NATIONAL ASSOCIATION OF Manufacturers

May 14, 2026

The Honorable Bill Cassidy, M.D.
Chair
Committee on Health, Education, Labor, and Pensions
United State Senate
Washington, DC 20510

Re: *Patients and Families First: Building the FDA of the Future*

Dear Chair Cassidy,

On behalf of the National Association of Manufacturers (NAM) and the 13 million people who make things in America, thank you for your leadership in releasing the Committee's February 2026 report on FDA modernization.

Manufacturers of all sizes across the country make products that are regulated by the FDA. These innovators, across several manufacturing sectors, need reliable timelines, clear guidance, and decision-making guided by Gold Standard Science. Manufacturers appreciate your shared commitment to these goals, and to ensuring that innovative, life-changing, safe products are available for the American people.

- Manufacturers are both providers of health coverage and producers of the technologies that make modern medicine possible, ranging from biopharmaceutical treatments to medical devices to diagnostics. As such, health care is central to the manufacturing industry's mission, identity, and economic strength. Manufacturers have an enduring stake in policies that support the health and wellbeing of workers and their families, and the industry has consistently advocated for reforms that make health care more affordable and for a predictable regulatory system that promotes innovation. As other nations advance their biomanufacturing capabilities, now is a critical time to support policies that strengthen manufacturing in the United States to ensure a global competitive advantage.

- Additionally, the food and beverage industry is the largest U.S. manufacturing sector and a global leader. Manufacturers are committed to rigorous safety standards, which ensure a high quality and robust food supply chain that delivers affordable, accessible, and nutritious food and beverage options to Americans. The federal regulatory system, grounded in science and risk-based decision-making, has enabled the food and beverage industry to feed families, grow the economy, and fuel innovation. Our nation's reliable food supply depends on consistent, uniform federal oversight. Any effort to modernize FDA should affirm the agency as the lead federal authority over the registration, labeling, sale, and marketing of food and beverage products in interstate commerce.

Manufacturers appreciate your report's focus on ensuring that "FDA's regulatory framework works efficiently for American patients and families" and removing "bottlenecks [that] slow patients and consumers getting the products they need." In addition to the specifics laid out in the report, manufacturers support a whole-of-FDA approach to public health leadership and product regulation. Such an approach will ensure all centers under FDA's purview are in sync and standardized, which will provide regulatory certainty and predictability to companies with multiple products that fall under the scope of different centers. When considering specific legislation or

oversight of FDA, manufacturers recommend that modernization efforts focus on the wide array of centers with jurisdiction over manufacturers' products in order to ensure that reforms cross the entire agency: Biologics Evaluation and Research, Devices and Radiological Health, Oncology Center of Excellence, Human Foods Program, Drug Evaluation and Research, Tobacco Products, Veterinary Medicine, Toxicology Research, Minority Health and Equity, Women's Health, and Inspections and Investigations. Each center has unique considerations and challenges that will need to be addressed in the modernization process. A whole-of-FDA approach to modernization should not discount individual center characteristics. Instead, it should take them into account to ensure each center can fulfill its core purpose, while striving for standardization across centers when possible.

The NAM respectfully submits the following recommendations, organized around two areas of focus. The first addresses broad, agency-wide reforms to modernize FDA's structure and operations. The second presents targeted policy changes affecting individual centers and product categories where specific regulatory changes would return significant benefits for manufacturers, consumers, and public health.

Modernize FDA's Structure and Operations

Authorization Timelines and Deadline Compliance

Every center that approves products needs to adhere to statutory authorization timelines and comply with set deadlines. Delays across any center undermine manufacturers' ability to plan, develop, and bring innovative products to market. Manufacturers appreciate that the Committee included reforms and suggestions with respect to timelines and deadlines in its report. We support the proposed changes, and further recommend an examination of whether the suggestions can be applied more broadly and across multiple centers.

Transparency

Transparency in decision-making processes and product review criteria across the relevant platforms is critical for patients and consumers to get the products they need. Manufacturers support regular-order advisory committees over expert panels, consistent with the position outlined in the NAM's citizen petition (Docket Number FDA-2026-P-3105). FDA should publish and abide by clear metrics, enabling manufacturers and the public to track progress toward modernization goals.

