Skadden

The Nucleus: Life Sciences Regulation and Enforcement Updates

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Makary Is Confirmed as Commissioner of an FDA in Transition

Dr. Martin Makary has been confirmed by the Senate as the next commissioner of the Food and Drug Administration (FDA). Dr. Makary is taking the helm at FDA during an unprecedented time for the agency, which has been subject to staffing and resource cuts by the Department of Government Efficiency (DOGE).

Dr. Makary's writings and public comments make clear that while he is skeptical about certain aspects of the medical establishment, he is also a purist with respect to reliance on valid scientific evidence. These positions may influence his policies as FDA commissioner and potentially lead to differing views from his new boss, Health and Human Services (HHS) Secretary Robert F. Kennedy Jr.

Below, we discuss:

- Dr. Makary's pre-FDA background.
- What has happened at FDA since President Donald Trump took office.
- Some of the issues Dr. Makary has previously spoken about that he may encounter in his new role as commissioner.

Dr. Makary's Pre-FDA Background

Prior to being appointed FDA commissioner, Dr. Makary was chief of Islet Transplant Surgery at Johns Hopkins University as well as a prolific writer and commentator on the medical establishment and scientific dogma. His most recent book, *Blind Spots*, focuses on "health topics that have been overlooked or dismissed because of medical groupthink," suggesting his skepticism in this regard.

Blind Spots also emphasizes Dr. Makary's views on the importance of randomized, controlled trials and not relying on "experts" to make decisions about our health that are not grounded in scientific evidence. In addition, Dr. Makary's op-eds, which are available on his website, give further insight into his philosophy as a scientist and physician. Many of his opinions encourage reliance on rigorous scientific evidence that is gathered faster and more transparently.

Interestingly, while Dr. Makary was a vocal critic of the medical and governmental response to COVID-19, he advocated for more accurate advice about vaccinations, in contrast to Secretary Kennedy, who questioned the utility of COVID-19 vaccines altogether.

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Recent Developments at FDA

In the time between President Trump's inauguration and Dr. Makary's first day as FDA commissioner, much has changed at FDA.

- Many staff have been let go or invited to resign or retire, including most of the senior staff at the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.
- DOGE has closed 30 field offices the agency uses for scientific research and inspections.
- FDA's public meeting schedule, which includes advisory committee meetings such as the Vaccines and Related Biological Products Advisory Committee, has become sparsely populated, and some meetings have been canceled without the intent to reschedule.
- FDA leadership has changed significantly, including, the FDA chief of staff, chief counsel, chief scientist and the deputy commissioner for human foods.

The agency is also determining how to navigate President Trump's new executive orders discouraging new guidance and regulations, both of which the agency historically has strongly relied on to share information with the industries it regulates. Indeed, Commissioner Makary may soon be required to grapple with this tension, as Secretary Kennedy recently directed the agency to explore rulemaking to eliminate the self-affirmed GRAS (Generally Recognized as Safe) pathway.

While FDA commissioners do not usually get involved in the day-to-day operations of the agency, their priorities tend to guide the agency's focus and attention. The FDA commissioner also leads the agency's budget requests with Congress, acts as an expert and spokesperson during major public health crises and navigates conflicts with HHS and the White House.

In that respect, Dr. Makary's experience as a scientist and advocate for clinical research may make him well positioned to navigate staffing decisions, user fee negotiations and the impact of a deregulatory agenda. In addition to these administrative matters, we expect that he may have to grapple with the following legal issues, which he has previously commented on publicly.

Compounded GLP-1s

At his confirmation hearing, Dr. Makary's involvement in Sesame, a telehealth provider that offers patients compounded GLP-1 medications, was raised as a potential conflict of interest. Industry-focused publications have questioned how Dr. Makary would approach the ongoing standoff between the compounding industry and FDA.

Currently, the Outsourcing Facility Association, which represents the industry, is in litigation with FDA over the agency's decision to remove GLP-1s, including those indicated for weight loss, from the drug shortage list. As we discussed in a previous client alert, inclusion on the drug shortage list had allowed the products to be compounded in large quantities; now that the products are no longer in shortage, compounders are precluded by statute from making products that are "essentially a copy" of FDA-approved GLP-1 drugs.

FDA currently is exercising some degree of enforcement discretion to allow compounding to continue while GLP-1 compounders wind their businesses down, but it is unclear how long this will continue. In any event, Dr. Makary may find himself almost immediately having to make a challenging policy decision with respect to the agency's exercise of enforcement discretion for GLP-1 compounders.

While FDA has prevailed at the district court level, the compounding industry has said it will appeal. In addition, some compounders may choose to continue making GLP-1 products even after the shortage has been declared over and the period of enforcement discretion runs out, testing FDA's commitment to removing compounded GLP-1 products from the market.

Healthy Lifestyle Choices

Dr. Makary is joining FDA during a time of significant focus on ultra-processed foods under the Make America Healthy Again (MAHA) Commission (see our previous client alert). On his book tour for *Blind Spots*, Dr. Makary spoke publicly about his beliefs that many negative health outcomes are linked to diet and lifestyle habits, and that drugs are only one part of overall medical treatment and health. Both positions are consistent with the MAHA Commission mission.

He also has been a vocal critic of ultra-processed foods and endocrine disruptors in pesticides, like his boss, Secretary Kennedy. It would not be surprising to see Dr. Makary working closely with the MAHA Commission to move forward with recommendations about ultra-processed foods. This could include implementing Secretary Kennedy's directive to reform the self-affirmed GRAS pathway, particularly in light of Commissioner Makary's remarks during his confirmation hearing that he would review chemicals in food ingredients, including those that are currently classified as GRAS.

In addition, Secretary Kennedy has publicly committed to withdrawing FDA approval for food dyes, similar to the agency's decision to revoke the approval of Red Dye No. 3.

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Deregulatory State

While many executive branch agencies communicate with stakeholders via guidance documents, guidances historically have played a key role in FDA's efforts to help industry navigate the complex approval processes for drugs, biologics and medical devices, as well as comply with regulatory requirements for manufacturing and post-market reporting.

During his confirmation hearing, Dr. Makary commented on improvements he'd like to make in FDA policy on issues such as:

- Streamlining the approval of biosimilars, generics and over-the-counter drugs to bring down costs.
- Using real world data to speed medical product reviews.
- Scrutinizing food additives.
- Maintaining clinical trial diversity.

To address these issues, FDA will need to issue guidance or regulations.

President Trump's deregulation executive orders may bring this strategy into question. One order requires the agency to review which of its guidances and regulations may go beyond its statutory authority, while another requires the agency to withdraw 10 guidances or regulations for each one it issues. (See our article on the administration's deregulatory initiative.)

At the end of the Biden administration, FDA issued a flurry of guidances and rules on a variety of topics, including:

- The definition of "healthy."
- Front-of-package nutrition labeling.
- Firm-sponsored communications of scientific information regarding off-label use.
- Lead in baby food.

These guidances and rules are all now in limbo.

The medical device industry, which is currently in litigation with FDA regarding its final rule on laboratory-developed tests (LDTs), is closely watching to see whether FDA will include its final rule on LDTs on the list of regulations it will no longer enforce because it believes it exceeds the agency's statutory authority.

Dr. Makary and his staff in the commissioner's office face challenges in determining how to maintain the value of scientific guidance and clear communication with regulated industry while adhering to a deregulatory agenda.

As Dr. Makary's tenure takes shape, we will continue to monitor for other policy issues impacting FDA and the industries it regulates.