

The Food and Drug Administration Under the Second Trump Administration

June 18, 2025

In just a few short months, the second Trump administration has made a significant mark on the policies and priorities of the Food and Drug Administration (“FDA”). As the dust settles after sweeping layoffs across the Department of Health and Human Services (“HHS”), including at FDA, and as HHS Secretary Robert F. Kennedy Jr. and FDA Commissioner Martin Makary begin to shape the future of the agency, now is an ideal time for FDA-regulated companies and investors to consider how the new administration may impact industry moving forward.

As HHS Secretary, Mr. Kennedy will likely play a bigger role in directing policy at FDA than has been typical in past administrations. Although FDA falls under the jurisdiction of HHS, HHS secretaries have historically allowed FDA to operate with little interference. It is clear from FDA’s early priorities during this administration, including changes to vaccine policy and the influence of the Make America Healthy Again (“MAHA”) initiative on the regulation of food additives, that Mr. Kennedy is influencing policy in a way past HHS secretaries have not. For example, in the first Trump Administration, FDA Commissioner Scott Gottlieb operated with minimal HHS interference prior to the COVID-19 pandemic.

Dr. Martin A. Makary, a former Johns Hopkins University surgeon, is the new FDA commissioner. Dr. Makary is respected within the medical community and is a proponent of technology-driven, innovative approaches to healthcare, which will be essential as FDA continues to develop policies addressing the use of artificial intelligence in medical devices, drug discovery, and manufacturing. Dr. Makary has expressed a personal interest in pursuing new treatments for diabetes, Alzheimer’s, and post-traumatic stress disorder.

The Trump administration, through the Department of Government Efficiency (“DOGE”), implemented extensive staffing cuts across the federal government, including at FDA. Approximately 3,500 FDA jobs were eliminated as part of the larger reduction of 10,000 jobs at HHS in April. Shortly thereafter, certain employees were informed that their layoffs had been reversed. Reinstated employees included food safety lab staff, support staff for FDA inspectors, and employees working on drug

regulatory policy, including user fee negotiations. Due to inconsistent reports of cuts and subsequent reinstatements, the final total for the reduction in force at FDA is unknown; however, Dr. Makary has said that approximately 1,900 people were laid off and an additional 1,200 took early retirement packages. Dr. Makary has asserted that no scientific reviewers or inspectors were cut. He indicated that certain functions have been consolidated, such as information technology services and communications teams. Additionally, in April, former FDA Commissioner Scott Gottlieb asserted that as many as 600 drug reviewers have recused themselves from product review processes because they were interviewing with pharmaceutical companies, suggesting there could be even more departures over the next few months.¹

Changes to staffing levels may affect FDA's ability to promulgate new guidance and rules or perform certain routine functions, including inspections. There are reports of FDA already missing certain deadlines, leading to delays in product development and approvals. For example, after experiencing delays in receiving guidance from the agency on its late-stage clinical trial for an investigational drug, one company decided to postpone the trial. Smaller biotech companies are particularly vulnerable to timing uncertainty because they typically focus on few product candidates and seek funding on a product-by-product basis.² Regulatory delays could be fatal for individual products or an entire company.

Dozens of biomedical investors, executives, and advocates wrote a letter urging Senate Committee on Health, Education, Labor and Pensions ("HELP") chair Senator Bill Cassidy, R-La., to take action to ensure FDA is adequately staffed. The authors noted, "Specifically, we worry that the institutional knowledge that makes the FDA the world's leading regulatory body will be irretrievably lost due to the agency's recent reduction in force and wave of retirements."³ Over the longer term, delays and regulatory uncertainty could lead companies to pursue product approvals first in foreign markets, reducing the availability of innovative medical treatments for Americans. Testifying before the Senate at a budget hearing, Dr. Makary asserted that the staffing reductions

¹ [Allison De Angelis et al., With the FDA in Turmoil, the "Revolving Door" with Industry Is Spinning Faster, STAT News \(Apr. 25, 2025\).](#)

² The significant cuts in federal funding of scientific research, including through the National Institutes of Health ("NIH"), is expected to impact the research pipeline and could have negative consequences for the U.S. biotech industry. According to one study, NIH terminated \$1.8 billion in grants in fewer than 40 days at the beginning of the second Trump administration. [Liu et al., Characterization of Research Grant Terminations at the National Institutes of Health, JAMA \(May 8, 2025\).](#) The funding cuts in the U.S. could be a boon for the Chinese biotech industry, which has been growing in recent years. In 2024, Chinese firms accounted for 42% of all global biotech licensing deals worth \$50 million or more, up 20% from 2023. [DealForma, China's Biotech Market is Staging a Comeback that US Biotech Can Only Wish For \(Apr. 23, 2025\).](#)

³ [A Letter to Senate HELP Committee Chairman Bill Cassidy on Preserving and Modernizing the FDA from US Biomedical Innovators, Investors, and Patient Advocates.](#)

have not impacted approval schedules and the agency is on track to meet its treatment review targets under the Prescription Drug User Fee Act (“PDUFA”).⁴

In addition to staffing cuts, the Trump administration has proposed a reduction in FDA’s budget for fiscal year 2026 (\$6.8 billion total, a 5.5% decrease from its \$7.2 billion budget this year). Congress, of course, must approve the budget. The proposed budget would move the responsibility for routine inspections of food facilities to the states.

