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FDA Leadership Shakeup: Impacts on Drug Approvals & AI

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Executive Summary

Update (November 2026): This article describes the situation as of May 2026. FDA's official biographies now list Michael Davis as CDER Center Director and Karim Mikhail as CBER Director, without the "Acting" label, so the acting-leadership details below reflect May 2026.

In May 2026, the Food and Drug Administration (FDA) was rocked by a major leadership turnover: Commissioner Dr. Marty Makary abruptly resigned after just 13 months in office. This surprised many, as Makary had pursued an aggressive "Make America Healthy Again" agenda of deregulation – for example, announcing a new default of requiring one study, rather than the two studies FDA had long expected, for new drugs and fast-tracking many high-profile therapies. The White House named Kyle Diamantas, FDA's Deputy Commissioner for Foods, as Acting FDA Commissioner (apnews.com). In parallel, veteran FDA leaders at the centers overseeing drugs and biologics were replaced: Dr. Michael Davis (a former FDA psychiatry-drug review team leader who later served as chief medical officer of a nonprofit developing psychedelic drugs, and returned to FDA in 2025) became Acting Director of CDER (drugs) (apnews.com) (www.fda.gov), and pharmaceutical executive Karim Mikhail was named Acting Director of CBER (biologics and vaccines) (apnews.com) (www.fda.gov).

This leadership shake-up injects new uncertainty into the drug-approval process. During Makary's brief tenure, the FDA launched many unprecedented initiatives – for example, targeting **1–2 month review times** for "national interest" drugs via a new voucher program (apnews.com) (www.axios.com), and proposing to **accept a single pivotal trial** (instead of two) for most novel drugs (apnews.com). He also pressed aggressively to deploy artificial intelligence (AI) across the agency, from an internal generative-AI assistant ("Elsa") to real-time clinical trial monitoring tools (www.healthcare-brew.com) (www.axios.com). Many of these changes were announced by media events and guidance rather than through formal rulemaking (apnews.com). Makary's successor, even on an acting basis, will decide which reforms to carry forward. Industry leaders (PhRMA CEO

Steve Ubl, for example) have publicly urged the new FDA leadership to “calm the waters” and restore predictability in the review process (www.axios.com). At the same time, the FDA’s broad effort to harness AI in drug development and regulation appears poised to continue under HHS Secretary Robert F. Kennedy Jr.’s pro-AI strategy (apnews.com) (www.healthcare-brew.com).

For drug sponsors, the net effect is mixed. On one hand, many trailblazing Makary policies could survive – for example, voucher programs and AI tools that speed review – potentially **accelerating** the path to approval for some products. On the other hand, uncertainty abounds: with acting leaders in key roles and a volatile policy environment, sponsors must plan for shifting requirements. We expect sponsors to closely monitor who is ultimately named permanent FDA commissioner (a post-May 2026 development this May 2026 snapshot does not cover) and any legal or legislative actions that might affirm or reverse Makary’s agenda. In the near term, companies should seek early communication with the FDA (to take advantage of new accelerated review pathways) and prepare for the continued use of AI in regulatory processes. Ultimately, this FDA shake-up likely portends a complex mix of faster pathways for some products and continued uncertainty elsewhere, with sponsors needing to adapt accordingly.

Introduction and Background

The FDA is the U.S. regulatory agency charged with ensuring that drugs, biologics, and medical products are safe and effective. Its leadership – notably the Commissioner and the heads of its four major centers (CDER for drugs, CBER for biologics/vaccines, CDRH for devices, and CFSAN for foods) – typically serves based on a combination of scientific expertise and policy direction. As of May 2026, the agency is operating in a politically charged environment. President Donald Trump has appointed a new Health and Human Services (HHS) Secretary, Robert F. Kennedy Jr.. Makary, a Johns Hopkins surgeon, was confirmed as FDA Commissioner 13 months earlier (March 2025). He arrived promising to “cut red tape” and accelerate approvals.

Importantly, this shake-up comes amid **unprecedented turnover across HHS**. By early May 2026, the Department had multiple senior vacancies: no permanent U.S. Surgeon General, an acting NIH Director doubling as CDC head, and a change in FDA Vaccines leadership. This context underscores the significance of Makary’s exit, which leaves another HHS agency under acting leadership.

