New American

Written by **Veronika Kyrylenko** on June 24, 2025

The "New FDA": Faster, Smarter, Friendlier to Pharma

When Robert F. Kennedy, Jr. took over the Department of Health and Human Services (HHS), he pledged to "Make America Healthy Again." The slogan became a central theme of his public-health vision during the 2024 campaign, when he endorsed Donald Trump and positioned himself as a reformer critical of pharmaceutical overreach.

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Yet just months into his tenure, a new phrase is echoing through the agency's top leadership: "Make American Biotech Accelerate." Notably, Kennedy never mentioned this biotech-centric slogan on the campaign trail. Its sudden debut signals a sharp, unannounced pivot — one that puts pharmaceutical and technological innovation at the center of federal health policy.

What does this pivot look like in practice?

The "New FDA": Speed First, Questions Later

The shift begins at the U.S. Food and Drug Administration (FDA) — an agency tasked with protecting the public from unsafe, ineffective, or fraudulent medical products.

In their June 10 *JAMA* article, FDA Commissioner Dr. Marty Makary and CBER Director Vinay Prasad unveiled a blueprint for a "new FDA" focused on expedited approvals, AI-driven automation, and industry collaboration.

For instance, their plan includes pilot programs promising decisions "in weeks" instead of a year. Drugmakers will be encouraged to submit manufacturing data, draft labels, and packaging *before* clinical trials are complete — allowing the agency to front-load reviews and accelerate approvals.

To streamline the process, in early June, Makary launched "Elsa," an agency-wide AI tool for first-pass document review. Generative AI, say the officials, is now a "top priority." The agency plans to overhaul "legacy" systems for evaluating AI-based products, calling the existing framework "byzantine."

Finally, they say the FDA will be more "user-friendly," even offering regulatory help to small firms. While the officials assure that they would guard against a "cozy relationship" with the industry, that promise rings hollow when paired with what comes next.

Pharma "Safe Spaces"

Shortly after the *JAMA* piece, the FDA launched a series of "listening sessions" with pharmaceutical executives. These weren't public hearings or forums for the vaccine-injured. Instead, they were framed — very explicitly — as closed-door "safe spaces" for CEOs to speak freely to regulators. In Makary's words,

> It's amazing when you get CEOs and leaders of these companies, drug developers, inventors, the scientists in the room, and you say, 'This is a safe space. Tell us your ideas for the FDA that work better for you.'

The contrast could not be starker. Setting aside the fact that the federal government has no enumerated authority under the Constitution to regulate healthcare, the FDA was created to be a watchdog — an adversarial regulator guarding the public. Its job is was never meant to make drug developers feel comfortable and "safe."

Yet under Makary's leadership, the agency increasingly acts as a therapeutic concierge, focused on pleasing "stakeholders." And who counts as a stakeholder? Apparently, not patients or injured. Not whistleblowers. Just the inventors, investors, and executives seated at the table.

To justify this shift, the FDA insists it wants "breakthroughs to reach patients faster, while upholding the highest standards of safety and scientific integrity." But what's being quietly dropped are the very safeguards that FDA once framed as essential.

Vouchers for Velocity

The clearest expression of this new posture came with the launch of the Commissioner's National Priority Voucher (CNPV) program. Billed as a one-year pilot, it allows select drug applications to be reviewed in as little as 30 days, rather than the usual 10-12 months.

Vouchers will go to companies "supporting U.S. national interests," including those addressing "public health emergencies," pushing "innovative therapies," or boosting domestic manufacturing. Makary framed the initiative as a way to cut red tape in the approval process:

> Using a common-sense approach, the national priority review program will allow companies to submit the lion's share of the drug application before a clinical trial is complete so that we can reduce inefficiencies. The ultimate goal is to bring more cures and meaningful treatments to the American public.

But what Makary calls inefficiencies are, in reality, essential safeguards. Under the new rules, a company needs only to submit a manufacturing file and what Makary earlier called a "plausible mechanism" of action — a theoretical guess at how the drug *might* work, not clinical evidence. There's no requirement for completed safety or efficacy trials at the time the voucher is granted.

Besides opening doors to untested products, this move marks a radical departure from statutory precedent. Previous voucher programs — for tropical diseases, rare pediatric diseases, and medical countermeasures — were all created through acts of Congress. The CNPV, by contrast, was imposed unilaterally by the FDA. If it holds, it sets a dangerous precedent: The agency can invent new regulatory shortcuts without public debate or legislative approval.

The result? Companies "aligned" with federal priorities get fast-tracked. Everyone else plays by the old rules. Meanwhile, the public becomes the test group.

Kennedy and Techo-capital

The FDA isn't the only federal body holding quiet meetings with powerful industry players.

On May 19, Kennedy hosted a closed-door roundtable with executives from health-tech startups. The

HHS announced the meeting on X, praising the companies as "leaders at the forefront of health technology." It also highlighted their alignment with Kennedy's vision to "Make America Healthy Again."

But beneath the optimistic language lies a revealing pattern: Reportedly, six of the seven companies are backed by Andreessen Horowitz, one of Silicon Valley's most politically ambitious and ideologically aggressive venture capital firms.

Why does that matter?

Andreessen Horowitz, also known as "a16z," isn't a neutral player in biotech or health. It has poured billions into surveillance-driven digital health, AI diagnostics, longevity experiments, and bio-platform companies with unmistakable transhumanist overtones. Marc Andreessen's 2023 "Techno-Optimist Manifesto" made clear that traditional constraints such as safety regulation and democratic oversight are seen as obstacles to be overcome, not principles to be preserved.

In this context, Kennedy's decision to grant special access to "a16z"-backed firms isn't just controversial. The same man who once warned of unchecked pharmaceutical power is now sitting down with venture-backed biotech executives behind closed doors, elevating private capital as the de facto selector of which "breakthroughs" matter.

Notably, in 2024, Marc Andreessen and Ben Horowitz each donated $2.5 million to a pro-Trump super PAC, openly aligning their firm with the political infrastructure behind Kennedy's appointment.

Fast-tracking Failure

Kennedy entered office as a fierce critic of Big Pharma. Now, his HHS is aggressively pharma-aligned — fast-tracking biotech, embracing technocratic venture capital, and turning the FDA into a tool of acceleration, not oversight.

Arguably, this pivot does little to address the chronic disease epidemic he once vowed to fight. While some might argue that America's health crisis is caused by a shortage of gene-editing therapies or AI health trackers, as Kennedy once rightfully warned, its real drivers are toxic food, chemical exposures, and a system built to manage illness — not prevent it.

Instead of tackling those root causes, Kennedy's HHS now courts biotech billionaires and introduces modest food reforms, such as phasing out food dyes — what critics call the "Chasing Froot Loops" approach to health policy. Meanwhile, it rushes to elevate companies selling new vaccines, biometric monitors, and behavior-tracking devices to a nation kept just sick enough to monetize.

Health won't be restored by speeding up the system that was one of the forces that broke it. It will come by breaking its grip, dismantling the unconstitutional machinery, and rebuilding care where it belongs — locally.

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