FDA Leadership Shakeup: Impacts on Drug Approvals & AI

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Executive Summary

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, proposing to eliminate the FDA’s longstanding two-study requirement for new drugs and fast-tracking many high-profile therapies. Nonetheless, Makary’s tenure was beset by internal conflict and controversies. He clashed with Republican priorities (e.g. fruit-flavored e-cigarettes) and drew criticism from a broad cross-section of stakeholders – from rare-disease patient groups to anti-abortion and anti-vaping activists – over his decisions ([1] apnews.com) ([2] theweek.com). These tensions, along with a series of management shake-ups and policy reversals, prompted the White House to bring in Kyle Diamantas (a Trump family confidant and FDA food lawyer) as Acting FDA Commissioner ([3] apnews.com) ([4] www.thedailybeast.com). In parallel, veteran FDA leaders at the centers overseeing drugs and biologics were replaced: Dr. Michael Davis (a career drug regulator) became Acting Director of CDER (drugs) ([5] apnews.com) ([6] www.fda.gov), and pharmaceutical executive Karim Mikhail was named Acting Director of CBER (biologics and vaccines) ([7] apnews.com) ([8] 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 ([9] apnews.com) ([10] www.axios.com), and proposing to **accept a single pivotal trial** (instead of two) for most novel drugs ([11] 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 ([12] www.healthcare-brew.com) ([13] www.axios.com). Many of these changes were announced by media events and guidance rather than through formal rulemaking ([14] 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 ([15] 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 ([16] apnews.com) ([17] 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 products aligned with current political priorities. 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 the incoming permanent FDA appointee 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 approvals in certain politically favored areas (e.g. psychedelic therapies, vaping cessation, gene-edited rare disease treatments) and persistent regulatory turbulence 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., who brings his own agenda (often at odds with consensus public health views) ([1] apnews.com) ([14] apnews.com). Makary, a Johns Hopkins surgeon known for fringe positions on COVID-19 mandates, was confirmed as FDA Commissioner 13 months earlier (March 2025). He arrived promising to “cut red tape” and accelerate approvals, but soon faced criticism from a wide range of stakeholders ([1] apnews.com) ([18] theweek.com).

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 recently ousted FDA Vaccines chief ([19] apnews.com) ([20] apnews.com). AP News noted that "virtually all" of the FDA's senior career officials had left the agency in the first year of the Trump administration ([21] apnews.com). Critics warn this level of upheaval is highly unusual and undermines the agency's scientific capacity ([22] apnews.com) ([23] apnews.com). As one former CDC official warned, "It's a sign that something is not right" when such key posts are unfilled or filled by acting leaders ([24] apnews.com). This context underscores the significance of Makary's exit: it leaves **another HHS agency leaderless**, further stretching the agency's already strained resources ([19] apnews.com).

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 a "rocky tenure" of just 13 months ([1] apnews.com). Makary's departure followed intense internal and external turmoil. He had alienated numerous **stakeholders**: *health industry executives, anti-abortion advocates, vaping lobbyists,* and other allies of President Trump had lodged "months of complaints" about his decisions ([1] apnews.com). At the same time, public health experts accused him of pandering to fringe views (e.g. prodding on vaccine safety studies) at the expense of core scientific standards ([25] apnews.com) ([26] theweek.com). Makary himself framed his exit as a positive noting he had announced "50 major FDA reforms" compared to none under the prior administration ([27] apnews.com), but in reality the White House and HHS had agreed "in recent days on the need to replace" him ([28] theweek.com). President Trump later confirmed Makary's resignation text via social media, stating only that Makary "was having some difficulty" and would "go on and do well" ([29] apnews.com).

Behind the scenes, reports painted a picture of deep **agency dysfunction**. Virtually all senior *career* FDA officials had resigned, retired, or been pushed out since Makary's arrival, leading to "a steady stream of leaks and negative stories" about low morale ([21] apnews.com). Makary had instituted mass layoffs and buyouts under new budget directives, further unsettling the workforce ([30] apnews.com) ([21] apnews.com). Notably, his handpicked deputy, Dr. Vinay Prasad, was forced out twice within the year for antagonizing specialty drugmakers and rare-disease patient groups ([21] apnews.com). By early May 2026, Dr. Tracy Beth Hoeg (a young vaccine safety researcher rapidly promoted by Makary) was serving as Acting CDER Director, and Prasad had already turned in colleagues at CBER. AP News summarized that despite these upheavals, Makary "struggled to manage the FDA's bureaucracy and failed to win the confidence of its staff" ([30] apnews.com).