Below we analyze this leadership change in depth. We first detail Makary’s tenure and resignation, then describe the new acting leaders at FDA. We then examine how the shockwaves of this shake-up may affect the **drug approval process** and the agency’s **AI policy** – highlighting data, case examples, and stakeholder reactions. Finally, we discuss the implications for drug sponsors and outline future directions for FDA policy and administration. Throughout, we draw on extensive reporting from reputable sources to provide a comprehensive, evidence-based assessment.

FDA Leadership Shake-Up (May 2026)

On May 12, 2026, the Associated Press reported that FDA Commissioner Marty Makary would resign after 13 months in the role (apnews.com). Makary framed his exit positively, noting he had announced “50 major FDA reforms” compared to none under the prior administration (apnews.com).

Key Point: *Makary’s resignation was reported in May 2026 after 13 months as Commissioner. During that time he announced a broad set of reform initiatives.*

New Acting Leadership at FDA

Shortly after Makary’s exit was confirmed, President Trump and HHS announced interim leaders for FDA’s top posts. On May 12, President Trump named **Kyle Diamantas** (FDA’s Deputy Commissioner for Foods) as the **Acting FDA Commissioner** (apnews.com). In practice, Diamantas’s mandate (as Acting Commissioner) is to steward the agency until Trump nominates – and the Senate confirms – a full commissioner.

Simultaneously, two key center directors were replaced on May 15, 2026. FDA announced that **Dr. Michael Davis, M.D., Ph.D.** – previously Deputy Director of the Center for Drug Evaluation and Research (CDER) – would become the *Acting Director of CDER* (apnews.com) (www.fda.gov). Davis is a physician-scientist with deep experience at FDA’s drug center. FDA’s website initially listed him as “Acting Center Director, CDER” (his current FDA biography lists him as Center Director) (www.fda.gov). Davis thus assumes responsibility for the center overseeing human drug review at a critical time; he will manage applications and career staff on a day-to-day basis.

In parallel, FDA named **Karim Mikhail, M.S.** as Acting Director of the *Center for Biologics Evaluation and Research (CBER)* (apnews.com) (www.fda.gov). Mikhail is a former pharmaceutical executive who joined the FDA in 2025; FDA announced him as Acting CBER Director in May 2026, and FDA’s current biography lists him as Director of CBER (www.fda.gov). He takes over the biologics/vaccines center (including regulation of vaccines, biotech therapies, blood products etc.) after Dr. Vinay Prasad’s April departure (apnews.com).

As of May 2026, these moves left **three of FDA’s top four leaders serving only in an acting capacity** (with CDER and CBER then led by acting directors, and the Commissioner’s post held on an acting basis). The acting leadership team (Diamantas, Davis, Mikhail) represents a mix of legal, scientific, and industry backgrounds. Table 1 summarizes the immediate leadership changes:

FDA Position	Outgoing Leader	New Acting Leader	Date of Change
FDA Commissioner	Dr. Marty Makary	Kyle Diamantas (Deputy Foods Commissioner) (apnews.com)	May 12, 2026
Acting Director, CDER (Drugs)	Dr. Tracy B. Hoeg (Acting)	Dr. Michael Davis (former Deputy CDER) (apnews.com) (www.fda.gov)	May 15, 2026
Acting Director, CBER (Biologics/Vaccines)	Dr. Vinay Prasad (until Apr 2026)	Karim Mikhail (former pharma exec) (apnews.com) (www.fda.gov)	May 15, 2026

Table 1: Key FDA leadership changes following Commissioner Makary's resignation (sources: AP News (apnews.com), FDA.gov leadership pages (www.fda.gov), AP News (apnews.com)).

In addition, Dr. Michael Davis became Acting Director of CDER on May 15, succeeding Dr. Tracy Beth Hoeg, who had been Acting Director since December (apnews.com).. All told, May 15 saw a broad shake-up: **Karim Mikhail** took over the FDA vaccines/biologics center, and **Michael Davis** took the drug center, while **Kyle Diamantas** had just assumed overall agency leadership.

The immediate implication is that FDA's highest scientific posts are again in flux. As AP emphasizes, Makary's departure "widen [ed] a leadership gap" at HHS (apnews.com). Having experienced FDA hands (like Davis) in acting roles may provide some steadiness while a permanent Commissioner is chosen. PhRMA CEO Steve Ubl said the industry needs the next FDA leader "to calm the waters and reestablish that certainty and predictability" (www.axios.com).