FDA’s user fee program also faces an uncertain future, although the budget presented to Congress does not propose reductions in user fees for fiscal year 2026. Mr. Kennedy has proposed doing away with user fees entirely due to his belief that drug user fees, for example, make FDA beholden to the pharmaceutical industry and lead to conflicts of interest. User fees are paid by FDA-regulated companies, comprise just under half of FDA’s annual budget, and help FDA ensure predictable timelines for its review process by funding staffing in certain areas. User fees for innovator drugs, generic drugs, medical devices, biosimilars, over-the-counter (“OTC”) drugs, and animal drugs must be reauthorized by Congress every five years and the statutorily directed negotiations for the next reauthorizations are set to begin this year. If user fees are reduced or eliminated, or if Congress fails to reauthorize user fees in time, it could have a significant negative effect on product review timelines absent a large appropriation from Congress to make up the difference.

We anticipate a decrease in agency rulemaking under the new administration. On January 31, 2025, President Trump issued an Executive Order requiring that for each new regulation or guidance issued, at least 10 prior regulations or guidance documents must be identified for elimination.⁵ An Executive Order issued on February 19, 2025, requires federal agencies to work with the White House to terminate regulations that extend past an interpretation of the underlying statute or other authority.⁶ The Supreme Court’s recent *Loper Bright Enterprises v. Raimondo* decision is also expected to affect policy-making during the new administration, as the agency may opt to issue nonbinding guidance instead of rules, which may be more difficult to challenge via litigation.⁷

⁴ [U.S. Senate Committee on Appropriations, A Review of the President’s Fiscal Year 2026 Budget Request for the Food and Drug Administration \(May 22, 2025\).](#)

⁵ [Executive Order 14192, Unleashing Prosperity Through Deregulation \(Jan. 31, 2025\).](#)

⁶ [Executive Order 14219, Ensuring Lawful Governance and Implementing the President’s “Department of Government Efficiency” Deregulatory Initiative \(Feb. 19, 2025\).](#)

⁷ The Supreme Court’s 2024 decision in *Loper Bright*, overturning the concept of “*Chevron* deference” (a standard mandating that courts defer to reasonable agency interpretations when an underlying statute is ambiguous), has also made it easier to challenge certain FDA regulatory decisions through litigation. FDA will continue to grapple with this decision, and it may affect the rulemaking process. See [After Chevron: FDA Regulations in the Crosshairs, Law360 \(July 8, 2024\).](#)

We see reason for both optimism and caution for FDA-regulated companies. Secretary Kennedy's interest in alternative, holistic, and preventive health solutions could lead to policies favoring companies marketing dietary supplements, OTC drugs, and digital health innovations that empower consumer choice without physician intervention.⁸ On the other hand, increased regulatory uncertainty may hinder development programs. FDA-regulated companies and investors should also be aware of the potential for increased enforcement in certain areas. For example, Mr. Kennedy has expressed a desire to ban direct-to-consumer prescription drug advertisements, and although a ban would be subject to challenge under the First Amendment, FDA's Office of Prescription Drug Promotion may nonetheless increase enforcement of prescription drug advertising. In addition, we anticipate greater scrutiny of foreign suppliers of FDA-regulated products and ingredients, particularly those located in China.

We address below a number of hot-button FDA regulatory issues. Of note, there have been many important developments at the Federal Trade Commission Bureau of Consumer Protection that also impact FDA-regulated companies, which we addressed in a separate article.⁹

"Make America Healthy Again" Agenda

Many of this administration's earliest FDA policy initiatives have centered around the MAHA agenda. For example, FDA announced a comprehensive review of nutrients in infant formulas under the "Operation Stork Speed" moniker and Mr. Kennedy urged "radical transparency" for infant formula ingredients. FDA has asked for public input "to help determine whether existing nutrient requirements should be revised based on the latest scientific data, including international [data]"¹⁰ and held an expert panel on infant formula on June 4, 2025. Dr. Makary has expressed concerns about the use of seed oils and sugars in infant formula.

Separately, FDA convened an expert panel to review data related to talc exposure and evaluate its continued use in foods, drugs, and cosmetics due to ongoing concerns about the ingredient's potential health effects.¹¹ Dr. Makary stated that FDA has "begun

⁸ In a recent podcast, Mr. Kennedy vowed to end FDA's "war with alternative medicine" and expressed support for controversial stem cell therapies, vitamins, peptides and chelation therapy. [Robert F. Kennedy Jr.: How to Fix America's Health Crisis as HHS Secretary, The Ultimate Human Podcast \(May 27, 2025\)](#).