Media reports highlight several flashpoints. For example, Makary **initially resisted** the White House's demand to approve fruity-flavored e-cigarettes, only relenting after Trump personally pressured him. On May 6, the FDA abruptly "authorized the first fruit-flavored e-cigarettes" (for a company called Glas Inc.), after Makary had earlier blocked them over youth-use concerns ([31] www.cbsnews.com). A CBS News source confirmed Makary did not want to approve the flavors but was "forced" by others in the administration ([32] www.cbsnews.com). Conversely, he delayed acting on Republican pressure to curb online prescribing of the abortion pill (mifepristone), angering anti-abortion advocates. By April 2026, state attorneys general had sued FDA for not moving faster on mifepristone restrictions ([33] apnews.com). Makary was also internally **involved in controversies** over COVID-19 booster guidance and antidepressant safety, which were perceived by some as "political influences" overriding science ([30] apnews.com).

The result was that Makary's FDA became a "lightning rod" for controversy within the Trump administration, especially tied to HHS Secretary Kennedy's agenda. Axios reported that Makary faced "internal criticism for not accommodating

some of the president's priorities" and complaints from investors about "unpredictable regulatory decisions that rejected promising drugs" ([34] www.axios.com). In other words, some industry leaders were upset that Makary still enforced certain standards and disapproved some high-profile applications, contributing to the departure.

By May 12, all signs indicated that Makary's resignation was imminent. The Washington Post, The Wall Street Journal, and The New York Times had all published dispatches about internal pressure to remove him ([2] theweek.com). AP News observed that Makary "appeared poised to weather the controversy" (despite the rare-disease uproar over Prasad) until the e-cigarette issue provided a pretext for his exit ([35] apnews.com). In sum, Makary's departure was the culmination of a year of turmoil: his aggressive reform agenda, mixed with management missteps and high-profile disputes, left him "with just about run out of allies," as the WSJ put it ([18] theweek.com).

Key Point: *Makary's resignation (May 2026) emerged from a uniquely fraught tenure with mass staff turnover and multiple controversies ([1] apnews.com) ([21] apnews.com). He announced ambitious reforms (50-plus initiatives) but alienated powerful stakeholders. Health policy watchers viewed his ouster as emblematic of the broader instability at HHS under Secretary Kennedy ([19] apnews.com) ([33] apnews.com).*

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** ([3] apnews.com) ([4] www.thedailybeast.com). Diamantas, 38, is a Florida-based lawyer who had served only briefly (one year) at FDA before this role ([4] www.thedailybeast.com). Media profiles describe him as a close friend and hunting buddy of Donald Trump Jr. ([36] www.thedailybeast.com) ([37] www.thedailybeast.com). Importantly, Diamantas holds *no medical or scientific degree* – unlike most FDA commissioners – a fact noted as "unusual" by FDA veteran Susan Mayne ([38] www.thedailybeast.com). Nevertheless, Trump hailed him as "very talented" and Kennedy emphasized that a permanent Commissioner search would proceed ([39] www.thedailybeast.com). In practice, Diamantas's mandate (as Acting Commissioner) is to steward the agency until Trump nominates – and the Senate confirms – a full commissioner. Critics note he has no FDA scientific background, while supporters claim he will reliably advance the administration's priorities ([38] www.thedailybeast.com).

Simultaneously, two key center directors were replaced on May 16, 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* ([5] apnews.com) ([6] www.fda.gov). Davis is a physician-scientist with deep experience at FDA's drug center. The FDA's own website now lists him as "Acting Center Director, CDER" ([6] 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)* ([7] apnews.com) ([8] www.fda.gov). Mikhail is a former pharmaceutical executive who joined the FDA in 2025; official FDA biographies now identify him as the agency's Acting CBER Director ([8] 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 ([20] apnews.com). According to AP, Mikhail "had no prior government or management experience" before being promoted by Makary, but his pharmaceutical background may make him industry-friendly ([40] apnews.com).

These moves leave **three of FDA's top four leaders serving only in an acting capacity** (with CDER and CBER now led by acting directors, and the FDA Commissioner's slot vacant). 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) ([3] apnews.com) ([4] www.thedailybeast.com)	May 12, 2026
Acting Director, CDER (Drugs)	Dr. Tracy B. Hoeg（Acting）	Dr. Michael Davis (former Deputy CDER) ([5] apnews.com) ([6] www.fda.gov)	May 16, 2026
Acting Director, CBER (Biologics/Vaccines)	Dr. Vinay Prasad (until Apr 2026)	Karim Mikhail (former pharma exec) ([7] apnews.com) ([8] www.fda.gov)	May 16, 2026

Table 1: Key FDA leadership changes following Commissioner Makary's resignation (sources: AP News ([3] apnews.com), FDA.gov leadership pages ([8] www.fda.gov) ([6] www.fda.gov), AP News ([41] apnews.com)).