Impact on Drug Approval Policies

The leadership turnover intersects directly with ongoing and proposed changes to the drug approval process. During Makary's tenure, FDA announced a flurry of **initiatives** intended to accelerate drug development. Many of these have not yet been fully codified (often being unveiled by news release or guidance), and their fate now hangs in the balance under new management. Below we analyze the major reform efforts and their potential consequences for sponsors.

Mandated Accelerated Review Programs

A centerpiece of Makary's agenda was **ultrafast review programs**. As early as June 2025, he unveiled a scheme whereby drugs aligned with "national health priorities" would be reviewed in 1–2 months (apnews.com) – a dramatic shortening from the usual FDA timeline. AP News reported in June 2025 that regular drug reviews take about 10 months; for comparison, FDA's priority-review goal is 6 months, versus 10 months under standard review (fda.gov) (apnews.com). The new "Commissioner's National Priority Voucher" program offers a special one-month target for select medicines (apnews.com), far faster than historical averages. Companies awarded such vouchers would receive enhanced communications with FDA and may submit data early to meet tight deadlines (apnews.com).

In practice, this means that sponsors of vaccines or therapies deemed urgent under the Trump Administration's priorities could see a much shorter review of their new drug applications (NDAs) – although a voucher shortens the review target and does not guarantee approval or any particular timeline. For example, on October 16, 2025 the FDA *proactively* selected nine candidates (across diabetes, vaping cessation, blindness, pancreatic cancer, etc.) to receive 1–2 month expedited review (www.axios.com). This was a marked shift: historically companies applied for priority review vouchers themselves, but the FDA under Makary began nominating promising therapies directly (www.axios.com). In another case, AP reports that in late April 2026 Makary personally announced "priority review vouchers" for three psychedelic mental-health drugs (psilocybin for depression, MDMA-like compound for PTSD) following a Trump executive order

(apnews.com). These vouchers, while not guaranteeing approval, promised to shorten the FDA's review from months down to weeks (apnews.com): Makary said the U.S. "ow [es] it to…veterans" to expedite such treatments (apnews.com).

In summary, under Makary the FDA was willing to dramatically **condense review timelines** for priority products — a boon to sponsors in those categories.

However, uncertainty remains. The one- to two-month review goal is a new approach, and its operational details are still developing. FDA's HHS spokesman has said the voucher program will still prioritize "gold standard scientific review" and genuine safety concerns (apnews.com).

Sponsor Perspective: Drug developers should recognize that ultra-rapid reviews are now *possible* for drugs tied to administration priorities – making the timelines far shorter than the historical ~10-month norm (apnews.com). Companies working on such drugs must be prepared to engage intensively with FDA and meet compressed deadlines. Conversely, developers of therapies outside these priority categories should be cautious: if reviewers are diverted to "one-month" projects, non-priority applications might face less attention or even delays. Industry groups have publicly called for stability; PhRMA's CEO urged new FDA leadership to "calm the waters" and re-establish predictability (www.axios.com). Achieving predictability will likely depend on clearer guidance as the new policies are implemented. In the interim, sponsors should actively seek dialogue with the FDA: for priority drugs, take advantage of accelerated programs, and for others, clarify expectations under the evolving regime.

Pivotal Trial Requirements

One of Makary's most significant pronouncements was changing the core evidence level for NDAs. In a February 18, 2026 *New England Journal of Medicine* article, Makary and a top deputy, Dr. Vinay Prasad, announced a shift from requiring two adequate and well-controlled trials (a standard since the 1962 amendments) to a *one-trial default* (apnews.com). Former CDER director Dr. Janet Woodcock said that "as we move toward greater understanding of biology and disease we don't need to do two trials all the time" (apnews.com). If implemented, this policy would lower the evidentiary bar for new drugs – potentially allowing approvals based on a single strong trial (supplemented by other data). Makary predicted this change would unleash "a surge in drug development" (apnews.com), and Dr. Janet Woodcock (former CDER Director) acknowledged that, for certain diseases like cancer, one trial plus supportive evidence is increasingly common (apnews.com).

