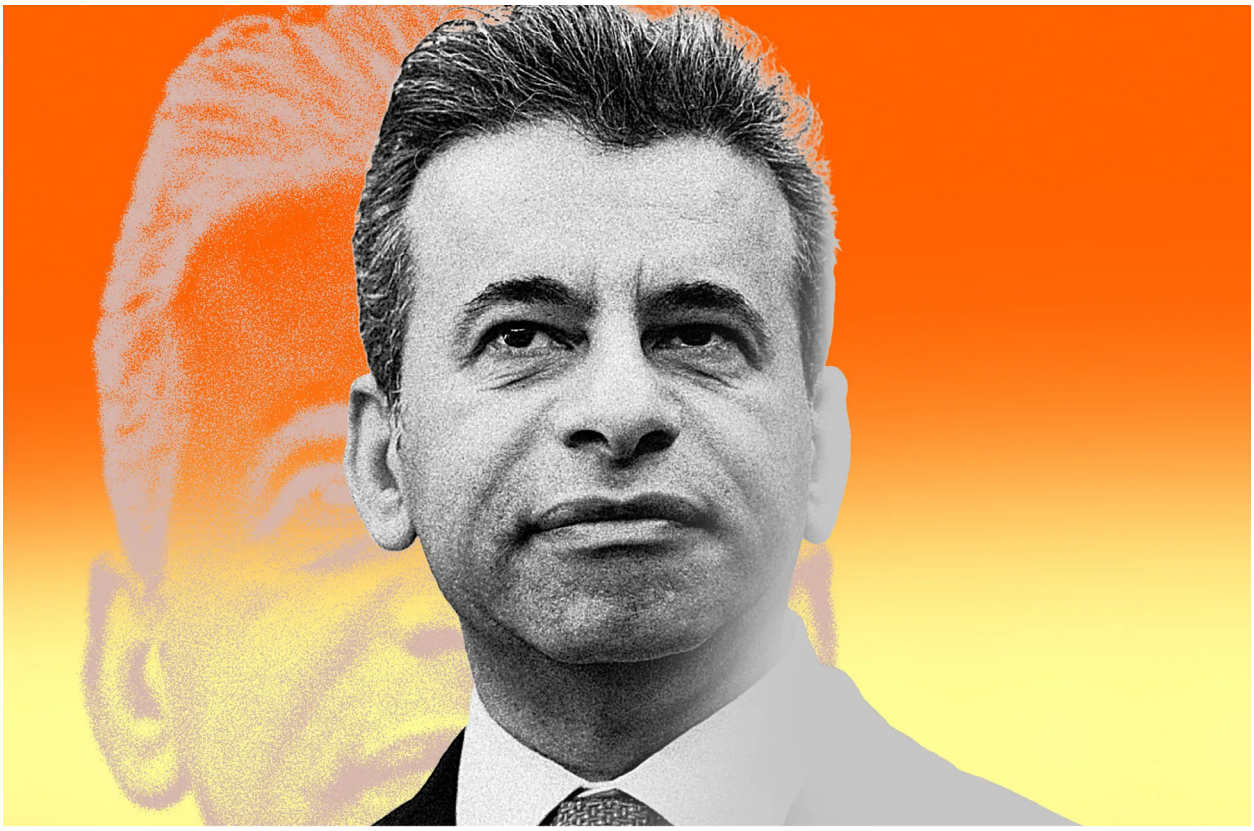

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Industries | Health

Paranoia, Turmoil and Backlash: Inside the FDA Under Marty Makary

Insiders say one more high-profile misstep could put the commissioner's job in jeopardy.

By Rachel Cohrs Zhang, Jessica Nix, Gerry Smith, and Riley Griffin
May 4, 2026 at 9:07 AM CDT
Updated on May 4, 2026 at 11:52 AM CDT

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Food and Drug Administration Commissioner Marty Makary was supposed tc be one of President Donald Trump's more conventional, qualified personnel picks, with sterling academic credentials and bipartisan support.

But just over a year into his tenure, those inside the agency that regulates roughly one-fifth of consumer spending in the US describe a culture rocked b staff clashes, leadership turmoil, industry backlash and an embattled,

paranoid leader. Outside, drug companies say they've been blindsided by setbacks.

Some people familiar with the dynamics called the situation unsustainable. While no immediate ouster is planned, people familiar with the matter who requested anonymity to discuss personnel matters say one more high-profile misstep could put his job at risk.

Makary, 55, and his allies defend his record, pointing to his successful moves to reduce synthetic food dyes, crack down on misleading television ads and streamline drug approvals. He's a regular guest on television and often appea over Trump's shoulder in the Oval Office, serving as the immaculately coiffed face of ambitious announcements.