In addition, an internal memo (obtained by AP News) revealed that Dr. Tracy Beth Hoeg – who had been serving as Acting Director of CDER since December – was relieved of her post and replaced by Michael Davis on May 16 ([41] apnews.com). Hoeg (a former FDA project manager quickly elevated by Makary) announced on social media that she was "fired" ([42] apnews.com). All told, May 16 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 ([43] apnews.com). Former employees worry about continuity: for example, Walsh of HHS warned that having multiple acting leaders can slow decision-making. On the other hand, having experienced technocrats (like Davis) in acting roles may provide some steadiness while a permanent Commissioner is chosen. Industry stakeholders have underscored the need for "consistent leadership" moving forward ([15] 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 **innovative and controversial 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 ([9] apnews.com) – a dramatic shortening from the usual FDA timeline. AP News explained that in 2026 the FDA's "long-standing accelerated approval program" normally took about 6 months, and routine reviews ~10 months ([44] apnews.com). The new "Commissioner's National Priority Voucher" program offers a special one-month target for select medicines ([9] 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 ([45] apnews.com).

In practice, this means that sponsors of vaccines or therapies deemed urgent under the Trump Administration's priorities could see their new drug applications (NDAs) approved in weeks, if the program is expanded. 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 ([46] 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 ([47] 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 ([48] apnews.com). These vouchers, while not guaranteeing approval, promised to

shorten the FDA's review from months down to weeks ([49] apnews.com): Makary said the U.S. "ow [es] it to…veterans" to expedite such treatments ([50] apnews.com).

This urgency is partly driven by political factors: Reuters and AP note that psychedelics had become a pet project of veterans' groups and RFK Jr., and Trump explicitly ordered the FDA to loosen restrictions on them ([48] apnews.com) ([50] apnews.com). Meanwhile, the flavored e-cigarette case illustrates that political pressure can similarly produce fast-track orders (Trump insisted Makary approve flavors, overriding his initial ban ([31] www.cbsnews.com) ([51] 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 exceptionally aggressive, and even proponents admit it pushes the bounds of precedent. Dr. Aaron Kesselheim (Harvard) told AP in January 2026 that "FDA cannot do the same detailed review" in one to two months and "doesn't have the resources" to match a regular application's scrutiny ([52] apnews.com). Similarly, Susan Mayne (former FDA food chief) noted that some speed strategies (like phasing out food dyes by announcement only) lacked the scientific documentation normally required ([23] apnews.com). FDA's HHS spokesman has insisted the voucher program will still prioritize "gold standard scientific review" and genuine safety concerns ([53] apnews.com), but critics view these fast-track schemes with skepticism.

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 ([44] 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 ([15] www.axios.com). Achieving predictability may require legislative action or clearer guidance, since many of Makary's ad hoc programs lack firm legal underpinning. (For example, Makary's two-trial proposal – dropping a rule dating from 1962 – would ultimately need rulemaking to enforce permanently ([54] apnews.com).) 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 controversial pronouncements was changing the core evidence level for NDAs. In a February 18, 2026 *New England Journal of Medicine* article, Makary and Deputy Commissioner Vinay Prasad announced a shift from requiring two adequate and well-controlled trials (a standard since the 1962 amendments) to a *one-trial default* ([11] apnews.com). They argued that "as we move toward greater understanding of biology and disease we don't need to do two trials all the time" ([55] 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" ([56] apnews.com), and Dr. Janet Woodcock (former CDER Director) acknowledged that, for certain diseases like cancer, one trial plus supportive evidence is increasingly common ([57] 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 ([58] apnews.com). In fact, the FDA simultaneously introduced a new "bespoke therapy" pathway for rare and hard-to-treat genetic conditions ([58] 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" ([59] apnews.com). FDA Commissioner Makary framed it as "our priority to remove barriers and exercise regulatory flexibility" for rare diseases ([60] 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 ([61] 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. Notably, some rare-disease patient groups were upset by earlier flips by FDA (e.g. when Prasad critiqued a pregnancy drug) – and they may monitor if any loosening of rules truly leads to approvals of high-need treatments.

