Cure COALITION

Research Brief No. 01

The science hasn't changed. *The spin has.*

Advocates in Washington are racing to phase out the animal research behind America's cures — citing a scientific consensus the scientists themselves never reached.

Washington says the science has moved on. *The scientists didn't.*

You've seen the campaign: the emotional images, the promise that new technology can finally end animal testing. It is working — across the federal government, the message has taken hold.

In 2025, the FDA published a roadmap to phase out animal testing in preclinical safety studies. The Secretary of Health and Human Services has made it a personal priority. The NIH director announced a parallel push to cut animal use. The Departments of Veterans Affairs and the EPA are moving the same way. And Congress has already cleared the runway: the FDA Modernization Act 2.0 removed the longstanding requirement that new drugs be tested in animals, and 3.0 directed the agency to formalize non-animal methods.

It sounds compassionate, and parts of it are genuinely promising. Reducing unnecessary animal testing is an important goal, but right now humane animal models are irreplaceable for the study of certain diseases, biological processes, and treatments. There's just one problem — the scientists who actually develop America's cures say the replacements aren't ready, and that moving this fast will cost patients and hand America's research lead to its rivals.

DON'T TAKE OUR WORD FOR IT.

The most respected research institutions in America say — on their own public websites — that animal research remains essential and irreplaceable to developing safe medicines:

- Stanford
- Harvard
- University of Michigan
- UT Austin
- University of Florida
- University of Virginia

That gap — between what advocates in Washington say the science shows and what the scientific institutions themselves say — is the whole story.

"NAMs" aren't *one thing.*

The proposed replacements share a friendly umbrella name: New Approach Methodologies, or NAMs. But the term covers three very different families of technology at very different stages of maturity:

In Vitro & Organoids

lab-grown human tissues and microfluidic "organ-on-a-chip" systems that mimic how a single organ behaves outside the body.

In Silico

Computer models and AI-driven simulations that predict how drugs will behave in the body. Powerful for screening, but limited by the data they're trained on.

Human-Cell Assays

Tests using human-derived cells to measure biological responses. Useful for toxicity screening but cannot capture systemic effects like immune response or metabolism.

Talked about together, they sound like a finished, ready-to-deploy substitute for animals. They are not. A few are genuinely useful today. Most are years away from being validated to protect human safety.

The real trouble is how they are sold. By folding every NAM into a single framework, advocates create a false equivalence — treating platforms with wildly different track records as if they were equally proven. **Some are ready for prime time. Many are not.** Lumping them together lets the future be sold as if it has already arrived, and leaves the sponsors and reviewers who must use these tools to guess where the line really is.

It's like clearing a bridge for traffic off the blueprints — *before it's built.* The plans look great. You still wouldn't drive your kid across it.

A cell on a chip *isn't a person.*

Start with the most celebrated NAMs: organoids and organ-on-a-chip systems. They are real achievements, able to mimic many features of living human tissue. But the National Academies' 2023 review was blunt about their ceiling. In their current state, these models cannot reproduce the full complexity of a living system, or capture the processes that require the whole body working at once.

A liver chip can tell you about a liver. It cannot tell you what a drug does to a living person whose dozens of organs are all reacting together. Some outcomes, like behavior, can only be studied in a living organism.

THE PRACTICAL PROBLEMS ARE JUST AS REAL.

A 2026 Government Accountability Office review found the same technology held back by hard, unglamorous obstacles:

! Researchers struggle to obtain enough **high-quality human cells** to run the tests reliably.*

! There is a **lack of benchmark and validation studies** to prove the chips measure what they claim to.

! Competing companies **share little data**, and federal guidance on meeting regulatory requirements is unclear.

None of this means the technology is worthless. It means the technology is early — and early is not the same as ready.

*U.S. GOVERNMENT ACCOUNTABILITY OFFICE · 2026

AI can't feel *a side effect.*

The other great hope is in silico modeling — computer simulation and artificial intelligence. It is powerful for speeding up early discovery, and it deserves investment. But it runs into a hard limit: a model is only as good as the data fed into it, and no simulation can fully account for the unforeseen ways a living body reacts.

The FDA's own analysis names the risks. AI can carry hidden **bias** that makes its results unreliable. Its conclusions can be a **black box** — difficult to interpret or explain even for the people who built it. And its performance can **drift** as it meets new data it was never trained on. These aren't reasons to abandon AI. They are reasons not to stake a patient's life on it yet.

THE VERDICT FROM THE TOP SCIENTIFIC BODY IN THE COUNTRY

After weighing, the National Academies reached a one-sentence conclusion that should give Washington pause: there are **"no alternative approaches that can replace nonhuman primate (NHP) models"** for research that requires complete, integrated biology.

They added a note of optimism — this *may* change as the methods mature.
May. Not has.

Two other authorities reach the same conclusion. Researchers reviewing the FDA's plan call the new methods "not yet ready for prime time." The leading biomedical research association states flatly that there is **no full replacement** for animal models in drug development. And critically, no one has yet run the head-to-head studies that would prove a NAM is as reliable as the animal model it would replace. Until that work is done, replacement is a leap of faith, not a finding.

The real driver isn't science. *It's activists.*

Here is the tell. If every leading research university still calls this work essential, and the National Academies say no replacement exists, then the "consensus" behind a forced phase-out is not a scientific finding. It is the product of a decades-long pressure campaign by activist groups like **PETA** and the **White Coat Waste Project** with a movement goal to end animal research.