FDA Commissioner Marty Makary, second from the left, speaks before President Donald Trump signs an executive order in the Oval Office of the White House in Washington, DC on April 18, 2026. *Photographer: JIM WATSON*

For now, Makary and his allies are seeking to right the ship. The Department Health and Human Services has implemented new processes around policy rollouts and hiring to impose more rigor as the agency fills important vacancies at the FDA. Makary himself has held meetings with biotech leaders and lawmakers, and he's met with former commissioners to pick their brains

Makary was a professor and surgical oncologist at Johns Hopkins, authored hundreds of academic journal articles and wrote three New York Times-bestselling books before his confirmation. His academic training includes a master's in public health from Harvard University and a surgical residency at Georgetown University.

It's unclear whether the course corrections will assuage anxious investors an biotech executives.

The announced exit of Makary's controversial deputy Vinay Prasad has eased tensions, people familiar with the situation said. Industry executives like Zacl Weinberg, chief executive officer of the biotech investment firm Curie.Bio, sa that if he were Makary's boss, he'd warn him to get his act together – and fast

"I'm going to give you the next eight months," Weinberg said he would tell th commissioner. "Get some important things done. Get some great people in here and show me you can do this. We should give him the time to do it. If he doesn't get it done, then OK, that's a problem."

Management issues

Makary's transition from being an academic, surgeon and television commentator to managing an agency of more than 16,000 employees has bee a rocky one.

He's regularly clashed with other officials in the administration, and tightene his inner circle in what people familiar with his management describe as a paranoid effort to control the flow of information. He also avoids putting things in writing, the people said.

Makary disputed the characterization in an interview, touting "the most transparent administration in history" and saying he eats lunch in the agency cafeteria and openly talks about the agency's ideas.

On Monday at the Milken Institute Global Conference in Los Angeles, Makary touted his accomplishments including his priority review voucher program, his commitment to transparency and previewed new reforms to ramp up early-stage clinical trials in the US.

“Commissioner Marty Makary continues to be an invaluable asset for the Trump administration because he continues to deliver on President Trump’s agenda of modernizing the FDA’s drug approval process, restoring Gold Standard Science in agency decision-making, and implementing the President’s MAHA agenda,” White House spokesman Kush Desai said in a statement.

But Makary acknowledged staff morale was low after thousands of layoffs and retirements spurred by the Department of Government Efficiency. While he maintains that staffing levels have stabilized, a string of hiring blunders attracted negative attention.

Prasad, whom Makary chose to lead the agency’s vaccine and gene therapy regulation, was a polarizing, outspoken academic and podcaster. Though officials described him as bright, he took a confrontational approach to working with biotech companies, repeatedly issuing dramatic rebukes that were walked back days later.

Prasad sparked a firestorm of controversy when he halted shipments of a Sarepta Therapeutics Inc. gene therapy after safety issues became public and refused to review an application for a Moderna Inc. flu vaccine after one of the largest industry-sponsored trials in recent years. Prasad also got into a dispute with a company producing a gene therapy for Huntington's disease after it claimed the FDA was requiring it to perform fake brain surgery to evaluate whether the treatment works.

Dr. Vinay Prasad, who led the agency's vaccine and gene therapy regulation, was a polarizing, outspoken academic and podcaster. *Photographer: Marvin Joseph/The Washington Post*

Prasad abruptly departed the agency last summer, then returned and subsequently announced a second departure this spring. In an interview with Bloomberg, Makary insisted Prasad accomplished several major initiatives while at the agency, including on rare disease policy and clinical trial design.

The upheaval extended to the FDA's drug center, which had five separate leaders last year alone – including former biotech executive George Tidmarsh who resigned amid accusations that he used his position to take revenge on a former associate. Tidmarsh was also sued for defamation by Aurinia Pharmaceuticals Inc. after publishing and then deleting a post on LinkedIn calling the company's lupus drug toxic, sending the drugmaker's shares plummeting.

Veteran cancer drug regulator Richard Pazdur, 73, reluctantly took the role b quit within a month, citing poor communication about personnel moves, top down decision-making and concerns that top officials didn't understand the regulatory process. He said there wasn't adequate communication after layof

as to why they were done or about how new management structures would work.

“That's just basic leadership skills,” Pazdur said in an interview with Bloomberg.

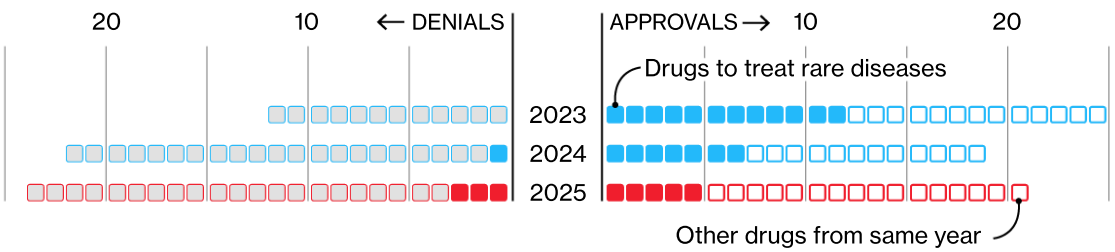
Controversy extended to lower-level appointments. Makary promoted a deputy in defiance of the White House, a clash that almost resulted in her firing, according to people familiar with the matter. The health department’s inspector general has investigated whether another top adviser used a sham divorce to circumvent ethics rules.