⁹ [Debevoise In Depth: The Federal Trade Commission Bureau of Consumer Protection Under the Second Trump Administration: Top 10 Things to Know About Priorities, Enforcement, and Case Law Developments \(Apr. 29, 2025\)](#).

¹⁰ [FDA News Release: HHS, FDA Initiate Comprehensive Review of Nutrients in Infant Formula \(May 13, 2025\)](#).

¹¹ [FDA Expert Panel on Talc \(May 20, 2025\)](#).

conducting a full inventory of concerning ingredients in the US that are not allowed in other developed countries.”¹²

The President’s Make America Healthy Again Commission released its first report on May 22, 2025.¹³ This report, titled “Make our Children Healthy Again: Assessment,” is intended to examine “the root causes of deteriorating child health” and establish “a clear, evidence-based foundation for the policy interventions, institutional reforms, and societal shifts needed to reverse course.”¹⁴ The content is consistent with the priorities and positions of the MAHA movement, and the report targets issues such as ultra-processed foods and their additives, environmental chemicals, lifestyle (e.g., exercise and screen time), and “overmedicalization” (including childhood vaccines). The report calls for studies on whether vaccines cause injury or disease and supports the new FDA COVID-19 vaccine framework, stating that vaccines should be tested against placebos in larger, longer trials. Shortly after issuance, journalists identified errors in the report’s citations to scientific studies, including cited sources that do not exist.¹⁵

The content of the MAHA Commission report may present new opportunities for food and dietary supplement companies. The Food and Drug Administration Modernization Act of 1997 (“FDAMA”) allows companies to use health or nutrient content claims in food labeling if the claims are based on current, published, authoritative statements from federal scientific bodies with official responsibility for public health or research directly relating to human nutrition.¹⁶ It is possible that statements included in the MAHA Commission report may qualify, although companies must first submit the claims for FDA review.

FDA has focused on the use of synthetic dyes in foods as part of the MAHA agenda and announced that it will initiate the process to revoke authorization for two synthetic food colorings, Citrus Red No. 2 and Orange B, within the coming months. The agency will also ask food companies to remove FD&C Red No. 3 sooner than the previous 2027 deadline (the ban was announced during the Biden administration).¹⁷ FDA has also said it is “working with industry to eliminate six remaining synthetic dyes—FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, and FD&C Blue No. 2—from the food supply by the end of next year.”¹⁸ It is unclear

¹² [Martin Makary & Vinay Prasad, Priorities for a New FDA, JAMA \(June 10, 2025\).](#)

¹³ [The President’s Make America Healthy Again Commission, Make Our Children Healthy Again: Assessment \(May 2025\).](#)

¹⁴ Id.

¹⁵ [The MAHA Report Cites Studies That Don’t Exist, NOTUS \(May 29, 2025\).](#)

¹⁶ FFDCA § 403(r).

¹⁷ [FDA, FD&C Red No. 3 \(Jan. 15, 2025\).](#)

¹⁸ [FDA News Release, HHS, FDA to Phase Out Petroleum-Based Synthetic Dyes in Nation’s Food Supply \(Apr. 22, 2025\).](#)

whether industry will agree to voluntarily remove these dyes from food products and, if not, how FDA will proceed. FDA is working to introduce alternatives to synthetic dyes and in May announced approval of three new color additive petitions for dyes from natural sources.¹⁹ It may be costly and time-consuming for manufacturers to replace synthetic dyes, however, as natural colors have a shorter shelf life and different characteristics that may necessitate changes to manufacturing processes and facilities.

Mr. Kennedy has instructed FDA's Center for Food Safety and Applied Nutrition ("CFSAN") to explore revising the agency's food additive standard to eliminate the option for companies to designate a substance as "generally recognized as safe" ("GRAS") without FDA review (i.e. "self-affirmation" of GRAS status). This could affect companies that have "self-affirmed" the GRAS status of their food or dietary supplement ingredients. The self-affirmation process provides companies with the ability to bring new ingredients to market without significant FDA oversight; if the system is reformed such that FDA must review each new ingredient, the agency would need significant additional resources or innovation would be stalled.

Final Rule on OTC Products With an Additional Condition for Nonprescription Use ("ACNU")

The ACNU final rule, issued in December 2024 and effective as of May 27, 2025, may provide significant opportunities for companies seeking to market new OTC drugs or to switch drugs from prescription to OTC status.²⁰ The rule allows for certain drug products to be marketed OTC, without a prescription, if an applicant implements an ACNU to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a practitioner licensed by law to administer such drug. It is intended to broaden the types of OTC drugs available to consumers by allowing companies to propose an ACNU when the label on its own cannot, by itself, provide all the information consumers need to appropriately select or use the drug in the non-prescription setting. ACNUs could include, for example, a questionnaire that consumers are required to complete on a secure website or a mobile app used to determine whether the drug product is appropriate for the consumer.