This proposal has major implications. Rare disease sponsors in particular would benefit if fewer confirmatory trials are needed, since recruiting patients is often difficult. AP News noted that rare-disease advocates have long lobbied for just this flexibility (apnews.com). In fact, the FDA simultaneously introduced a new "bespoke therapy" pathway for rare and hard-to-treat genetic conditions (apnews.com). Under these tentative guidelines, gene-edited or individualized treatments tested only in a handful of patients could proceed under a special framework – an initiative "long sought by patients" (apnews.com). FDA Commissioner Makary framed it as "our priority to remove barriers and exercise regulatory flexibility" for rare diseases (apnews.com). In practice, this could accelerate approvals of gene therapies or orphan drugs.

However, roll-out of these rules remains provisional. It was presented as “proposal” and “guidelines” rather than firm regulations, and actual implementation may require further rulemaking. The change from two trials to one also invites scientific pushback: experts warn that in many cases a single study may not fully capture safety, and accelerated approvals already have conditions. In the current environment, it is unclear whether a new FDA leader would embrace or slow- down this paradigm shift. Sponsors should watch carefully: if the one-trial policy is cemented, it will reduce costs and time to approval; if reversed, companies may have to plan traditional dual trials as before.

Other Regulatory Reforms

Several other Makary-era initiatives bear on sponsors of new therapies:

- **Orphan and Rare Therapies:** Beyond the niche “bespoke” pathway mentioned above, Makary advanced multiple orphan/drug priorities. He made clear that tackling “unprofitable” rare diseases was a goal, signaling support for relaxed requirements in those fields (apnews.com). Sponsors of orphan drugs – already accustomed to special rules (like Orphan Drug Act) – might have expected additional incentives. The FDA’s stated intention to consider more flexible evidence (one trial, as noted) is directly relevant to rare-disease sponsors. However, it’s uncertain how far FDA will go without new legislation.
- **Stakeholder Involvement:** His administration often preferred *voluntary industry agreements* over formal rulemaking (apnews.com). Sponsors should thus be alert to FDA announcements via press releases or talks (which may signal future policy), as opposed to waiting only on formal guidance documents.
- **Payer and Pricing Policies:** Although outside FDA’s formal purview, the agency’s activities intersect with drug pricing policy. Industry groups have publicly debated the administration’s “most favored nation” (MFN) pricing proposals (e.g. PhRMA publicly opposed Trump’s plan to set U.S. prices to lower OECD price levels (www.axios.com)). Sponsors should track how pricing policy and FDA programs develop.
- **Staffing and Review Backlog:** Staffing levels at CDER are a factor for sponsors to monitor, since review capacity can affect timelines. Sponsors should plan for possible variation in review timing and engage early with the agency. Makary’s push for AI and vouchers may also have been intended to make reviews more efficient (see next section).

Table: Comparison of Key Regulatory Practices

Regulatory Aspect	Pre-2025 FDA Practice	Makary-era Proposal/Change	Citation
Approval timeline	Standard review: goal of ~10 months; Priority review: goal of ~6 months (apnews.com).	New “voucher” scheme targeting 1–2 month review for priority drugs (apnews.com) (www.axios.com).	(apnews.com) (www.axios.com)
Required pivotal trials per NDA	Statute requires “adequate and well-controlled investigations”; FDA long interpreted this as at least two studies (apnews.com).	Proposed default of one trial for new drugs (apnews.com).	(apnews.com)

Regulatory Aspect	Pre-2025 FDA Practice	Makary-era Proposal/Change	Citation
Handling of prioritized therapies	Sponsors apply for priority reviews; FDA reviews all submissions sequentially.	FDA proactively identifies “national priority” drugs and issues fast-track vouchers (www.axios.com).	(www.axios.com)
Use of artificial intelligence (AI)	Modest pilot programs (e.g. internal FDA “Elsa” tool) (www.axios.com).	Roughly 150 new AI systems reported by Makary (per a March 2026 interview) for review tasks; new AI-driven trial monitoring (www.healthcare-brew.com) (www.axios.com).	(www.axios.com) (www.healthcare-brew.com)

Table 2: Key differences in FDA drug review practices under Makary’s proposals vs. historical norms (sources as cited).

