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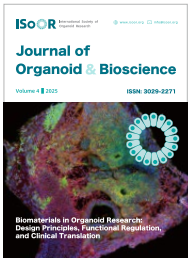

Industry News

Major Shift in U.S. Research Policy: CDC to End All Nonhuman Primate Experiments by 31 December 2025

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Abstract

On 21 November 2025, the U.S. Centers for Disease Control and Prevention (CDC) received an internal directive from the Department of Health and Human Services (HHS) ordering the complete termination of all in-house research involving nonhuman primates – approximately 200 macaques – by the end of the calendar year. This is the first time since the NIH chimpanzee retirement in 2015 that a major federal agency has fully shuttered an active, government-owned NHP colony. The decision, driven by persistent primate shortages, documented biosafety incidents, translational failures of NHP models, and the accelerating maturity of human-relevant alternatives (organoids, microphysiological systems, organ-on-chip platforms, and AIintegrated digital twins), constitutes one of the most far-reaching policy realignments in U.S. biomedical research since the Animal Welfare Act of 1966 and the FDA Modernization Act 2.0 of 2023. This Industry News analysis places the CDC directive in full scientific, ethical, and regulatory context, evaluates the evidence base, addresses remaining challenges, and explores the transformative opportunities this shift creates for the organoid and bioscience sectors.

Keywords

Organoids; microphysiological systems; nonhuman primates; CDC policy; translational research; human-relevant models; organ-on-chip; infectious disease; FDA Modernization Act 2.0; ISoOR standards; NAMs

Introduction

For more than seven decades, rhesus and cynomolgus macaques have been considered the gold-standard model for HIV, tuberculosis, Zika, Ebola, and biodefence research within the CDC.

On 21 November 2025, however, Science magazine published an exclusive report revealing that HHS Secretary Robert F. Kennedy Jr., through deputy chief of staff Sam Beyda and the "Make America Healthy Again" (MAHA) initiative, had ordered the CDC to end all monkey experiments and decommission its remaining colonies by 31 December 2025 [1]. Subsequent reporting in Scientific American,Nature, FierceBiotech, and STAT confirmed the directive and revealed that the approximately 200 animals currently housed at the Roybal Campus in Atlanta and associated facilities face either retirement to accredited sanctuaries or, in the likely event of insufficient sanctuary capacity, euthanasia [2,3].

Background:Four Converging Crises That Made Continuation Untenable

1.Translational discordance – Decades of comparative genomics and immunology have documented systematic species differences in ACE2 receptor affinity, innate immune signalling (e.g., type I interferon pathways), cytokine storms, and drug metabolism that frequently invalidate NHP findings in human trials.

2.Supply-chain collapse and biosafety incidents – Between 2021 and 2024, the CDC documented 69 cases of tuberculosis in newly imported macaques during quarantine, highlighting ongoing zoonotic and reverse-zoonotic risks. Import restrictions implemented during and after the COVID-19 pandemic reduced annual U.S. primate imports by >80 %, driving per-animal costs above $100,000 [1].

3.Ethical and political pressure – Sustained public advocacy made continued federal funding politically radioactive [4,5].

4.Maturation of alternatives – By mid-2025, more than 40 organoid and MPS assays had achieved formal context-of-use validation under FDA and NIH NAM programmes, many of them directly relevant to CDC mission areas.

The CDC Directive: Timeline and Details

Internal CDC documents leaked to Science state explicitly that "nonhuman primate research no longer meets the agency's optimal scientific, operational, biosafety, and ethical criteria" [1]. The directive mandates:

- Immediate freeze on new NHP protocol approvals
- Termination of all ongoing studies by 31 December 2025
- Full decommissioning of primate housing facilities
- Reallocation of the estimated $20–30 million annual NHP budget toward New Approach Methodologies infrastructure

HIV researchers such as Jonah Sacha (Oregon Health & Science University) and Dan Barouch (Harvard) have publicly warned that the abrupt timeline could "set back HIV cure and prevention research by a decade" [2]. Conversely, the Physicians Committee for Responsible Medicine and PETA have launched campaigns urging Congress to appropriate dedicated sanctuary funding to prevent euthanasia [4,5].