Industry Collaboration

Collaboration with regulated industry is vital for clear and predictable outcomes at FDA. For centers where this is not the norm, industry collaboration and continuous dialogue should be formalized to ensure manufacturers are sufficiently involved in the process as experts who work with the centers. FDA should establish structured, reoccurring forums with industry across all sectors and centers so that practical manufacturing and product development expertise informs regulatory decision-making. For the centers where statutory or regulatory pathways for continued collaboration already exist, regulators should work to more fully meet the standards outlined in commitments with industry.

Regulatory Consistency and Innovation Framework

All centers at FDA should have established and consistent pathways to support the development and authorization of new products. Manufacturers that require FDA approval are constantly innovating and developing new, previously inconceivable products, and the centers need to work with industry to ensure product review processes are consistent yet able to adapt with rapid advances in technology. A clear, predictable review framework within a consistent regulatory structure is critical for long-term industry planning and innovation investment.

Advance Targeted Policy Reforms to Accelerate Safe Innovation

In addition to ensuring FDA focuses on consistent modernization across all centers, the following specific reforms should also be considered:

Artificial Intelligence

Manufacturers commend the Trump Administration for its recent proposal of a risk-based, pro-innovation legislative framework for artificial intelligence (AI) and recommend using this approach at FDA.[1] Policymakers should leverage existing laws and regulations and address gaps with sensible, risk-based frameworks that facilitate AI-enabled manufacturing platforms and lean on manufacturers' years of experience through ongoing dialogue. As AI continues to evolve at record pace, regulation should provide needed guardrails to encourage the uptake of AI capabilities while mitigating existing and future challenges. For example, with the right regulation, AI-enabled platforms will significantly reduce costs for training, documentation, process oversight, and data review associated with Good Manufacturing Practices. Similarly, for products that use AI and are under FDA review, the agency should ensure regulatory expectations are proportionate to clinical risk, not simply triggered by the presence of AI.

There is a lack of transparency around FDA's internal use of AI that should be addressed in modernization efforts as well. Lack of visibility into development, validation, and reviewer use makes it harder for manufacturers to prepare high quality submissions and could cause delays. FDA should set governance standards for its use of AI in review processes. This should include rules on when FDA is required to disclose AI use, information on validation/performance, auditability, and safeguards for companies' data and IP.

Specifically, in health care settings and products, FDA should address the importance of interoperability, harmonized data standards, guidelines for secure data access as critical enablers of AI-driven care, and transition to cloud-based data submissions. These updates could enable the safe and effective integration of AI-enabled diagnostics and connected care solutions into existing health care operating systems. FDA should also implement clear regulations for adaptive AI and focus on post-market monitoring. Adaptive algorithms need a clear post-market approach rather than heavier premarket burdens.

User Fees

User fee reauthorization processes should be included as part of FDA modernization efforts and incorporated across all centers, while ensuring each user fee structure is relevant to its specific center. Manufacturers are concerned about a lack of performance requirements or accountability metrics tied to user fees, including collaboration with regulated industry to identify shared policy goals and fill data gaps. Across all centers and programs that collect user fees, there needs to be clarity that such fees are being used appropriately and resulting in more consistent, efficient, and predictable review processes to keep pace with American innovation. Any registration or user fee structure must come with clear accountability measures ensuring fees translate directly into increased effectiveness, inspection consistency, regulatory predictability, and improved review timelines while careful to maintain the proper approval requirements.

Clinical Trials

As other countries are attempting to outpace the United States in their ability to initiate clinical trials, FDA should simplify regulatory requirements to reduce unnecessary barriers to U.S.-based research and create a more predictable, collaborative environment. To modernize clinical trials,

[1] National Policy Framework on Artificial Intelligence. See more at: https://www.whitehouse.gov/wp-content/uploads/2026/03/03.20.26-National-Policy-Framework-for-Artificial-Intelligence-Legislative-Recommendations.pdf

FDA will need to address geographic and economic barriers to trial participation, enhance the provision of digital health technologies in trial design and execution, and increase acceptance of novel clinical endpoints, such as biomarkers and surrogate endpoints. These changes would improve the data collected from trials, as more patients would be able to participate, and ultimately reduce trial costs. Additionally, agreements between FDA and industry on clinical trial designs to support registrations should be adhered to during the review of the scientific data.