Cutting-edge biotech firms have become disillusioned with Makary and what they describe as an inconsistent drug review process. Companies including Moderna, UniQure NV, and Replimune Group Inc. all said that setbacks in the review processes came as surprises. UniQure said negative feedback from the FDA was a “key shift from prior communications” with the agency, and Moderna Chief Executive Officer Stéphane Bancel said the FDA had become unpredictable in a way that “threatens US leadership in innovative medicines

The angst has been especially concentrated among companies that develop drugs to treat rare diseases. Those patient populations are small and difficult to study, and people have few options. Republican Senator Ron Johnson of Wisconsin said in March that he’s launched an investigation into the FDA’s recent rare disease rejections.

Rare Disease Drug Approvals Have Decreased

The Center for Biologics Evaluation and Research has started denying more applications



Source: FDA

Companies have resorted to appealing directly to HHS Secretary Robert F. Kennedy Jr., the White House and Congress to challenge processes they view

as unfair, according to people familiar with the efforts.

Others describe Makary as a grandstander who pushes to attend public administration events and focuses his efforts on generating attention rather than the nuts-and-bolts work of regulating. He's taken the unusual step of announcing major new policies, including a Covid-19 vaccine approval framework, through journal articles and press releases instead of robust agency guidance.

His push to hire the communications firm Pinkston as an agency contractor, described by people familiar with the matter, was ultimately nixed by Chris Klomp, the broader health department's chief counselor. Makary's chief of staff worked at the firm for five years before entering the government. Contracts for external communications work at health agencies drew scrutiny during Trump's first administration. Makary said he wasn't picking contracto to work on communications.

But Makary's willingness to publicly champion many of his announcements only exacerbates frustration among some Republicans on Capitol Hill who ar frustrated by a slow-walking of a long-awaited safety study on abortion pills.

'Toxic methodological purity'

Makary said he wants to both provide real-time transparency into the agency thinking and pursue normal processes with opportunities for public input. H noted meetings with 500 pharmaceutical CEOs in his first nine months in office, and contends that the FDA always makes some people angry about its approval decisions. He believes that the agency has stood by scientific review teams that analyze applications for new drugs and biologics.

"One hundred percent of the accept or reject drug decisions coming out of th agency, on my watch, have been the accept or reject recommendations of the primary review team or the decisions coming out of the center," Makary said. He said he didn't think center directors overruled scientists, either.

Richard Pazdur reluctantly took the role leading FDA's drug center but quit within a month. *Photographer: Joshua Roberts/Bloomberg*

The FDA commissioner is generally not involved in review decisions, but ther have been several instances of Makary's deputies overruling scientific review teams.

Public documents show Prasad overruled the recommendations of career sta on approvals of Covid vaccines made by Moderna, Novavax Inc. and Pfizer In The Wall Street Journal and Stat reported that career staff objected to the decision not to consider Moderna's flu vaccine application, an extreme regulatory step usually reserved for a tiny minority of applications.

"The biotech community wants to see Marty Makary be successful," said Tim Hunt, chief executive officer of the Alliance for Regenerative Medicine, which represents cell and gene therapy companies. But many are "extremely frustrated" by the agency's "toxic methodological purity," he said.

'Trying to get better'

Makary still has well-placed allies who want to see him succeed, according to people familiar with the dynamics. His supporters view him as an effective external communicator with big ideas for reforming the agency. Plus, a confirmation process to replace him would crowd the Senate committee that

also needs to approve a new Surgeon General and leader at the Centers for Disease Control and Prevention.

Klomp helped broker a meeting between Makary and Scott Gottlieb, his predecessor during Trump's first administration, according to people familia with the matter. Makary acknowledged he had spoken with former commissioners to get advice on how to be most effective in his role. Gottlieb declined to comment.

Makary also expanded outreach to biotech executives and investors and Capitol Hill offices, people with knowledge of the meetings say.

And HHS has looked to alleviate some bottlenecks, implementing an organizational overhaul elevating some of Makary's high-performing hires wh worked on policy and food issues. New processes have been put in place to ensure more visibility and collaboration in decision making, including at the FDA, people familiar with the matter said.

The agency also has installed what people speaking on the condition of anonymity called new systematic rigor in the department's hiring practices. The FDA has multiple high-level vacancies. Makary said he's searching for "straight as an arrow" scientists in recruiting. He selected career official Mallika Mundkur as acting chief medical and scientific officer after Prasad's departure.

"The FDA is trying to get better," Weinberg said. "There are a bunch of peopl who are listening and asking questions and taking feedback and they are meeting with the biotech industry. I'm very happy about that. That wasn't always the case."

– With assistance from Robert Langreth, Madison Muller, Anna Edney, and Adrienne Tong

(Updates with comments from Milken conference in 12th paragraph.)