The ACNU rule is FDA's attempt to address frustrations from industry, lawmakers, and consumers about the regulatory roadblocks to obtain OTC marketing status and the barriers to accessing common medications. Indeed, in a June 4, 2025, hearing, Senate HELP Committee chair Bill Cassidy urged FDA officials to accelerate approvals for

¹⁹ [FDA News Release, FDA Approves Three Food Colors from Natural Sources \(May 9, 2025\)](#).

²⁰ [FDA, Final Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use, 89 Fed. Reg. 105288 \(Dec. 26, 2024\)](#).

switching prescription drugs to OTC. Whether the ACNU rule will indeed lead to more OTC drug approvals is unclear, but it would be consistent with the administration's stance on encouraging self-care and consumer choice.

While industry is generally supportive of the ACNU rule, there are two key criticisms. The first criticism is that the rule allows for "simultaneous marketing" of the same drug product as both a prescription and OTC drug because, according to FDA, the ACNU constitutes a "meaningful difference" between the two. Industry has argued that allowing the identical prescription drug to remain on the market will disincentivize the development of OTC products with ACNUs. The other key criticism is related to what is known as the "fail first" requirement. Under the rule, a sponsor must first demonstrate that conventional labeling wouldn't support an OTC switch before submitting a proposal for an ACNU switch. FDA has stated that the applicant must conduct or reference adequate testing to show that labeling alone would not support the safe and effective use of the nonprescription drug product. Stakeholders commented that the obligation to "fail first" and provide failed study data is unnecessary and burdensome, and applicants should be allowed the flexibility to propose an ACNU as part of an original Rx-to-OTC switch application, without needing to fail first. The Trump administration delayed the effective date of the rule twice, and there was some hope among industry that FDA would revise the rule to address these criticisms; however, the rule went into effect with no changes.

Artificial Intelligence ("AI")²¹

Dr. Makary has been an outspoken proponent of the use of AI by FDA staff to streamline internal processes and improve operational efficiency. FDA's newly appointed Chief AI Officer, Jeremy Wash, is coordinating these efforts.

On June 2, 2025, FDA launched an early rollout of an internal AI tool called "Elsa." Elsa is a large language AI tool designed to assist with reading, writing, and summarizing, and is designed to "accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets."²² According to FDA, Elsa can "summarize adverse events to support safety profile assessments, perform

²¹ For more on the use of AI in the life sciences and healthcare industries, see [Debevoise In Depth: Artificial Intelligence and the Life Sciences Industry: FDA and FTC Regulatory Update \(May 16, 2023\)](#); [Debevoise In Depth: Artificial Intelligence in Healthcare: Balancing Risks and Rewards \(July 31, 2023\)](#); [AI in Healthcare and Life Sciences: Regulatory Perspective and Corporate Governance Implications, Competition Policy International \(Feb. 24, 2025\)](#). Additionally, Debevoise regularly posts articles related to AI policy on the [Debevoise Data Blog](#).

²² [FDA News Release, FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People \(June 2, 2025\)](#).

faster label comparisons, and generate code to help develop databases for nonclinical applications.”²³ Dr. Makary has set a deadline of June 30, 2025, for agency-wide adoption of AI capabilities and touted the ability of AI to dramatically speed drug approvals. FDA will be using AI to “make a first-pass review of documentation received by the FDA as part of an application that often exceeds 500,000 pages and aid in generating standardized tables.”²⁴ Whether the use of AI during the application review process will shorten review times remains to be seen. Sources familiar with Elsa have said that it struggles with simple tasks and may not be ready for widespread use.²⁵

During the Biden administration, FDA began developing the regulatory framework for AI-enabled medical devices. We expect this administration will continue to develop the framework and may take steps to reduce regulatory burdens for AI products. Dr. Makary has said FDA will modernize how it reviews AI-based technologies by “[r]ethinking our approach to AI, balancing safety and accuracy while fueling innovation.”²⁶

As of August 2024, FDA had cleared or approved more than 1,000 AI-enabled devices. As explained below, FDA’s approach emphasizes a balance between fostering innovation and ensuring patient safety, particularly through the use of Predetermined Change Control Plans (“PCCPs”). PCCPs allow AI developers to define, during their premarket submissions, potential modifications or updates the device may undergo post-approval. By detailing the methodology and scope for these future changes, developers can incorporate updates without repeatedly going through a lengthy approval or clearance process. While the focus remains on ensuring that all software, particularly software using AI, is as safe as more traditional medical device technologies, the PCCP approach enables continuous monitoring and improvement of devices.

