

Comment

The Turning Point: April 2025 Marks Historic Shift in US Animal Testing Policy

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Recent developments in the United States mark a significant turning point in the global transition away from animal testing toward more human-relevant approaches in biomedical research and regulatory science. In April 2025, we witnessed a remarkable synchronicity of policy initiatives across major US regulatory agencies, namely FDA, EPA and NIH, that signals a paradigm shift in how we approach safety testing and biomedical research.

The United States takes decisive action

On April 10, 2025, FDA Commissioner Martin A. Makary unveiled an ambitious roadmap aimed at rapidly reducing animal testing in preclinical safety assessments¹. This decisive action recognizes the significant limitations of animal models, highlighted by compelling statistics showing that more than 90% of drugs successful in animal tests ultimately fail in human trials due to unexpected efficacy and safety issues. On the same day, EPA Administrator Lee Zeldin announced a revival of the Agency's previous reduction targets for vertebrate testing, recommitting to eliminate animal tests by 2035².

Just weeks later, on April 29, the National Institutes of Health (NIH) announced a groundbreaking initiative to expand innovative, human-based science while reducing animal use in research³. Under the leadership of NIH Director Dr Jay Bhattacharya, this initiative will establish the Office of Research Innovation, Validation, and Application (ORIVA) to coordinate NIH-wide efforts to develop, validate, and scale the use of non-animal approaches across the agency's biomedical research portfolio.

These coordinated actions demonstrate a level of regulatory alignment rarely seen in policy shifts of this magnitude. The FDA's centralized regulatory role, combining responsibilities that in the EU are distributed among several agencies, has facilitated more streamlined decision-making processes and accelerated integration of innovative scientific advancements.

New approach methodologies take center stage

Central to these initiatives is the adoption of scientifically validated new approach methodologies (NAMs), including microphysi-

ological systems (MPS), computational modeling, and advanced human-based *in vitro* assays. These technologies not only promise enhanced predictability regarding human responses but also significantly mitigate the ethical dilemmas inherent in animal experimentation.

Microphysiological systems, in particular, stand at the forefront of this scientific revolution (Hartung and Smirnova, 2025). By combining microfabrication techniques with modern tissue engineering, these technologies offer new *in vitro* approaches to drug screening by mimicking the complicated mechanical and biochemical behaviors of human organs.

The MPS World Summit: A critical platform for progress

As these regulatory shifts accelerate the adoption of human-relevant technologies, the 4th MPS World Summit represented a crucial milestone in this global transition. Held on June 9-13, 2025⁴, in Brussels, Belgium, organized by the International MPS Society (IMPSS⁵), taking over from our center CAAT, and co-organized by EUROoCS⁶, this summit brought together almost 1,500 participants and 124 sponsors from international organizations and companies to present the latest scientific achievements, discuss advances and challenges, and enable communication between young scientists and pioneers in the MPS field.

The timing of this summit could not have been more opportune. With the FDA, EPA, and NIH all embracing NAMs and MPS technologies, the summit provided a critical platform for translating these policy commitments into practical scientific applications.

Europe at a crossroads

While the United States has taken decisive action, the European Union finds itself at a critical juncture. Long positioned as a global leader in ethical science, particularly regarding the reduction of animal testing, the EU is now engaged in a comprehensive yet protracted process of developing its own roadmap. Prompted by the European Citizens' Initiative "Save Cruelty-Free Cosmetics"⁷, which gathered over 1.2 million signatures, this process has led to extensive consultations and stakeholder engagements.

¹ <https://www.fda.gov/media/186092/download?attachment>

² <https://www.washingtontimes.com/news/2025/apr/10/epa-chief-lee-zeldin-eyes-ban-animal-testing/>

³ <https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies>

⁴ <https://mpsworldsummit.org>

⁵ <https://impss.org>

⁶ <https://euroocs.eu>

⁷ https://citizens-initiative.europa.eu/save-cruelty-free-cosmetics-commit-europe-without-animal-testing_en



However, the EU's methodical approach risks being outpaced by its faster-moving global counterparts⁸. Finalization of the EU roadmap is anticipated early 2026, with concrete implementation timelines still uncertain. This cautious progression stands in stark contrast to the immediate, actionable steps outlined in the FDA's roadmap.

The EU must recognize and learn from the urgency and effectiveness embodied by recent US actions. By reducing the complexity inherent in multi-agency interactions and adopting a more streamlined decision-making framework, the EU could significantly enhance its regulatory agility and responsiveness. Central to this, the EU Partnership for the Assessment of Risks from Chemicals⁹ must be transformed into a more sustainable structure as suggested earlier (Busquet and Hartung, 2017).

Looking forward: A global perspective

The convergence of mounting evidence on animal model failures, mature NAM toolboxes, and regulatory pressure against animal testing has created a unique moment of opportunity. The recent leadership changes at FDA, NIH and EPA, together with bipartisan support for the FDA Modernization Act 2.0 and major investment in NIH programs¹⁰, have aligned actor coalitions and funding priorities in the United States. Hopefully, the next EU Framework Program for research funding will provide for similar expansion and re-orientation.

As we move forward, it is essential that these advances in human-relevant technologies are implemented globally, not just in Western nations. Countries in the Global South – as importers of medicines and chemicals – will effectively be asked to align their safety assessments with NAM-based evidence. This presents both opportunities for technological adoption and challenges for capacity-building. Implementation strategies must emphasize co-development of NAMs with low- and middle-income countries, including shared training programs, technology transfer grants, and regional validation centers.

The MPS World Summit in Brussels and the upcoming one in Washington, DC, in 2026, represent a pivotal opportunity to advance these global considerations. By bringing together researchers, regulators, and industry representatives from across the world, the summit can help ensure that the benefits of human-relevant technologies are shared equitably across regions and economies.

Conclusion

We stand at the brink of a new era in biomedical research – one that promises not only more ethical practices but also more effective and efficient scientific outcomes. The coordinated actions of US regulatory agencies have demonstrated that decisive progress is possible when scientific evidence, ethical considerations, and regulatory willpower align.

As we return from the MPS World Summit in Brussels, let us bring this same spirit of urgency and purpose to the global stage. The transition to human-relevant technologies represents not just scientific advancement but a fundamental reimagining of how we conduct research to benefit human health while respecting animal welfare and advancing ethical science.

The road ahead will require continued collaboration, innovation, and determination, but the destination – a research paradigm that better serves both human health and ethical principles – is clearly within reach.

References

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⁸ <https://policylabs.frontiersin.org/content/commentary-roadmap-to-reduce-animal-testing>

⁹ <https://www.eu-parc.eu>

¹⁰ <https://commonfund.nih.gov/complementarie>