Scientific Evidence Supporting the Transition

High-profile failures have eroded confidence in NHP models:

- SARS-CoV-2 causes only mild, self-limiting disease in most macaque species, severely limiting utility for severe COVID-19 or long COVID studies
- HIV-1 mucosal transmission efficiency, viral set-point, and elite-controller rates differ markedly from human epidemiology

- Multiple tuberculosis vaccine candidates that protected macaques failed spectacularly in human efficacy trials

In parallel, human organoid platforms have achieved unprecedented fidelity:

- Cerebral organoids recapitulate Zika microcephaly and SARS-CoV-2 neurotropism with patient-specific genetic backgrounds
- Airway and alveolar organoids support full replication cycles of influenza A/B, RSV, and human metapneumovirus
- Intestinal organoids sustain norovirus, rotavirus, and enterovirus propagation – pathogens that historically required primates or gnotobiotic animal models
- Vascularised, multi-lineage lung- and liver-on-chip platforms now integrate circulating human immune cells, mechanical breathing, and perfusion, enabling modelling of cytokine storms and antibody-dependent enhancement

Rise of Human-Relevant Alternatives

The FDA Modernization Act 2.0 (2023) and the subsequent 2024-2025 FDA/NIH NAM Roadmaps have created a clear regulatory pathway for organoid and MPS data in IND and BLA submissions. By December 2025, the following platforms had achieved formal qualification or context-of-use letters:

- Emulate Lung-Chip for viral infectivity and drug-induced pulmonary injury
- HUB multi-organoid systems for hepatotoxicity and intestinal barrier function
- TISSUSE Humimic Chip 4 for multi-organ pharmacokinetics

In March 2025, the International Society for Organoid Research (ISoOR) published the ISoOR-ISOB international biobanking and quality-control standards, providing the first globally harmonised framework for organoid identity, viability, and functional benchmarking – a critical step toward regulatory-grade replacement of NHP cohorts [1,2].

Implications for Biomedical Research and Public Health

1.Infectious-disease modelling - Organoid panels now enable same-week, highthroughput pathogenicity screening of novel isolates with human-specific receptor usage.

2.Vaccine development - HLA-typed lymphoid organoids and tonsil organoids permit precise measurement of germinal-centre reactions and neutralising antibody maturation without cross-species artefacts.

3. Biodefence - Multi-organ chips with integrated immune compartments can model select-agent pathogenesis under BSL-4 conditions using far lower biocontainment burdens.

4. Resource reallocation - The CDC's liberated budget is expected to seed major new initiatives, including a rumoured FY2027 NIH "Moonshot for Human- Relevant Infectious Disease Models".

Remaining Challenges

Full systemic physiology (neuro-immune-endocrine axes, long-term chronic infection, pregnancy models) remains difficult. Standardisation of vascularisation and immune-cell integration is still evolving. However, 2025 high-throughput droplet,

microwell, and bioreactor platforms have reduced per-assay costs below those of many historical NHP studies, and reproducibility metrics now routinely exceed those of primate cohorts.

Ethical, Regulatory, and Global Dimensions

The CDC decision aligns with Europe's parallel trajectory: the Netherlands announced closure of its Biomedical Primate Research Centre by 2028, and the European Parliament is debating a 2030 phase-out roadmap. Sanctuary capacity remains the immediate humanitarian bottleneck; only ~500 lifetime spaces exist in accredited U.S. facilities for the thousands of federally owned primates[3,4].

Outlook for Organoid Science and Biotechnology

The CDC directive is expected to catalyse:

- Multi-hundred-million-dollar funding lines for organoid biomanufacturing and MPS scale-up
- Expanded pre-competitive consortia (ISoOR, IQ Consortium, NC3Rs, FDA ISTAND)
- Commercial launch of cryopreserved, ready-to-use, HLA-diverse organoid panels targeting the $2–3 billion infectious-disease modelling market
- Accelerated regulatory acceptance of multi-organoid platforms as standalone evidence for vaccine efficacy and countermeasure licensure

Conclusion

The CDC's decision to end all nonhuman primate research by 31 December 2025 marks the end of an era and the decisive beginning of another. It is a policy built on decades of evidence that NHP models frequently mislead rather than illuminate human disease, compounded by supply, safety, and ethical crises that have become insoluble. For the organoid and bioscience communities, the responsibility is immense: to deliver standardised, reproducible, regulatorily accepted human platforms at scale within the next 3–5 years. The opportunity is historic: to redefine infectious-disease research, vaccine development, and public health preparedness on the unshakable foundation of actual human biology.

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Conflicts of interest

The authors declare no conflicts of interest.