Near the end of the Biden administration, FDA issued a series of guidance documents, including final guidance titled “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions.”²⁷ This guidance enables manufacturers to adopt PCCPs to facilitate iterative changes to AI-enabled devices without requiring new marketing submissions for each update. FDA also issued draft guidance titled “Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission

²³ *Id.*

²⁴ [Martin Makary & Vinay Prasad, Priorities for a New FDA, JAMA \(June 10, 2025\).](#)

²⁵ [Berkeley Lovelace Jr., FDA’s AI Tool for Medical Devices Struggles with Simple Tasks, NBC News \(June 3, 2025\).](#)

²⁶ [Martin Makary & Vinay Prasad, Priorities for a New FDA, JAMA \(June 10, 2025\).](#)

²⁷ [FDA, Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions \(Dec. 2024\).](#)

Recommendations.”²⁸ This guidance establishes a life cycle approach to managing the lifecycle of AI-enabled medical devices, addressing risk management, transparency and bias mitigation.

FDA also recognizes the role AI can play in the drug and biologic product lifecycles. In a 2023 discussion paper on the use of AI in drug development, FDA acknowledged that companies are exploring or already deploying the use of AI in drug discovery (e.g., drug target identification, selection, and prioritization), nonclinical research (e.g., in vivo predictive models), clinical research (e.g., data analysis and designing non-traditional trials such as decentralized clinical trials), post-market safety surveillance (e.g., identification and validation of adverse events), and pharmaceutical manufacturing (e.g., early detection of deviations).²⁹ Although in the discussion paper the FDA was generally supportive of these emerging uses, the agency cautioned that AI algorithms may have certain risks such as the potential to amplify errors and preexisting biases in the underlying data sources.

In January 2025, FDA issued draft guidance entitled “Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products,” intended to provide recommendations on the use of AI to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality.³⁰ Specifically, it provides a risk-based credibility assessment framework for establishing and evaluating the credibility of an AI model for a particular context of use.

Looking ahead, the Trump administration could bring about changes in regulatory priorities. Priority may be placed on accelerated market access or reduced regulatory burdens, which could manifest in modifications to the stringency of PCCP requirements or a shift in the level of scrutiny applied to post-market surveillance. While the current FDA guidance provides a framework for navigating the regulatory landscape, companies must remain adaptable and prepared for potential shifts in emphasis or resource allocation within the agency.

²⁸ [FDA, Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations \(Jan. 2025\).](#)

²⁹ [FDA, Discussion Paper: Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products \(May 2023; Revised Feb. 2025\).](#)

³⁰ [FDA, Draft Guidance: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products \(Jan. 2025\).](#)

Vaccine Policy

Given Mr. Kennedy's longstanding skepticism of vaccines, including as founder and chair of Children's Health Defense (a non-profit focused on anti-vaccine advocacy), it is unsurprising that the administration has moved swiftly to make changes in vaccine policy. Personnel changes at the agency will undoubtedly affect the direction of the agency. Dr. Peter Marks, longstanding director of the Center for Biologics Evaluation and Research ("CBER") (the FDA center that oversees vaccines), was forced to resign in March. Dr. Vinay Prasad, a vocal critic of Dr. Marks' leadership and the government's vaccine policies during the pandemic, was announced as his replacement at CBER. Additionally, Tracy Beth Høeg, a vaccine skeptic who is special advisor to Commissioner Makary, is the new representative to the CDC's Advisory Committee on Immunization Practices ("ACIP") and a senior clinical advisor at CBER.

On June 9, 2025, Mr. Kennedy announced the removal of all 17 members of ACIP, asserting that a "clean sweep is needed to re-establish public confidence in vaccine science."³¹ Mr. Kennedy subsequently announced the names of eight of the ACIP replacements, including a number of vaccine skeptics. On June 13, 2025, Senator Sanders (I-VT), called for a bipartisan investigation of the ACIP firings and appointments.³²

FDA issued a new "framework" in May indicating COVID-19 vaccines will only be approved for use in people over age 65 and certain high-risk groups.³³ Otherwise, manufacturers will need to perform new placebo-controlled clinical studies evaluating clinical outcomes in healthy children and adults. This change raises concerns that seasonal updates and boosters for new strains of SARS-CoV-2 will face significant delays. Previously, manufacturers could obtain approval for updated vaccines based on immunogenicity data, showing that the vaccine generates antibodies. Mr. Kennedy also announced the CDC will no longer recommend the COVID-19 vaccine for healthy children or during pregnancy; however, the CDC issued updated advice shortly thereafter that kept COVID-19 vaccines on the schedule for healthy children.

The new administration's vaccine skepticism has already affected product reviews and approval. FDA missed an April 1 deadline to issue a decision on the Novavax COVID-19 vaccine application. Novavax finally received an approval in May, but with a narrowed indication limiting the use of the vaccine to people over 65 and high-risk individuals

³¹ [HHS, HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP \(June 9, 2025\)](#).

³² [Letter to Senate HELP Committee Chairman Cassidy from Senator Sanders \(June 13, 2025\)](#).

³³ [Vinay Prasad & Martin Makary, An Evidence-Based Approach to Covid-19 Vaccination, The New England Journal of Medicine \(May 20, 2025\)](#). The new "framework" was issued as a New England Journal of Medicine article, and FDA did not publish a Federal Register notice or solicit public comment. Critics argue that the issuance of new policy in this manner may violate the Administrative Procedure Act and/or FDA's good guidance practices.

aged 12 to 64. The Moderna and Pfizer vaccines are licensed for use in all individuals over 12 years of age regardless of health-risk status.

