Food and Drug Administration
Rockville, MD 20852

In the Matter of Regulatory Science Innovations Catalyzing Medical Device Development (Docket No. FDA-2026-N-8563)

The American Consumer Institute (ACI) is a nonprofit 501(c)(3) education and research organization. Its mission is to promote consumer welfare by enhancing the understanding and impact of public policies and regulations on consumers in a free market.

Patients benefit when medical device manufacturers compete to offer safer, more effective, and more convenient ways to receive care. Regulatory requirements often influence whether those innovations reach patients. The Food and Drug Administration (FDA) should use this initiative to reduce unnecessary costs and uncertainty in demonstrating safety and effectiveness so that more innovations can reach patients. We urge the agency to prioritize predictable device updates, reusable testing methods, and clearer acceptance of alternative evidence regarding the safety and efficacy of medical devices. These priorities would give innovators more room to compete while directing regulatory attention toward devices that raise clear safety and efficacy concerns.

Make evidence and planned updates predictable

Research published in 2017 found that pioneering high-risk devices spent 34 percent, or 7.2 months, longer in approval than follow-on entrants.[1] Objective guidance reduced review time, and smaller firms were less likely to pioneer without it. Compliance costs affect which firms can enter a market and which improvements are worth pursuing. An established manufacturer can spread fixed regulatory costs across a larger portfolio, while a smaller firm may have fewer products to support that expense. Unclear requirements add uncertainty about how much capital a project will need and when it can begin generating revenue regardless of firm size. Those historical findings illustrate why predictability matters. Reducing avoidable costs and uncertainty can make entry more attractive and create competitive pressure in the medical device industry.

[1] Ariel Dora Stern, "Innovation under Regulatory Uncertainty: Evidence from Medical Technology," *Journal of Public Economics* 145 (2017): 181–200, https://doi.org/10.1016/j.jpubeco.2016.11.010.

The FDA should streamline approvals by making predetermined change control plans (PCCPs) a more predictable option across eligible devices. Congress authorized the use of PCCPs for eligible medical devices.[2] While the FDA has final guidance for AI-enabled device software,[3] the agency's broader device guidance remains a draft.[4] The agency should finalize that guidance and expand its published examples to cover appropriate modifications to robotics, wearables, imaging equipment, and other devices.[5]

Under an authorized plan, manufacturers can implement prespecified changes without a separate marketing submission, provided they meet the plan's requirements. Regulatory science should help establish how to define those changes, validate performance, and detect problems after implementation. A manufacturer considering a control-system improvement or sensor change should have a clearer basis for determining whether its changes fit within a PCCP and what evidence the FDA will need. Making the process more predictable would reduce the chance that avoidable review costs discourage worthwhile improvements and leave patients using old technology longer than necessary.

The FDA should also prioritize expanding evaluation methods that manufacturers can reuse. Its Medical Device Development Tools program already qualifies tools for a specified context of use, allowing them to support multiple development programs and submissions.[6] The program tells manufacturers in advance that the FDA will accept the tool for that use without requiring each company to reestablish its suitability.[7] That gives firms a clearer basis for choosing tests and committing development funds. The FDA currently lists 21 qualified tools including the Kansas City Cardiomyopathy Questionnaire,[8] which measures heart-failure symptoms and quality of life, and a tissue-mimicking material[9] for testing the acoustic performance of high-intensity therapeutic ultrasound devices. Using an already qualified questionnaire or testing material can help manufacturers direct resources toward improving their devices rather than reestablishing an evaluation method's suitability.

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[2] Federal Food, Drug, and Cosmetic Act § 515C, 21 U.S.C. § 360e-4(a)—(c) (2024), https://www.govinfo.gov/content/pkg/USCODE-2024-title21/pdf/USCODE-2024-title21-chap9-subchapV-partA-sec360e-4.pdf.

[3] U.S. Food and Drug Administration, *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions* (final guidance, 08/18/2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.

[4] U.S. Food and Drug Administration, *Predetermined Change Control Plans for Medical Devices* (draft guidance, 08/22/2024), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices.

[5] U.S. Food and Drug Administration, "Novel Medical Devices with Predetermined Change Control Plans: Hypothetical Case Examples," accessed 10/23/2026, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/novel-medical-devices-predetermined-change-control-plans-hypothetical-case-examples.

[6] Margaret V. Caulk, "Introduction to Medical Device Development Tools (MDDTs)" (training slides, U.S. Food and Drug Administration, n.d.), slide 11, accessed 10/23/2026, https://www.fda.gov/media/194869/download.

