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FDA Commissioner – Year in Review … What's Next?

A little over a year and a half ago, I participated in the first-ever FDA Watch podcast episode where – after reading expected FDA Commissioner Marty Makary, M.D.'s book, Blind Spots: When Medicine Gets it Wrong, and What It Means for Our Health, and watching Makary's previous interviews – I tried to predict his platform as FDA Commissioner. I did not expect his tenure would be so short lived, but some things I did get correct and some things less so.

What were my predictions?

Makary criticized FDA for making decisions without proper evidence and its over-reliance on advisory committees with financial and other conflicts of interest. He noted that FDA banned silicone in breast implants and then later rescinded its decision because there was no evidence it caused systemic disease. I thought Makary would institute a more evidence-based review platform with more transparency. Instead, Makary reduced advisory committee meetings in favor of FDA selected "expert panels" and roundtables and limited circumstances where individuals employed by FDA-regulated companies may serve on FDA advisory committees.

Makary lowered the default number of pivotal trials required for drug approvals from two to one and built a consolidated adverse event reporting system to consolidate the databases. Makary also initiated a ground-breaking concept for FDA to conduct real-time clinical study reviews to facilitate expedited clinical studies.

Due to the departure of many senior FDA officials and a reduced workforce, Makary placed an increased reliance on AI tools such as ELSA (Electronic Language System Assistant). ELSA has been used to summarize review submissions and modernize document production such as responses to Freedom of Information Act requests or

disclose FDA's decision letters, known as Complete Response Letters (CRLs). Makary recently announced FDA would further use AI to prioritize inspections, including targeted, one-day inspections.

Makary said FDA let oxycodone sales go unchecked and missed how it would help fuel the opioid addiction crisis. I thought Makary would place increased warnings on opioid medications and require more evidence-based clinical data. Makary did place increased warnings on opioid drugs, including warnings about higher doses, extended-release formulations, and that longer-term use may lead to risks of overdose or death.

In addition, Makary established a Commissioner's National Priority Voucher Program that reduced traditional 10-12 month-reviews to just one or two months for critical US health priorities focusing on domestic manufacturing needs.

Makary, however, reportedly was asked to leave in part because he "angered" pharmaceutical companies by making CRLs public or asking for additional studies for drug products that had previously been reviewed by FDA staff. Makary appeared to slow down the review of FDA's previous approval of mifepristone as an early-term abortion drug, which angered anti-abortion groups. In addition, Makary created uncertainty in the vaccine development area by linking deaths of about 10 children to mRNA COVID-19 vaccines and adding additional risk information to mRNA labels. Makary sought to overhaul vaccine approvals by initiating a risk-stratified strategy, which appeared to then block approval of a Moderna's flu vaccine developed with mRNA technology.

Next, Makary criticized FDA for placing boxed warnings on female replacement hormones that he thought carried more benefits than demonstrated health risks. I predicted that Makary would look to reduce or remove the health risk warnings on female hormones used as a replacement therapy. I was correct – Makary did remove the box warnings on female hormone replacement therapies and even approved two new drugs to expand treatment options for menopausal symptoms, including approving a generic version of Premarin (conjugated estrogens) to help with treating menopause symptoms.

Prior to being selected as Commissioner, Makary had ties to the compounding industry, such as Sesame, a telehealth platform that connected consumers to

physicians who prescribed compounded weight loss drugs, and he served on the board of Harrow, an ophthalmic compounding company. I thought that Makary would preserve telehealth treatment options including compounded medications such as weight loss drugs. While FDA did issue a series of Warning Letters to compounding pharmacies, FDA took little action to actually stop compounding weight loss drugs that were no longer in shortage (GLP-1s).

Makary criticized the food pyramid and other food initiatives as outdated and contributing to ongoing and new diseases, as well as poor cardiovascular health and obesity. I predicted Makary would take an increased interest in food products and additives, as well as dietary supplements. Not long after, Makary began the rulemaking process to eliminate the ability for companies to self-affirm that a dietary ingredient/additive is generally recognized as safe (GRAS) without notifying the FDA, making it mandatory to notify FDA regarding a company's GRAS affirmation and triggering an FDA review of the notice.

Concerning Public Health & Food Safety, Makary initiated new dietary guidelines as well as a robust review of chemicals in the food supply e.g., phasing out petroleum-based artificial food dyes as well as other additives like BHT, BHA, and ADA, as well as phthalates, propylparaben, and titanium dioxide. Makary continued work of Operation Stork Speed by hosting an expert roundtable on infant formula and exploring new ways to bring healthier options without ingredients like seed oils, added sugars, and heavy metals. Makary also launched the Nutrition Regulatory Science Program in partnership with the National Institutes of Health to better address issues such as the impact of ultra-processed foods and effect of certain food additives.

More recently, FDA took steps to reduce unnecessary animal testing as a prerequisite for clinical (human) studies and instead use more human-relevant information like organ-on-a-chip, advanced computer simulations, and pre-existing international data.

The Next Acting Commissioner

What can we expect from Kyle Diamantas, J.D., as Acting Commissioner? Prior to this role, Diamantas was Deputy Commissioner for Food, so Makary's food initiatives are

likely to continue. Since February 2026, Diamantas was a Senior Counselor for the FDA, serving as a liaison between the agency, the U.S. Department of Health and Human Services, and The White House, which may allow him to continue the role while the Trump administration looks for another candidate for FDA Commissioner.

Currently, several reports appear to have indicated that three candidates are being vetted for the role of FDA Commissioner: White House domestic policy aide Heidi Overton, MD, oncologist Jeffrey Vacirca, MD, and Pentagon health official Stephen Ferrara, MD.

This blog was drafted by Brian Malkin, a Spencer Fane attorney on the FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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