Mr. Kennedy has also announced his intention to reform the current Vaccine Adverse Event Reporting System to automate and increase data collection and to look for negative impacts of vaccines. The idea of reforming the system is largely uncontroversial, but experts say Mr. Kennedy has exaggerated the extent to which vaccine side effects go unrecorded.

Manufacturing, Supply Chain, and Tariffs

The pharmaceutical and medical device supply chain has been a focal point for the Trump administration. Despite a trend toward onshoring of pharmaceutical manufacturing in the last few years, the U.S. pharmaceutical supply chain is still heavily reliant on foreign manufacturing. The U.S. imports roughly 36% of its pharmaceuticals, both branded and generic.³⁴ China and India are the leading sources of generic drugs. Less than 15% of active pharmaceutical ingredients (“APIs”) are made in the U.S., and many are sourced from China and India (Chinese imports account for 90% of the APIs needed for some antivirals and antibiotics).³⁵ Additionally, 40% of medical devices sold in the U.S. are imported, and Mexico is the largest supplier.

The Trump administration wants to reduce the country’s reliance on foreign sources of pharmaceuticals and increase domestic manufacturing capacity. On May 5, 2025, President Trump issued an Executive Order directing FDA to reduce the regulatory burden of building domestic pharmaceutical manufacturing plants.³⁶ Specifically, the Executive Order directs FDA to streamline reviews and work with manufacturers to provide support, increase fees for and inspections of foreign manufacturing facilities, and improve enforcement of API source reporting by foreign manufacturers. Even with reduced regulatory burdens, planning and building domestic manufacturing facilities will take years.

On April 14, 2025, the administration announced the initiation of an investigation into tariffs on imports of pharmaceuticals.³⁷ This investigation can take up to 270 days, but the administration has indicated it may proceed more quickly. It is unclear whether a

³⁴ [ING, Trump Set to Break WTO Rules with Potential Pharma Tariffs \(Feb. 19, 2025\)](#).

³⁵ [USP, Over Half of the Active Pharmaceutical Ingredients \(API\) for Prescription Medicines in the U.S. Come from India and the European Union \(Apr. 17, 2025\)](#).

³⁶ [Fact Sheet: President Donald J. Trump Announces Actions to Reduce Regulatory Barriers to Domestic Pharmaceutical Manufacturing \(May 5, 2025\)](#).

³⁷ Section 232 of the Trade Expansion Act of 1962 allows the president to restrict imports of products that threaten to impair national security.

blanket tariff will be applied to all pharmaceutical products—including APIs and finished products—or whether the administration will take a piecemeal approach with tariffs tailored to product type and country of origin. Tariffs may have the largest impact on generic drug companies because they have the smallest profit margins and may struggle to absorb rising costs. This could lead to facility closures and drug shortages.³⁸

FDA recently announced plans to carry out more unannounced inspections of foreign facilities, building on a pilot program for unannounced inspections in China and India.³⁹ This is a significant change because foreign facilities historically received advance notice of inspections. The advance notice has been criticized as a loophole because facilities could theoretically remediate good manufacturing practices violations prior to an inspector's arrival. Even with advance notice, however, inspectors have found major safety violations at foreign facilities more than twice as often as at domestic facilities. Dr. Makary said the new policy will level the playing field between foreign and domestic facilities and noted that FDA "is authorized to take regulatory action against any firm that seeks to delay, deny, or limit an inspection, or refuses to permit entry for an unannounced drug or device inspection."⁴⁰

The Trump administration is also pursuing drug importation as a tool to lower drug prices. HHS and FDA have historically been resistant to the importation of unapproved drugs from other countries due to supply chain security concerns, but this opposition may be thawing. A May 12, 2025, Executive Order directed FDA to consider drug importation from other countries to lower prices in the U.S. through the existing importation program under Section 804 of the Federal Food, Drug, and Cosmetic Act ("FFDCA").⁴¹ This statutory provision, however, enables only states to import prescription drugs from Canada under limited circumstances. Although regulations by FDA authorizing importation under this program have been in place for five years, only Florida has received FDA approval to import drugs from Canada under this program. Moreover, according to public reports, Florida has not yet implemented the program. FDA announced on May 22, 2025, that it will facilitate importation applications by individual states and Indian tribes to revive the program. It may be difficult to facilitate drug importation at scale, however, due to stringent rules designed to ensure the supply chain is not infiltrated by counterfeit drugs.

³⁸ For more information on tariffs, see [Debevoise in Depth: The U.S. Tariff Turmoil: Navigating the Potential Sources of Risk \(June 11, 2025\)](#).

³⁹ [FDA News Release, FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities \(May 6, 2025\)](#).

⁴⁰ Id.