- **Stakeholder Involvement:** Makary repeatedly invited input from outside experts, e.g. hosting external panels on drug development and aging (Matignon initiative). His administration often preferred *voluntary industry agreements* over formal rulemaking ([14] apnews.com). The AP reported that, for food dyes, Makary announced a phase-out based on industry pledges – but never issued draft rules or scientific reports on it ([62] apnews.com) ([23] apnews.com). This “announce first, regulate later” style is likely to continue under Diamantas, at least short term. 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 have become intertwined with drug pricing politics. Makary’s voucher programs are linked to voluntary pricing concessions: an HHS fact sheet revealed that companies getting vouchers often agree to cap prices in other programs ([63] apnews.com). For example, when the White House announced “most favored nation” (MFN) pricing plans, the HHS spokesman noted corresponding FDA vouchers for those companies ([63] apnews.com). More recently, in 2026 sponsors have faced calls to tie price controls to expedited approvals. Industry leaders are already pushing back on MFN (e.g. PhRMA publicly opposed Trump’s plan to set U.S. prices to lower OECD price levels ([64] www.axios.com)). It remains to be seen whether the new FDA leadership will seek greater alignment of approval speed with pricing concessions – a landscape that sponsors must navigate carefully.

- **Staffing and Review Backlog:** Not all of Makary’s initiatives were forward-looking. Some created headwinds: major layoffs and turnover at CDER have raised concerns that drug reviews could slow. An April 2025 Axios report warned that broad cuts might “set the agency back” on review timelines ([65] www.axios.com). Indeed, even before Makary’s resignation, drug companies had expressed anxiety that FDA staff reduction could “disrupt timelines…driving up prices” ([65] www.axios.com). Although FDA insisted no application deadlines had been missed yet ([66] www.axios.com), sponsors may encounter longer waiting periods or less predictable PDUFA clock outcomes if the agency remains lean. Understanding that, Makary’s push for AI and vouchers may partly have been intended to offset lost manpower by making 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: ~10 months (full review); Accelerated: ~6 months for life-threatening drugs ([44] apnews.com).	New “voucher” scheme targeting 1–2 month review for priority drugs ([9] apnews.com) ([46] www.axios.com).	([9] apnews.com) ([46] www.axios.com)
Required pivotal trials per NDA	Two adequate trials (by statute, since 1960s) ([54] apnews.com).	Proposed default of one trial for new drugs ([11] apnews.com) ([54] apnews.com).	([11] apnews.com) ([54] 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 ([46] www.axios.com).	([46] www.axios.com)
Staff evaluation vs. oversight	Review decisions made by career FDA scientists and supervisors.	Increased political oversight – e.g. senior officials (or Commissioner's office) directly sign off on voucher-designated drugs ([67] apnews.com).	([67] apnews.com)
Use of artificial intelligence (AI)	Modest pilot programs (e.g. internal FDA "Elsa" tool) ([68] www.axios.com).	Mandated 150+ new AI tools for review tasks; new AI-driven trial monitoring ([69] www.healthcare-brew.com) ([13] www.axios.com).	([68] www.axios.com) ([69] 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 ([44] apnews.com) ([49] apnews.com). Similarly, the classic two-trial evidence standard might vanish ([11] apnews.com) ([54] 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 ([68] www.axios.com). Elsa is designed to assist reviewers by summarizing adverse event reports and even generating database queries ([68] www.axios.com). In addition, Makary encouraged FDA staff to develop any AI solution that could improve workflows: he reported receiving 181 submissions from staff to apply AI across the agency ([69] www.healthcare-brew.com). Of those, about 150 new AI-based systems were built by early 2026 – spanning document processing, safety-signal detection, manufacturing optimization, labeling checks, and more ([69] www.healthcare-brew.com). Early metrics suggest these tools are having an impact: by June 2025, FDA reported that its AI tools collectively saved over **17,000 staff-hours** of work ([70] www.healthcare-brew.com). The goal, Makary said, was to free reviewers from "tedious tasks" (like verifying application completeness) so they can focus on higher-order analysis ([71] 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 ([13] www.axios.com). For example, the agency is working with AstraZeneca on an AI tool to track safety signals in a lymphoma trial, and a similar project with Amgen for lung cancer. FDA Chief AI Officer Jeremy Walsh told reporters these tools could shave "20–40%" off overall trial time by identifying issues faster ([72] www.axios.com). Commissioner Makary framed this as challenging the notion that it must take 10–12 years to get a drug to market ([72] 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 ([73] 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 ([16] apnews.com). Under the Trump administration, Biden-era AI guardrails have been repealed in favor of a "tear down barriers to progress" mentality ([74] 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 ([75] www.healthcare-brew.com). He emphasized that none of these tools were making final decisions – they simply automated mundane checks and document reviews ([71] www.healthcare-brew.com). But by improving efficiency, he argued, AI could help drugs reach patients faster. For example, Makary pointed out that every missed FDA filing day "costs the drugmaker millions" in lost sales ([76] 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 ([70] 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. On the flip side, the FDA's embrace of AI raises questions about data privacy and transparency. Industry experts (e.g. Dr. Eric Topol) have already questioned what proprietary data the FDA is feeding into AI models ([77] www.axios.com). Companies 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 ([16] 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:

