November 25, 2025

Jay Bhattacharya, MD, PhD
Director, National Institutes of Health

Marty Makary, MD, MPH
Commissioner, U.S. Food & Drug Administration

Nicole Kleinstreuer, PhD
Acting Deputy Director for Program Coordination, Planning, and Strategic Initiatives, National Institutes of Health

Dear Drs. Bhattacharya, Makary, and Kleinstreuer,

On behalf of Americans for Medical Progress (AMP), we appreciate the National Institutes of Health (NIH) and the Food and Drug Administration's (FDA) ongoing efforts to strengthen biomedical research innovation and public trust while advancing meaningful progress in non-animal alternatives and New Approach Methodologies (NAMs).

The United Kingdom's (UK) new national strategy, *Replacing Animals in Science: A Strategy to Support the Development, Validation and Uptake of Alternative Methods*, presents a timely opportunity for U.S. science agencies to align and provide clarity around a complex and highly visible policy issue. Although the roadmap's long-term goal is to reduce reliance on animals, it is distinguished by its balanced perspective, the absence of bans or arbitrary deadlines, and its acknowledgment that animal studies remain necessary where alternatives are not yet validated. The roadmap also reinforces the notion that policy should follow evidence rather than ideology and calls for coordinated collaboration among regulators, industry, academia, and funders. This model offers a constructive framework for realistic, responsible, and coordinated progress.

As U.S. strategies around NAMs and alternative methods continue to evolve, we respectfully offer the following recommendations to support a balanced, evidence-driven path forward:

Key Recommendations

1. **Emphasize integrative research strategies rather than exclusionary approaches.**
   Policy discussions should continue to recognize that alternatives are not yet capable of fully replacing animal studies in all contexts, and that responsible progress depends on using the most appropriate tools for each scientific question. In many cases, this requires applying non-animal methods in conjunction with animal studies, rather than in isolation. Policy discussions and strategic planning should reflect a realistic spectrum of readiness, such as the UK's three-basket model, which distinguishes between:
   a. Alternatives ready for immediate use and regulatory transition;
   b. Alternatives that are promising but require further validation and investment; and
   c. Emerging tools that represent longer-term research priorities

A similar landscape analysis in the United States, led jointly by NIH (specifically the newly established

Office of Research Innovation and Application, ORIVA) and FDA, could help set realistic public expectations, inform funding priorities and regulatory planning, and enhance interagency coordination.

2. **Strengthen collaboration and coordinated regulatory strategies across research sectors.** Transparent, cross-stakeholder engagement—including active involvement from medical research organizations and other public stakeholders—will accelerate progress and strengthen public confidence. Importantly, success will depend on aligning communication and research strategies across federal agencies to streamline expectations and minimize confusion. Such coordination is essential to prevent regulatory contradictions that could delay scientific advancement or the approval of emerging technologies.

3. **Clarify terminology and promote equitable investments in the full 3Rs framework.** Exploring terminology alignment—including the potential use of the term "alternatives," as adopted in the UK—could improve clarity around NAMs and the 3Rs, support consistent communication across agencies, and mitigate confusion stemming from multiple acronyms and varied definitions. However, if NIH and FDA proceed with adopting the term "alternatives," we encourage ensuring explicit investments and resources for reduction and refinement. These two "Rs" are foundational to achieving long-term replacement but are currently under-supported relative to replacement-focused efforts.

Taken together, we respectfully urge NIH and FDA to develop a U.S. strategy modeled after the UK roadmap's balanced and collaborative approach. We welcome the opportunity to provide feedback, participate in stakeholder conversations, or assist in convening scientific and institutional voices to help ensure that implementation in the U.S. remains guided by rigor, transparency, and shared purpose.

Thank you for your leadership and for your continued stewardship of science and public health. We look forward to supporting meaningful, measured, and evidence-based progress that advances innovation while protecting the integrity of research and regulatory decision-making.

Sincerely,

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