Read the federal roadmap closely, and its rationale rests as much on ethical concerns as on evidence. Those are values arguments — reasonable people can hold them — but they are not safety data, and they should not be dressed up as if they were. Many people agree that it is important to reduce unnecessary animal testing, but with replacements that are scientifically defensible alternatives. When a values campaign is relabeled "scientific recognition," lawmakers are being asked to vote on a slogan, not a finding.

The picture ends up distorted in both directions — overstating what these methods can do today while tempting us to dismiss what they genuinely offer. The truth is more useful than the slogan.

NAMs matter. *Just not as a replacement.*

None of this means the new methods are worthless — far from it. The science is clear that NAMs cannot yet replace non-human primates (NHPs), but several are already earning their place: **complementing NHP studies** and **reducing how many animals a program needs.** The goal is a smarter overall approach to safety — not a one-for-one swap for the animal test. A few examples:

In vitro immunoassays

Tests built on cultured human cells can help predict how a person will react to biologic therapies — like monoclonal antibodies, which can trigger deadly cytokine release syndrome — and cut the need for NHPs in that specific work.

Microphysiological systems (MPS)

These 3D, lab-grown "organ" platforms are now sophisticated enough to model a drug's effect on individual human organs, and even some organ-to-organ interactions. Promising, though still unable to reproduce the full complexity of a living body.

Brain organoids

Lab-grown neural tissue lets researchers study neurodevelopment and brain physiology in ways that were previously out of reach.

AI and machine learning

Trained on decades of existing NHP data, these tools can surface fresh insights from past studies — and even serve as a virtual control group in later trials, cutting the number of animals a program has to use.

These are real contributions. But notice what even their strongest champions concede. As Harvard Medical School puts it, these technologies **"cannot yet replace animals fully"** — because some biology can only be understood in a whole, living system. Drug metabolism is the textbook case: how the body processes and breaks down a compound, and whether it harms any organs along the way, simply can't be seen outside the complexity of a living body.

TO BE CLEAR ABOUT WHERE WE STAND

The Cure Coalition is for progress. We support better, more humane research methods — the moment they are proven to protect patients as well as the tools they would replace, with a real validation standard behind them. What we oppose is pretending they are proven when they are not.

Validate first. Replace second. Not the reverse.

"...rigorous validation of these new methods is essential — and we're just not there yet."

PROF. SARA GERKE · CO-AUTHOR, "THE FDA'S PLAN TO PHASE OUT ANIMAL TESTING" (2026)

When the model goes before the replacement is ready, patients become the test.

A risk America *can't outsource.*

There is a dimension to this debate that rarely makes the headlines, and it matters most of all. Research that is shut down here does not simply disappear. It relocates.

IF WE WON'T DO IT, BEIJING WILL.

Shifting nonclinical safety standards faster than NAMs are matured and validated for use may create serious unintended consequences. When America hollows out its own research before replacements are ready, the work doesn't stop — **it moves.** It moves to China, where oversight, transparency, and ethical standards do not meet the American gold standard.

We would be handing our chief rival the lead in the very science that produces the next generation of cures and vaccines — and **making American families dependent on Beijing for their medicine.** When the next pandemic arrives, we would be slower, less prepared, and reliant on an adversary for the cure.

And there is a quieter danger here at home. When solid preclinical research is weakened, the pressure grows to rush treatments to market with safety questions still unanswered — effectively turning patients, including children and pregnant women, into the first real test. That is not only a health decision. It is a national-security risk, and a patient-safety one.

CHINA CONCERNS UNITE A SPLIT ELECTORATE.

(62% VS. 8%)

ROUGHLY 8 TO 1

voters trust U.S.-made medicine over Chinese.

ONLY 41%

are confident drugs made in China are safe.

74%

are concerned that rolling back U.S. testing rules would push research to China.

What Congress *should do.*

No one in this debate wants more animals in laboratories than necessary. The disagreement is only about sequence — and getting the sequence wrong puts patients and American leadership at risk. Three principles should guide every vote:

1. **Reject arbitrary deadlines.**
No legislated three-to-five-year clock for phasing out animal research. A calendar is not a scientific milestone. Timelines must follow the evidence, not drive it.

2. **Demand validation before replacement.**
Require any new method to prove — through real head-to-head studies — that it is at least as safe and reliable as the animal model it would replace, before it replaces anything.

3. **Keep American research American.**
Protect domestic research capacity and supply chains so the science, and the safety standards that come with it, stay here — not in Beijing.

The goal we share is fewer animals in labs and faster cures for families. The way there is to build the replacements right — and prove they work — before we tear down what keeps patients safe today.

FDA, *Roadmap to Reducing Animal Testing in Preclinical Safety Studies* (2025); FDA guidance on the limitations of AI models in regulatory decision-making; FDA Modernization Acts 2.0 and 3.0; National Academies of Sciences, Engineering, and Medicine, *Nonhuman Primate Models in Biomedical Research* (2023); U.S. Government Accountability Office report on organ-on-a-chip technologies (2026); National Association for Biomedical Research, statement on FDA animal-testing plans; S. Gerke et al., "The FDA's Plan to Phase Out Animal Testing" (2026); Harvard Medical School, "New paper urges caution as FDA plans to phase out animal testing in drug development" (2026). University positions drawn from the public research-program pages of Stanford, Harvard, the University of Michigan, UT Austin, the University of Virginia, and the University of Florida.