictest legislations in the world" but "it does not provide a clear strategy for transitioning to innovation without the use of animals."

> Our decrease in animal use is so slow that at this pace, about 1.3 million animals per year would still be used in the EU at the turn of the 22nd century!

The results of this lack of strategy are clear. The EU statistical reports on animals used in scientific research published annually since 2015 show that our decrease in animal use is so slow (about 2.3 percent per year) that at this pace, about 1.3 million animals per year would still be used in the EU at the turn of the 22nd century!

In September the Parliament will vote on a resolution asking the Commission to prepare an action plan to phase out the use of animals in experiments in the EU.

Such a plan is needed because, despite all the progressive animal protective language embedded in European law and impressive advances in science and technology, our product safety regulations and health research are still largely rooted in archaic approaches using millions of animals each year.

For example, in 2021, the most frequently performed animal tests in Europe are variants of the "lethal dose 50 percent" procedure developed in 1927 which refers to the dose of a chemical administered at once that kills 50 percent of a group of test animals.

And the current "state-of-the-art" animal models for testing the effectiveness of new anti-depressant medicine involve forcing mice to swim, or be suspended upside-down by their tails, until they stop trying to escape.

With a system built on the 19th century presumption that mice and other animals are miniature humans who respond precisely as we do to drugs and diseases (history has shown this is often not the case), is it any wonder that more than 90 percent of drugs that pass animal tests go on to fail in human clinical trials?

> It's time to humanize European health research and safety science.

It's time to humanize European health research and safety science by making human — rather than rodent — biology the "gold standard."

The toolbox of advanced, non-animal technologies and predictive biology approaches ready to join the scientific and regulatory mainstream include:

- microphysiological systems such as organs-on-chips, for addressing health concerns such as lung and cardiac disease as well as personalized medicine;
- 3D organoids that have been used, among other things, to study the effects of viruses such as Zika and COVID-19 on the brain and to test the effects of available drugs in order to accelerate the availability of existing treatments;
- induced pluripotent stem cells that are widely used for everything from disease modelling to drug discovery to all sorts of chemical toxicity;
- computer or *in-silico* models used for predicting physical properties of chemicals, such as genotoxicity and protein reactivity, metabolism and movement through the body;
- integrated or "next generation" approaches that combine non-animal methods based on biological hypotheses.

These methods are centered on obtaining data based on human biology and, as such, have the potential to produce results that are more relevant to human health than animal models.

Better understanding the biology at the root of human diseases and toxicity brings us closer to personalized medicine tailored to each patients' specific genetic traits — or even to the use of bioprinting to grow living human organs from the cells of the patients who need them.

The EU's Beating Cancer Plan provides an excellent example of how we could make such technologies the preferred choice for public funding. In its communication, the Commission grounded its hopes to save millions of human lives on "the remarkable potential of new technologies" — in particular computer-based approaches, in order to "better address cancer across the entire disease pathway."

The Commission's Joint Research Centre has published a series of reports on advanced non-animal models, including for breast cancer, declaring that "breast cancer research currently relies heavily on animal models, which, however, have limitations in capturing important cancer traits". One of the main approaches recommended by the JRC to improve this is the use of human induced pluripotent stem cells (iPSCs).

How near is European cancer research and testing to achieving this vision? In 2019, EU-based researchers authored or co-authored more than 5700 academic articles on cancer research based on animal experiments. Only 67 used iPSCs, and 154 used organoids, while *in silico* methods fared somewhat better with 634 articles.

It says something about the current state of affairs that a rodent test devised more than half a century ago is still the go-to method for assessing the carcinogenicity of chemical substances, in spite of decades of proof from testing of hundreds of chemicals that the current rodent-based test fails to predict human outcomes.

> To change the paradigm we need to reverse the reliance ratio from largely animal to largely non-animal data.

To change the paradigm we need to reverse the reliance ratio from largely animal to largely non-animal data — starting with a concerted effort to redirect research funding. We can do so by identifying and defunding animal models that lack human relevance and clinical translation; investing more heavily in new technologies; training the research and regulatory workforce to use them; reforming regulations; and bringing together experts from the scientific community, regulated industries, NGOs and member states with EU institutions to advance our shared goals.

Nothing less than a comprehensive EU regulatory and research action plan is needed to achieve a paradigm shift in an acceptable timeframe. During the September plenary, MEPs can lead the way by voting in support of the resolution to "accelerate a transition to innovation without the use of animals in research, regulatory testing and education."

This chance is too important to miss — for animals and humans alike.

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