This table highlights how dramatically FDA’s paradigm has shifted. In a span of one year, ordinary NDA approvals (previously ~10 months) could be trimmed to weeks under special programs (apnews.com). Similarly, FDA’s long-standing two-study expectation is being replaced, as the announced default, by a one-study approach (apnews.com). These changes promise faster pathways for sponsors – but many of them lack formal rulemaking, leaving them vulnerable to reversal.

AI Policy and Automation

A major theme of Makary’s tenure was **aggressive adoption of artificial intelligence** within FDA operations. This has direct implications for sponsors, both in terms of regulatory efficiency and future expectations. Under Makary, the FDA undertook several AI initiatives:

- **Internal AI Tools:** The agency launched an in-house generative AI tool named *“Elsa”* in June 2025 (www.axios.com). Elsa is designed to assist reviewers by summarizing adverse event reports and even generating database queries (www.axios.com). In addition, Makary encouraged FDA staff to propose AI solutions that could improve workflows: he said the agency received 181 staff submissions across workflows such as document processing, review automation, safety-signal detection, manufacturing and compliance support (www.healthcare-brew.com), but that those submissions had not yet been implemented and were still being reviewed. Separately, the interviewer noted that Makary had said at the January 2026 JPMorgan Healthcare Conference that FDA had built 150 new AI systems (www.healthcare-brew.com). Early metrics suggest these tools are having an impact: Makary said FDA’s AI tools saved 17,000 hours of human work time in the measurement period since implementation at the end of June 2025 (www.healthcare-brew.com). The goal, Makary said, was to free reviewers from routine steps such as ensuring submission formatting is correct, which he called “a very tedious task that’s done by humans” so they can focus on higher-order analysis (www.healthcare-brew.com).
- **Clinical Trial Monitoring:** On April 29, 2026, FDA announced two “proof-of-concept” projects to use AI and data science to monitor ongoing clinical trials in real time (www.axios.com). FDA Chief AI Officer Jeremy Walsh told reporters these tools could shave “20–40%” off overall trial time by identifying issues

faster (www.axios.com). Commissioner Makary framed this as challenging the notion that it must take 10–12 years to get a drug to market (www.axios.com). For sponsors, such innovations imply that even clinical phase may be shortened by algorithmic analysis and adaptive oversight.

- **Engagement with AI Industry:** Reports have surfaced that FDA has been in talks with major AI developers. A Wired (and Axios) story revealed that the FDA was reportedly discussing a custom OpenAI-based chatbot, tentatively dubbed **"cderGPT,"** to assist CDER reviewers (www.axios.com). While details remain limited, this indicates FDA aims to leverage cutting-edge AI language models for regulatory work. Alongside, a broad HHS AI strategy (December 2025) explicitly encourages rapid AI adoption across all health agencies (apnews.com). Under the Trump administration, Biden-era AI guardrails have been repealed in favor of a "tear down barriers to progress" mentality (apnews.com), which the FDA has embraced.

Makary himself publicly heralded an "AI revolution" at the agency. In a March 2026 interview he noted that the FDA had implemented an **"AI reviewer tool"** and even an "agentic AI" feature for inspectors (www.healthcare-brew.com). He emphasized that none of these tools were making final decisions – they simply automated mundane checks and document reviews (www.healthcare-brew.com). But by improving efficiency, he argued, AI could help drugs reach patients faster. For example, Makary pointed out that the 60-day filing period leaves smaller drug developers burning cash while they wait for the FDA to confirm an application is complete (www.healthcare-brew.com); AI can speed up administrative steps.

Implications for Sponsors: Drug companies should expect the FDA to increasingly **use AI in the background** of regulation. The agency's internal efficiency gains (17,000 hours saved (www.healthcare-brew.com)) suggest reviews may become faster and more data-driven. Sponsors will likely encounter more requests for electronic dataset formats, and may need to engage with new FDA tools. For example, if FDA reviewers use AI to check completeness of applications, sponsors might preemptively use AI to ensure their submissions are fully consistent and organized. Sponsors should seek clarity on how FDA handles their confidential data when using generative models.

Regarding **AI policy or guidelines for industry**, the situation is still evolving. The FDA has existing guidance for Software as a Medical Device (SaMD), including AI/ML-based medical algorithms, but Makary's tenure did not produce a landmark new regulation for AI products. However, given HHS's pro-AI strategy (apnews.com), sponsors developing AI-powered diagnostics or therapeutics should anticipate a generally supportive stance (at least under the current administration). Manufacturers should track the FDA's announcements, as the agency may issue specific guidance on AI/ML in pharmaceuticals or digital health in the near future, driven by the broader federal AI agenda.

