Can the FDA fulfil its mission with a smaller workforce?

The US Food and Drug Administration's new commissioner promises to restore public trust despite mass layoffs. Washington Correspondent Susan Jaffe reports.

Martin Makary fielded questions for nearly 2 h from a Senate committee last month before winning approval to take the helm as commissioner at the Food and Drug Administration (FDA). His early actions have provided some additional answers about how he will likely run an agency that impacts Americans' daily lives but is depleted by the forced departure of at least 3500 scientists and other staff.

The cuts have downsised divisions responsible for the safety of prescription and over-the-counter drugs (for human and animal use), biological therapies, medical devices, tobacco products, and food. Some positions might be filled by temporary contract workers, the Associated Press reported, and some former employees have been asked to return for an indefinite period. A spokesperson for the Department of Health and Human Services, the FDA's parent agency, said the loss of 3500 full-time employees will streamline operations and centralise administrative functions without affecting inspections or drug, medical device, and food reviewers.

Makary, appointed by President Donald Trump, is a surgical oncologist and health-care policy researcher who worked at Johns Hopkins University School of Medicine. Senator Bill Cassidy, a Louisiana Republican and chairman of the Senate Committee on Health, Education, Labor, and Pensions, has praised Makary as a leader who can restore public trust in the FDA, and its "gold standard around the world in safeguarding public health".

In Makary's first 3 weeks on the job, he has begun to signal that he will steer the agency in a manner closely aligned with the Trump Administration. Politico has reported that shortly after his private swearing-in ceremony, Makary supported the decision of his boss, Secretary of Health and Human Services Robert F Kennedy, to remove Peter Marks as head of the vaccine division. Marks led the effort to develop COVID-19 vaccines during the first Trump Administration. "It has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies", Marks wrote in his resignation letter.

In his first media interview, Makary told reporter–podcaster Megyn Kelly that Marks resigned before Makary became commissioner, contradicting the timing in the Politico account. In response to the staff cuts, reported to be about 20% of the agency's 19 000 US and international workforce, Makary told Kelly that "there are no plans for any mass cuts".

Ellen Sigal, chair and founder of the patient advocacy group Friends of Cancer Research, is not reassured. "It's very hard to know exactly where Dr Makary wants to go", she said. "On one hand, I think he supports innovation and science and on the other hand, what's going on is completely disruptive", she said. She called Marks' departure "devastating".

Rather than declare his support for several controversial FDA decisions, Makary told senators that he plans to re-evaluate them but offered few details. Among those he intends to review is the FDA's ruling allowing doctors to prescribe—without an in-person patient visit—mifepristone, used with misoprostol to induce an abortion. The FDA approved mifepristone in 2000 and removed the in-person dispensing requirement in 2016. Also slated for review are COVID-19 and influenza vaccine recommendations.

Makary's first official actions include unveiling a new policy limiting pharmaceutical and other FDA-regulated industry representatives from serving on the agency's advisory committees unless their participation was legally required. He echoed Kennedy's criticism of the FDA, saying the agency "has a history of being influenced unduly by corporate interests". He also announced the development of a new strategy to reduce the use of animals to test monoclonal antibody therapies and other drugs. He is also expected to join Kennedy to announce phasing out the use of synthetic dyes in foods. Makary has said ensuring Americans' access to healthy foods will be a top priority.

But Robert Califf, FDA Commissioner during the Biden Administration, questioned whether the staff cuts have damaged the agency. "Issue number one is, can the basic work of the FDA get done?" he said. "There are products in the pipeline, where decisions need to be made about whether they're approved or advance to the next phase of development, and you lost a very large part of the workforce and a large part of the leadership with institutional memory. People weren't even given an opportunity to hand off their work to the next person."

The Association for Accessible Medicines, which represents generic drug manufacturers whose user fees help fund FDA drug reviews, is also "deeply concerned" about the diminished ranks of officials responsible for administering the user fee programmes, said the group's president and CEO John Murphy. Such changes "may undermine the agency's ability to approve and ensure the safety of lower-cost generic and biosimilar medicines", he said.

Susan Jaffe

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For the **Politico story on the removal of Peter Marks** see https://www.politico.com/news/2025/03/31/new-fda-commissioner-signed-off-on-ousting-top-vaccine-regulator-after-private-swearing-in-00260582

For **Peter Marks' resignation letter** see https://static01.nyt.com/newsgraphics/documenttools/c946b864e1dc08f9/05e7e4f0-full.pdf