⁴¹ [Executive Order 14297, Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients \(May 12, 2025\)](#).

Accelerating Drug and Device Development

Dr. Makary has designated “accelerating cures” as one of the top priorities for FDA under the Trump administration.⁴² He provided the example of fast product reviews and approvals during the COVID-19 pandemic as evidence that FDA can provide “rapid or instant reviews” of new products.⁴³ FDA is starting to use artificial intelligence to accelerate the review process (see Artificial Intelligence section above). Dr. Makary has also suggested reducing animal testing requirements, particularly for drugs that are already approved and in use outside the United States.⁴⁴ Based upon these developments, we expect the Trump administration to continue supporting the Accelerated Approval Program⁴⁵ and other existing policies to bring products to market more quickly.

On June 17, 2025, FDA announced its extra-statutory “Commissioner’s National Priority Review Voucher” (“CNPV”) program, designed to shorten the review time for sponsors receiving a voucher from approximately 10-12 months to 1-2 months following new drug application (“NDA”) submission.⁴⁶ To qualify, sponsors must submit the chemistry, manufacturing, and controls portion of the NDA, as well as the draft labeling, at least 60 days before submitting the final NDA, allowing FDA to review this information prior to clinical trial completion. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will convene for a one-day meeting. The Commissioner will use specific criteria to make the vouchers available to companies that are aligned with the following national health priorities: (i) addressing a health crisis in the U.S.; (ii) delivering more innovative cures for the American people; (iii) addressing unmet public health needs; and (iv) increasing domestic drug manufacturing as a national security issue. FDA has said CNPV vouchers can be issued for a specific investigational drug or granted to a company as an undesignated voucher to be used at the company’s discretion, but the vouchers will expire within two years of

⁴² [Martin Makary & Vinay Prasad, Priorities for a New FDA, JAMA \(June 10, 2025\).](#)

⁴³ Id.

⁴⁴ Dr. Makary indicated FDA will use AI to reduce animal testing by “using AI-based computational modeling to predict toxicity leveraging chip technology.” Id.

⁴⁵ The FDA’s Accelerated Approval Program expedites therapies for serious or life-threatening conditions that address unmet medical needs and show evidence of effectiveness through a surrogate endpoint (i.e., a marker that predicts clinical benefit but is not itself a measure of clinical benefit). Drug companies are still required to conduct post-market studies to confirm the anticipated clinical benefit. If the confirmatory trial shows that the drug provides a clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market.

⁴⁶ [FDA News Release: FDA to Issue New Commissioner’s National Priority Vouchers to Companies Supporting U.S. National Interests \(June 17, 2025\).](#)

receipt and will be non-transferrable. FDA intends to issue vouchers in 2025, but how the program will work in practice remains to be seen.

In a May 12, 2025, Executive Order aimed at lowering drug prices, President Trump directed FDA to provide recommendations for administrative and legislative actions intended to create competition for high-cost prescription drugs by accelerating approval of generics, biosimilars, combination products and second-in-class brand name medications (i.e., the second drug in a particular drug class). The Executive Order, however, does not state how the process of drug approvals can be accelerated, especially at a time when significant layoffs at FDA may constrain the FDA's ability to operate.

In an April 2025 interview, Dr. Makary discussed plans to create a new pathway for drugs that treat rare diseases based on a "plausible mechanism." He proposed approving drugs for rare conditions on a conditional basis if they "make[] sense physiologically" and "the mechanism is scientifically plausible."⁴⁷ Dr. Makary emphasized the importance of allowing patients access to new therapies even in the absence of robust data and randomized controlled trials, which may be difficult or impossible to conduct for ultrarare diseases. FDA would then monitor the patients and collect real-world data. FDA has not taken official steps to enact this policy, and it remains to be seen whether Dr. Makary's statements will mark a possible step toward a long-debated "mechanism-based" approval pathway, which would create a regulatory route to approval based on a product's mechanism of action (i.e., how a drug or biologic produces an effect in the body) instead of relying solely on clinical data.

Such a pathway could present significant opportunity for companies developing drugs to treat rare diseases. Even absent such a pathway, Dr. Makary has advocated leveraging the "mass availability of health data and cloud computing" to "enable a broad move from a requirement for 2 pivotal clinical trials used by FDA regulators for many products in the past down to 1" or even relying solely on postapproval monitoring for safety and efficacy for drugs addressing rare diseases.⁴⁸

Compounding and Telehealth

Over the past several years, online services providing compounded drugs via telehealth have proliferated. This practice has come under scrutiny in recent months because many customers had been obtaining compounded GLP-1 (glucagon-like peptide-1

⁴⁷ [Fighting the Swamp and Conflicts of Interest, and Finding Autism Cause, with Dr. Marty Makary, The Megyn Kelly Show \(Apr. 17, 2025\).](#)

⁴⁸ [Martin Makary & Vinay Prasad, Priorities for a New FDA, JAMA \(June 10, 2025\).](#)

receptor agonists) drugs at significant discounts when compared with the prices of the brand name drugs such as Ozempic, Wegovy, and Mounjaro.