In summary, **Makary's FDA accelerated the adoption of AI** as a core tool for drug review. That momentum is unlikely to vanish because it aligns with both political leadership and industry efficiency goals. Sponsors should leverage AI in their own development pipelines and be ready to integrate with FDA's AI-driven workflows. At the same time, they must remain vigilant about data governance and possible new requirements for algorithmic validation, since regulators globally are debating how to oversee AI in healthcare.

Case Studies and Real-World Examples

To ground these policy changes, we examine several concrete examples from the past 12 months:

- **Rare Genetic Therapies:** FDA's proposal of a "bespoke therapy" pathway for rare diseases (apnews.com) offers a potential boon. Suppose a biotech is developing a CRISPR-based gene therapy for an ultra-rare metabolic disorder. Under traditional rules, the lack of large trials could stymie approval. Makary's proposed guidelines, however, would allow such a therapy to be considered based on limited patient data. This could dramatically shorten development time. If finalized, sponsors of custom gene therapies may proceed more swiftly. Conversely, if new leadership rolls back this flexibility, sponsors may need to rebuild cases with additional trials.
- **Clinical Trial Duration:** The FDA's April 2026 initiative to use AI for real-time monitoring (www.axios.com) could, if it proves out, shorten trial lengths; any savings remain speculative. Imagine a mid-stage oncology trial: rather than waiting years to accrue data, FDA's AI tools might detect efficacy or safety signals early. For sponsors, this could accelerate phase 3 launches and NDA filings. While still experimental, it signals that even the **clinical phase** might speed up under Makary's vision. Sponsors should watch how these proof-of-concept projects develop.
- **Drug Approval Trends:** In 2025 and early 2026, approvals continued. By May 2026, FDA had announced a one-trial default policy (apnews.com) and ultrafast voucher reviews (apnews.com); these are policy announcements, not repeal of the statutory standard. Sponsors should track whether they change the official approval statistics. For context, FDA reports that CDER approved 46 novel drugs in 2025 (fda.gov).

Implications for Sponsors and Future Outlook

The FDA leadership shake-up of May 2026 leaves drug sponsors with a complex outlook. A few key messages emerge:

- **Acceleration for Priority Drugs:** Any sponsor working on a drug that the Trump administration deems a "national health priority" (e.g. psychedelics for PTSD, gene therapies for rare diseases, etc.) should aggressively pursue FDA's fast-track options. The Makary-era policies created explicit accelerants (voucher programs, one-trial standard, extensive AI use) that can all benefit sponsors who align with those priorities (apnews.com) (www.axios.com) (apnews.com). Sponsors of such products should ensure readiness to meet tight FDA timelines; the reward could be much faster approval and market entry.
- **Need for Predictability:** Conversely, sponsors of drugs outside these designated areas face uncertainty. The regulatory environment is less predictable than normal. Trade groups like PhRMA have already voiced alarm, stressing the need for "certainty and predictability" in FDA leadership (www.axios.com). For these companies, a prudent strategy is early and transparent engagement with

FDA. For example, making full use of pre-submission meetings (Q&As) is more important than ever to clarify expectations. If a development program has any flexibility (e.g. design of trials), companies should consider building in options for both accelerated and standard review scenarios.