FDA should expand the allowable inclusion of real world evidence and patient experience data in applications and provide transparent consistent standards for both types of data. Additionally, as your report details, evidence generation needs to continue to modernize as technology improves. FDA should also develop formal guidance on the acceptability of single pivotal trials for demonstration of effectiveness. The NAM recommends that FDA provide guidance about using these types of data to ensure manufacturers can plan appropriately.

Nonprescription Drugs

FDA modernization efforts should include nonprescription, or over-the-counter (OTC), drugs, for both the pathway available to transition prescription drugs to OTC and programs for novel drugs. FDA should remove unnecessary burdens in OTC regulatory processes and ensure switch application requirements are fully applicable for nonprescription drugs. For novel OTC drugs, FDA should address the long approval timelines, some of which can be as long as five to ten years. FDA should also provide clarity on the performance metrics the agency currently uses to assess timeliness and consistency of switch pathways and novel drug programs.

Biosimilars

FDA oversight of biologics is essential to patient safety, treatment quality, and long-term access to innovative therapies. Because biologics are complex products derived from living systems, determinations of biosimilarity and interchangeability require product-specific, evidence-based scientific assessment. Current law appropriately requires interchangeable biosimilars to meet additional standards beyond biosimilarity. FDA's discretion to require additional data reflects the totality of the evidence approach needed for these decisions. Proposals to deem all biosimilars interchangeable would eliminate this discretion and remove an important patient safeguard. Such an approach would depart from the existing statutory framework without establishing clear or scientifically grounded standards applicable across diverse biologic classes, potentially increasing the risk of adverse outcomes.

A more balanced path forward would preserve FDA's case-by-case authority while improving transparency and consistency. For example, an FDA-managed interchangeability framework—analogous to the agency's therapeutic equivalence ratings for generic drugs—could enhance predictability while ensuring thorough scientific judgment and patient protections. Maintaining FDA's discretion to apply sound, transparent interchangeability standards is critical to sustaining provider and patient confidence, high-quality care, and a competitive biologics market over the long term.

Generally Recognized as Safe

A stable, predictable Generally Recognized as Safe (GRAS) framework helps keep manufacturers at work providing safe, affordable, and available food and beverage products for all American families. Manufacturers support focused improvements to GRAS that increase transparency and trust without unnecessarily raising costs or inhibiting innovation—including a centralized public listing of self-GRAS determinations, systematic risk-based post-market assessment, and a unified national standard to prevent a patchwork of state laws. Proposals requiring FDA pre-approval for every ingredient use or manufacturing change would strain resources and disrupt food and

agriculture supply chains. Any major changes to GRAS should be made by Congress, not through regulatory shortcuts, to ensure FDA's authorities remain clear, predictable, and grounded in statute.

Food Safety Modernization Act

The Food Safety Modernization Act (FSMA), enacted in 2011, was the most significant overhaul of food safety law in decades, yet there has not been oversight to assess the impact FSMA has had on food safety. FDA should develop a performance management framework to assess whether FSMA rules are achieving their public health goals, as no such framework currently exists. Manufacturers also urge Congress to ask FDA to regularly report on overall FSMA implementation, including timelines for completing pending FSMA requirements.

Manufacturers also seek congressional review and clarification of food safety regulation post-FSMA, specifically addressing duplicative regulations that are not risk-based, such as certain regulations for seafood Hazard Analysis Critical Control Point (HACCP) or acidified foods. In general, such specialized food safety regulations should be specifically authorized for carefully identified products that may warrant special treatment (e.g., sushi, pickled vegetables), while foods that are most appropriately managed within a single food safety standard should be completely brought within FSMA. Any FSMA modernization efforts should be accompanied by realistic compliance timelines developed in collaboration with industry.

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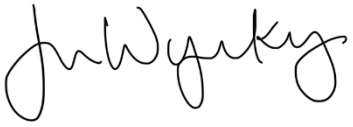
Manufacturers are invested in a modernized FDA with standardized and efficient centers that empower companies to bring critical products to market safely and without unnecessary delay. A well-functioning FDA is a cornerstone of American competitiveness and manufacturing innovation. When the regulatory environment works as it should, manufacturers can develop safer products, pioneer new innovations, and ensure that Americans have access to the highest quality food, beverage, and health products in the world. Please consider the NAM a partner and resource as the Committee and Congress work to implement these recommendations.

Sincerely,



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