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FDA Signals Flexibility In Pitch To Reduce Animal Testing

By **Dan McKay**

Law360 (April 21, 2026, 5:34 PM EDT) -- New guidance proposed by the U.S. Food and Drug Administration suggests federal regulators are willing to be flexible as they encourage drug developers to reduce animal testing and shift instead to other methods of researching drug safety, experts say.

It may take years, however, for the new methods to take hold. Researchers and regulators will need time to work through real-world examples that set a precedent for when it's safe to substitute a computer model or laboratory experiment for an animal study, experts say.

The draft guidance "is just the next step. I think there's a lot more to come," said Sara M. Klock, a partner at Holland & Knight LLP and member of the firm's public policy and regulation group.

The **guidance** — open for public comment through May 18 — outlines what FDA regulators will look for when a drug developer proposes using a nonanimal method to test the safety of a product before human trials. The alternatives to animal testing are known as new approach methodologies, or NAMs.

The agency's guidance calls broadly for companies to show that any new method will produce reliable results while leaving unanswered plenty of key questions about what will be deemed an appropriate alternative, lawyers said.

Jacqueline R. Berman, a partner at Morgan Lewis & Bockius LLP, called the guidance a "mixed bag."

Regulators didn't provide many specifics, she said. But they showed real flexibility by revealing they'll consider alternative methods even if a new approach hasn't been through a formal "validation" process to verify its accuracy.

"The big question is what NAMs FDA will accept and what they will substitute for," Berman said in an interview. "And I think that we'll only really see as industry begins to use these, begins to talk with FDA about these, and products that have relied on these work their way through the pipeline."

President Donald Trump's administration unveiled the draft guidance March 18, promoting it as a vital move toward reducing the use of mice, primates and other animals in drug testing.

While the administration has locked horns with drugmakers over vaccines and drug pricing, among other issues, reducing reliance on animal testing is common ground.

Drug companies "don't especially want to experiment on animals for a lot of reasons, including accuracy, time, money, animal welfare, public opinion," said Delcianna Winders, a professor and director of the Animal Law and Policy Institute at the Vermont Law and Graduate School.

"But they've been put, oftentimes, in a really tough position of not knowing what the FDA is going to be OK with — what they're going to demand," she said.

Growing Campaign

A bipartisan push to replace animal testing has accelerated in recent years. Congress passed an FDA modernization law in 2022 authorizing the use of alternatives to animal testing in drug development.

Reduced animal testing is also a priority of the Trump administration's "Make America Healthy Again" movement, and it was **recommended** last year by a MAHA Commission led by Health and Human Services Secretary Robert F. Kennedy Jr.

Under Kennedy, the FDA has cast doubt on the value of data derived from animal testing and supported a shift in drug testing to computer modeling, a still-emerging technology known as "organ-on-a-chip," and laboratory experiments.

A year ago, the agency **issued** a broad "roadmap" for reducing animal testing. Regulators followed up with draft guidance in December that says primate studies aren't always necessary for testing monoclonal antibodies.

The FDA has also established a searchable database outlining examples of when drugmakers can reduce the use of animal testing.

Certain toxicology studies for a biologic product, for example, don't necessarily require the inclusion of "recovery animals," which are used to determine whether a toxic effect is permanent or temporary, according to the database.

The Trump administration doubled down on the effort March 18 with the draft guidance, which outlines how drug developers can convince the FDA it's safe to use NAMs as part of the process to secure approval for human trials.

The draft guidance "shifts the burden from 'prove this alternative is acceptable' to 'demonstrate this method meets established validation principles,' a subtle but significant change that positions human-relevant methods as the default rather than the exception," FDA officials said Monday in a **report** outlining the progress toward reduced animal testing.

In the guidance, the FDA suggests submitting evidence that the NAM can produce risk data that's as accurate as an established testing method. But the agency left open the possibility that a formal validation process may not be required, with regulators considering the total weight of the evidence and whether the nonanimal method is fit for the purpose proposed by the drugmaker.

Kennedy and FDA Commissioner Marty Makary, a physician, have pitched the draft guidance as a way to get new treatments to patients faster, not just protect animals.

The newly developed alternatives "can often be better, cheaper, safer and more humane in predicting toxicity," Makary said in a social media video.

"Animal testing is also just not very good when it comes to scientific predictive modeling," he said. About "90% of drugs that pass on animal testing do not pass in human testing when it comes to safety and efficacy."

Coinciding with the draft guidance, the National Institutes of Health on March 18 unveiled a $150 million effort to develop computer- and lab-based alternatives to animal testing.

Alternatives to animal testing may also surface in the next reauthorization of the Prescription Drug User Fee Act, or PDUFA. Talks are already underway to reauthorize the law, which allows the FDA to impose fees to fund efforts to expedite the review of drug applications.

Anna K. Abram, a senior adviser at Akin Gump Strauss Hauer & Feld LLP, said streamlining drug development is a "perpetual interest of policymakers."

"This is definitely an area to watch as momentum on NAMs is picking up ahead of Congress considering the next PDUFA reauthorization," she told Law360 Healthcare Authority.

Drugmakers Should Communicate Early, Often

Winders, the law professor, said the guidance sends an important message to the FDA's own staff, not just drug companies, instructing frontline regulators to consider alternatives to animal testing.

"This signals to the FDA reviewers, 'Here are the guidelines you're supposed to apply. Here's some objective criteria, and you need to take seriously when a developer proposes to use a NAM,'" Winders said.

Winders is optimistic about the possibility of reduced animal testing given the bipartisan federal support and industry desire to cut development costs. But there's also a long way to go. The NIH's $150 million funding announcement is tiny compared to the amount the agency spends on animal experiments each year.

About 100,000 primates and 40,000 dogs are in U.S. research labs, in addition to hamsters, gerbils, birds and zebra fish, she said.

"You name it — we're probably experimenting on them in some way. But rats and mice are the biggest category," Winders said.

Berman of Morgan Lewis said the draft guidance "signals an FDA willingness to work with sponsors" and reduce the time and cost to develop new drugs.

Drug companies should get in touch with the agency early and communicate clearly if they're planning to use an alternative to animal testing, she said.

"It's really important for companies who are thinking about using these to talk to FDA — because it will initially likely be a case-by-case decision," Berman said.

Klock of Holland & Knight said it will take time for the new methods to take hold, but it's "possible that we can get clinical trials done at a faster, cheaper rate."

"Ultimately that's the goal — that you still have the same efficacy and the same safety, but the way you got from A to Z looks a little bit different," she said.

In response to a comment request, an FDA spokesperson on Tuesday highlighted Makary's recent public statements touting the agency's efforts to reduce animal testing.

"In addition to ushering in more scientifically accurate way to test drugs before they are used in humans, the agency has made great strides to reduce research and development costs, which will lower drug prices for everyday Americans," Makary said Monday in a news release.

--Editing by Abbie Sarfo.