- **Watch for Rulemaking and Guidance:** Many Makary proposals are not yet law. In the coming months, sponsors should watch Federal Register and FDA webpages for any draft guidances or rules. FDA announced the one-study "default position" in a journal article rather than a final rule, so sponsors should watch for guidance or rulemaking that would formalize it. If FDA proposes to make a one-trial standard binding, companies should prepare to either capitalize on it (if favorable) or argue for exceptions. Similarly, the future of AI in submissions (e.g. whether sponsors must reveal machine learning models or algorithms used) is unsettled. Given FDA's past reliance on guidance documents, we anticipate new guidance on expedited programs and on digital submissions in late 2026 or 2027.
- **Equity and Safety Considerations:** Sponsors must also be aware of the risk environment. Accelerating review and cutting trial requirements could raise safety concerns. FDA's historical commitment to rigorous evidence remains a touchstone. Sponsors should therefore ensure robust post-marketing and Phase IV plans, especially if they seek accelerated approvals. Demonstrating strong safety monitoring and data transparency will be critical to maintain FDA confidence.
- **AI Integration:** On the AI front, sponsors should proactively incorporate data science into their development and regulatory strategies. If the FDA is using AI to detect trial issues or review content, companies can leverage AI to optimize trial design, endpoint selection, and submission formatting. For instance, sponsors might use NLP tools to pre-screen regulatory submissions for completeness – anticipating the "AI reviewer" at FDA. They should also consider how their own use of AI (in drug discovery, patient selection, etc.) will be viewed by regulators: transparency about algorithms and validation processes could be important, and staying informed about FDA's future AI guidelines is prudent.
- **Pricing and Policy Phalanxes:** Lastly, sponsors must navigate the broader healthcare policy battles that intersect with FDA's work. The Trump Administration (aligned with Makary, Kennedy, and conservative lawmakers) has pushed aggressive price reforms (e.g. Most Favored Nation linking) alongside expedited approvals (www.axios.com) (apnews.com). Sponsors should monitor how pricing policy and FDA programs evolve.

In summary, this FDA shake-up can be seen as both an **opportunity and a risk** for drug developers. Opportunities lie in novel, faster pathways and a broader openness to innovation (especially using AI). Risks lie in unpredictability and the unsettled legal footing of many new policies. Sponsors should actively engage with the FDA to clarify the post-Makary landscape, and adjust their development plans accordingly.

Looking ahead, much depends on future appointments. This article is a snapshot as of May 2026, when the Senate had not yet confirmed a new FDA Commissioner; later developments in the nomination process are not covered here. Axios noted at the time that confirmation of a nominee could be delayed by competing priorities in Congress (www.axios.com). As of May 2026, if the acting leadership were to remain in place for many months, sponsors would essentially be dealing with interim officials. Permanent leadership – and possibly new

statutes – would be required to make deep changes permanent. The outcome of this unsettled period will likely shape FDA policy for years: either embedding Makary's deregulatory vision, or curbing it in favor of more traditional standards.

Conclusion

The May 2026 leadership shake-up at the FDA marks a critical inflection point for drug regulation. The abrupt exit of Commissioner Marty Makary – after a year of reform efforts – and the installation of new acting leaders in Washington and at the drug/biologics centers have created both **exciting possibilities and great uncertainties** for drug sponsors. On one hand, we have seen unprecedented commitments to speed up approvals: from one-month review targets (apnews.com) to more flexible evidence requirements (apnews.com), and an aggressive push to harness artificial intelligence (www.healthcare-brew.com) (www.axios.com). On the other hand, the agency's top posts are largely held on an acting basis and many of the new policies remain unsettled..

For drug developers, the path forward is clear: engage attentively with FDA, align with areas of regulatory priority, and prepare for evolving rules. Those able to plug into expedited programs (e.g. through voucher applications for high-need drugs) may find themselves on an accelerated track. Others should advocate for clear guidance to restore predictability in the review process. In all cases, sponsors must be mindful of the new FDA's embrace of AI and digital tools, and ensure that their own development processes remain robust.

Ultimately, as of May 2026, the new acting FDA leadership was poised to set the tone for Donald Trump's second-term health agenda. With all top positions in flux as of May 2026, final outcomes will depend on who is confirmed and what Congress does (for example, whether it codifies any of these FDA experiments). Meanwhile, the near-term implication is mixed: **faster pathways for some products, and continued uncertainty elsewhere**. Drug sponsors should stay informed of policy updates (through official FDA channels and credible news sources) and remain flexible. The Makary era may have ended, but its imprint on the FDA – and on drug approval timelines and AI policy – is likely to shape the agency's course well into 2027 and beyond.

References: This report draws on extensive contemporaneous reporting (AP News, Axios, FDA releases, etc.) to cite facts and quotes (see inline citations) and to present multiple viewpoints. Key claims above are supported by sources such as AP News (2026-05-12) (apnews.com), Axios (2026-05-13) (www.axios.com), and official FDA publications (www.fda.gov), among many others listed in the text.

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About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore AI enablement, pharma and biotech software development, data engineering and BI, and Veeva services. Contact IntuitionLabs to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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