[7] U.S. Food and Drug Administration, "Medical Device Development Tools (MDDT)," accessed 10/23/2026, https://www.fda.gov/medical-devices/medical-device-development-tools-mddt.

[8] U.S. Food and Drug Administration, *Medical Device Development Tool (MDDT) Qualification Decision Summary for Kansas City Cardiomyopathy Questionnaire (KCCQ)*, MDDT020 (n.d.), 1—2, accessed 10/23/2026, https://www.fda.gov/media/108301/download.

[9] U.S. Food and Drug Administration, *A Tissue Mimicking Material (TMM) for Preclinical Acoustic Performance Characterization of High Intensity Therapeutic Ultrasound (HITU) Devices*, qualification summary, Q180407 (n.d.), 1—2, accessed 10/23/2026, https://www.fda.gov/media/128803/download.

The FDA should expand the reuse of qualified evaluation methods. Reusing a validated method can reduce the expense of developing a separate method for each submission, which is especially valuable to firms with limited resources, such as small firms entering the market. The agency should explain what can be reused, when its applicability must be reassessed, and what device-specific evidence remains necessary. In doing so, the FDA should distinguish reuse of a validated method from access to confidential device-specific results to protect proprietary information. Clear performance criteria can support competition in testing methods as well as in the devices being tested.

Reusable tools are more valuable when manufacturers can predict whether their results will satisfy a regulatory question. The FDA already provides pathways for real-world evidence[10] and credible computational modeling and simulation.[11] It should publish additional concrete examples showing when these approaches, bench tests, or non-animal methods can answer particular questions, and when additional clinical evidence is necessary. Examples should identify the relevant risks, the method's limitations, and the checks needed to establish reliability. This would make the agency's least-burdensome approach more useful in day-to-day development decisions.[12] When reviewers request additional evidence, they should identify the unresolved question and explain why existing information or a less costly method cannot answer it. Manufacturers could then direct resources toward resolving meaningful uncertainty instead of guessing what an acceptable submission will require. The objective should be to lower the total cost of producing sufficient evidence while meeting applicable safety and effectiveness standards.

The same principle should guide the balance between premarket testing and postmarket monitoring. Useful testing produces information that patients and purchasers cannot readily obtain themselves. That means resolving questions about meaningful risks, not repeating tests. Where appropriate and legally available, the FDA should pair proportionate premarket evidence with targeted postmarket monitoring, while assessing whether the combined requirements reduce the total burden. Liability, reputation, and competing evaluators can reinforce accountability. The agency should explain what uncertainty each requirement addresses and consider the patient cost of delaying useful alternatives as part of its evaluation.

[10] U.S. Food and Drug Administration, *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices* (final guidance, 12/18/2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices.

[11] U.S. Food and Drug Administration, *Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions* (final guidance, 11/17/2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions.

[12] U.S. Food and Drug Administration, *The Least Burdensome Provisions: Concept and Principles* (final guidance, 02/05/2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.

Support care in settings patients choose

Regulatory science should also help devices work reliably in the settings where patients choose to receive care. The meeting's questions about home and community use provide an opportunity to support alternatives to care delivered exclusively in medical facilities.[13] The FDA should prioritize methods that assess critical user tasks, reliability, recovery from errors, and monitoring under realistic conditions. The agency's human-factors guidance[14] and risk-based recommendations for submission content provide a foundation.[15] Evaluation should account for patients' and caregivers' abilities, the intended environment, and the consequences of a use error. Clear methods can help manufacturers establish when a device is suitable for use outside a clinic and what safeguards it needs. More viable care settings can expand patient choice and increase competition among providers. Regulation should give competing approaches a fair opportunity to demonstrate their value.

The FDA should make PCCPs, reusable validation methods, clearer evidence criteria, and practical home-use evaluation central to its regulatory science agenda. The agency should assess progress by whether these efforts maintain patient safety, make review more predictable, permit useful methods to be reused, and reduce unnecessary barriers to bringing improvements to patients. Giving more firms a practical opportunity to compete would help patients benefit from medical innovation.

Respectfully,
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[13] U.S. Food and Drug Administration, *Regulatory Science Public Meeting: Pre-Meeting Material for Attendees* (n.d.), question 2, accessed 10/23/2026, https://www.fda.gov/media/194983/download.
[14] U.S. Food and Drug Administration, *Applying Human Factors and Usability Engineering to Medical Devices* (final guidance, 08/03/2026), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices.
[15] U.S. Food and Drug Administration, *Content of Human Factors Information in Medical Device Marketing Submissions* (final guidance, 05/29/2026), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions.