

Committee on Energy and Commerce

**Opening Statement as Prepared for Delivery
of**

Subcommittee on Health Ranking Member Diana DeGette

***Hearing on "Maintaining America's Leadership in Biomedical Innovation: FDA's Role in
Advancing U.S. Drug Development"***

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I'm glad we're having a hearing on a topic near and dear to my heart, biomedical research. FDA plays a critical role in regulating clinical trials, centering the safety of trial participants and making sure trials are asking the right questions.

Over the past year and a half, FDA's staff has been decimated, political appointees have been making decisions that are properly left to scientists, and industry and researchers have been left in the dark about what current agency policy actually is.

The disastrous reign of Elon Musk and DOGE early last year resulted in 3,500 jobs being eliminated at FDA, the most of any HHS agency. Low morale was pervasive at the agency, and it showed: FDA shed senior leaders and rank and file scientists alike.

Under Commissioner Makary, an agency famously insulated from political pressures became instead captured by them. He started the Commissioner's National Priority Voucher program, which provided incentives to companies with no predefined criteria, simply rewarding general alignment with administration priorities. Without set, public criteria, companies don't know what to focus on for the program and the public doesn't know what—legitimate or not—is being rewarded.

In another example, bowing to Secretary Kennedy's anti-vaccine nonsense, FDA under Commissioner Makary refused to even review a mRNA-based flu vaccine before being forced to change course.

And who can forget FDA's initiation of a label change for Tylenol indicating a lack of safety for use in pregnancy, contrary to scientific evidence and against the advice of medical organizations, simply because Secretary Kennedy wanted something to blame for increasing documented rates of ADHD and autism.

All of these decisions placed ideology above science.

FDA's instability and shoot-from-the-hip approach to policy also impacted industry. Commissioner Makary and FDA leadership made major policy announcements through journal articles, press releases, and even podcasts, circumventing FDA's policymaking processes and making it so researchers did not know what was official policy.

FDA would even contradict its own past guidance, as in the case of an experimental gene therapy for Huntington's disease. FDA reversed direction, demanding a new trial for the product, even though advocates and scientists believed the new trial to be unethical.

Luckily, there is evidence that with Makary gone, things are slowly improving. The agency is in the process of hiring thousands of staff to fill critical gaps, though this is hindered by reputational damage to the agency from Makary and DOGE.

There are responsible leaders atop the critical centers at FDA, and Acting Commissioner Kyle Diamantas has shown every indication that he will empower career experts to do their jobs to protect American patients and get good products to market.

In February, I sent a letter to FDA regarding the agency's failure to follow its own good guidance practices—announcing policy through journal articles and such, which is expressly prohibited in regulation.

Last week, the agency finally responded, indicating that the announcements we asked about were in fact not guidance and did not communicate FDA policy on the issues.

I'd like to enter both my letter and the agency's response into the record.

I hope this is a turning point—back to transparency, to consistency, and to a focus on good science. This is particularly important for developers trying to get promising medicines into the clinic. Innovative researchers need to trust FDA will treat their applications fairly and without political favor or disfavor—always in service of the patient.

Former Commissioner Makary and DOGE did untold damage to FDA, but the agency has never been perfect. As science our capabilities evolve, so must our regulators.

I look forward to hearing more from our witnesses on just how we can work to improve the agency, get new treatments and cures to patients as quickly and safely as possible, and maintain American leadership in biotechnology and medicine through the 21st Century.