Compounded drugs generally have the same active ingredients as brand-name drugs, but they do not undergo FDA review and approval prior to marketing. The purpose of the compounded drug regulatory regime is to make drugs available to patients when a commercially available drug is not medically appropriate. For example, a patient may seek a compounded drug if they have an allergy to a certain dye found in the commercially available product. Compounded drugs are not intended to be mass produced and mass marketed, and the law prohibits compounding a drug that is “essentially a copy” of a commercially available product.

Until recently, pharmacies could compound copies of Ozempic and Wegovy because the drugs had been on FDA’s drug shortage list since 2022 and therefore were not considered “commercially available.” On February 21, 2025, FDA announced the end of the shortage and ordered all compounding of these drugs to cease by May 22, 2025.⁴⁹ Some telehealth companies are circumventing this ban by marketing GLP-1 drugs in formulations and dosage forms not found in FDA-approved products, claiming that these products can be lawfully compounded because they are personalized to patient needs and are not “essentially copies” of the FDA-approved drugs. Eli Lilly, the company marketing Mounjaro, recently filed lawsuits accusing telehealth companies of engaging in the corporate practice of medicine by unilaterally changing the compounded formulations that can be prescribed by its affiliated doctors without provider input or consideration of individual patients.⁵⁰

We expect to see continued FDA scrutiny and enforcement related to popular compounded products. FDA’s website carries a public warning about unapproved GLP-1 drugs, informing consumers that “the agency does not review compounded drugs for safety, effectiveness or quality before they are marketed.”⁵¹ FDA noted “areas of concern,” including adverse events related to dosing errors for compounded injectable GLP-1 products resulting from “patients measuring and self-administering incorrect doses of the drug, and in some cases, health care professionals miscalculating doses of the drug.”⁵² In April 2025, FDA issued an alert about risks associated with compounded topical finasteride products, also widely available through telehealth companies.⁵³ FDA

⁴⁹ [FDA, Declaratory Order: Resolution of Shortages of Semaglutide Injection Products \(Ozempic and Wegovy\) \(Feb. 21, 2025\)](#).

⁵⁰ [Eli Lilly & Co. v. Mochi Health Corp.](#), No. 3:25-cv-3534 (N.D. Cal. Apr. 23, 2025); [Eli Lilly & Co. v. Aios Inc. d/b/a Fella Health and Delilah](#), No. 3:25-cv-03535 (N.D. Cal. Apr. 23, 2025).

⁵¹ [FDA, FDA’s Concerns with Unapproved GLP-1 Drugs Used for Weight Loss \(May 30, 2025\)](#).

⁵² *Id.*

⁵³ [FDA, FDA Alerts Health Care Providers, Compounders and Consumers of Potential Risks Associated with Compounded Topical Finasteride Products \(Apr. 22, 2025\)](#).

warned of adverse events associated with the hair loss product, including erectile dysfunction and suicidal ideation.⁵⁴

Laboratory-Developed Tests (“LDTs”)

The debate surrounding the regulation of LDTs continues, with the device industry pitted against clinical labs that develop and market diagnostics in the absence of FDA oversight (but subject to other Federal and state regulatory requirements). LDTs are *in vitro* diagnostic tests that are designed, manufactured, and used within a single laboratory (e.g., a hospital’s in-house laboratory). FDA traditionally exercised enforcement discretion for these tests and has not enforced premarket review or other applicable requirements. Under this policy, FDA would generally allow traditional LDTs to remain on the market but would enforce as necessary if an LDT presents a safety risk (e.g., by requiring premarket review). Because LDTs are ubiquitous, FDA had been hesitant to alter the status quo, much to the frustration of companies marketing equivalent FDA-cleared tests.

FDA’s long-held position of enforcement discretion ended on May 6, 2024, when the agency issued a final rule classifying LDTs as medical devices subject to premarket review and implementing a phaseout policy during which FDA would gradually exercise increased oversight.⁵⁵ A federal judge in Texas, however, struck down the rule in March 2025, using the *Loper Bright* ruling (see Introduction) to rule that FDA exceeded its statutory authority because the FFDCA does not expressly grant FDA the power to regulate LDTs as medical devices.⁵⁶

The Trump administration decided not to appeal the ruling, so the LDT rule is effectively dead. During the Biden administration, Congress had been working on legislation to create a regulatory framework for LDTs, but it is unlikely to be advanced during this administration. At least for the remainder of the second Trump administration, we expect LDT policy to remain unchanged.

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Please do not hesitate to contact us with any questions.

⁵⁴ Id.

⁵⁵ [FDA, Final Rule: Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37286 \(May 6, 2024\)](#).

⁵⁶ [American Clinical Laboratory Association v. FDA, No. 4:24-cv-479-SDJ \(E.D. Tex. Mar. 31, 2025\)](#).



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