- **Psychedelic Therapies:** As noted, in April 2026 FDA granted priority review vouchers to three investigational psychedelic drugs (psilocybin-based and MDMA-related) following a Trump order ([48] apnews.com). This highlights a key point: *political and public interest can drive regulatory priority*. The companies (unnamed) now enjoy accelerated review timelines. However, FDA Commissioner Makary was clear that *vouchers shorten review time, not guarantee approval* ([49] apnews.com). Sponsors of psychedelics should be aware that the same product could easily lose this advantage under a new administration or if legal restrictions change.

- **Flavored E-Cigarettes:** The Glas, Inc. vaping product saga illustrates intra-agency conflicts. For almost a year, Makary and FDA leadership had kept fruit-flavored e-cigarettes off the market, citing youth-vaping fears. Only when President Trump intervened in late April 2026 did FDA announce approval of some flavors (with marketing restrictions) ([31] www.cbsnews.com) ([78] apnews.com). In short, the White House's stance on tobacco products directly overruled prior FDA delays. For sponsors, this implies that FDA's political oversight can be decisive. A company like Glas had to navigate changing directives – initially facing rejection, then a green light. It underscores that under the current regime, alignment with administration priorities (e.g. veteran support programs, tobacco heir's interest) can yield approvals.

- **Rare Genetic Therapies:** FDA's proposal of a "bespoke therapy" pathway for rare diseases ([58] 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 ([13] www.axios.com) could shorten trial lengths by up to 40%. 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 engaged in these proof-of-concept projects (e.g. AstraZeneca, Amgen) will be key case studies to watch.

- **Drug Approval Trends:** In 2025 and early 2026, despite the FDA's chaos, approvals continued – but with controversies. For example, in December 2025 an AP summary noted that a "tipping point" was reached after several high-level departures (including Makary's allies) ([79] www.axios.com). By May 2026, some longstanding FDA policies had begun shifting: as mentioned, the two-trial rule was officially slated for removal ([11] apnews.com) and ultrafast reviews were instituted ([9] apnews.com). Sponsors should track whether these published proposals actually change the official approval stats. To date, the number of NDAs approved each quarter has remained near historical annual averages (around 30–40 drugs per year), but the **composition** of approvals is shifting toward those favored by Trump's agenda (mental health, rare diseases, deregulated substances).

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, dietary supplements for men's health if also FDA-regulated, 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 ([9] apnews.com) ([46] www.axios.com) ([48] 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 ([15] 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. The age-old rule that two trials are required cannot be changed without a formal rule (or Congressional change), and it may face legal challenges. 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. Experts like Dr. Kesselheim warn that compressing reviews "may endanger patients" ([52] apnews.com) if not done carefully, and 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 ([64] www.axios.com) ([63] apnews.com). Pharmaceutical companies should be prepared for negotiations. For instance, some priority vouchers have been tied to price concessions, meaning sponsors may get faster reviews **in exchange** for limiting list price increases. Getting entangled in drug pricing deals might be acceptable trade-off for a several-month head start in commercialization, but each sponsor must weigh these choices carefully.

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, potential political interference, 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. The Senate has not yet confirmed a new FDA Commissioner; the confirmation of Diamantas (or any nominee) could be delayed by competing priorities in Congress, as Axios notes ([80] www.axios.com). If the acting leadership remains in place for many months, sponsors will be essentially 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 reform-driven but chaotic year ([1] apnews.com) ([21] apnews.com) – 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 ([9] apnews.com) to more flexible evidence requirements ([11] apnews.com), and an aggressive push to harness artificial intelligence ([69] www.healthcare-brew.com) ([13] www.axios.com). On the other hand, the agency's traditional science-based processes have been disrupted by political pressure, staffing churn, and incomplete regulatory groundwork ([25] apnews.com) ([14] apnews.com).

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, the new acting FDA leadership is poised to set the tone for Donald Trump's second-term health agenda. With all top positions in flux, 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 approvals in certain politically-favored areas, 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.

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