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FDA Leadership Provides Revised Priorities at Reagan-Udall Foundation Annual Board of Directors Meeting

On July 21, the Reagan-Udall Foundation for the Food and Drug Administration held its 2026 Annual Public Meeting of the Board of Directors. The Foundation is an independent 501(c)(3) organization created by Congress to advance the mission of the U.S. Food and Drug Administration (FDA). As a neutral convener, the Foundation brings together the FDA, patient groups, academia, industry, and government to modernize product development, accelerate innovation, and enhance the safety of the products people rely on every day.

The meeting provided an opportunity for the Foundation to engage with its external stakeholders, including patients and consumers, regulated industry, health care providers, academics, and other public health advocates. This year the annual meeting featured Acting FDA Commissioner Kyle Diamantas, FDA Chief Scientist Steven Kozlowski, and Acting FDA Chief of Staff Lowell Zeta.

The Foundation also discussed several priorities with FDA, including demand forecasting for controlled substances and the current uses of ketamine. The Foundation also highlighted animal health as a priority, including its potential implications for human health.

Susan Winckler, CEO of the Foundation, then moderated a discussion with the guest FDA speakers. Zeta highlighted FDA's increased inspections now up to 17,000 with over 25,000 product samples examined, and the Administration's increased recruitment and hiring. Kozlowski discussed how FDA is using more artificial intelligence to help FDA accelerate product reviews while maintaining safety and quality. As we reported, FDA along with its sister agencies, is partnering to accelerate early product development with its Operation TrialBlazer to help the U.S. compete

with ex-U.S. countries who are beginning to overtake the U.S. with more early-phase clinical studies. In addition. FDA is looking to address root causes of disease through its four pillars: Innovation and Global Leadership, Advancing National Health Security, Increasing Access to Affordable Medicines and Medical Products, and Preventing Chronic Disease and Promoting Wellness in America.

The Foundation's board members discussed how the Foundation can help FDA achieve its goals. Some of its goals include:

- Encouraging more clinical studies for women,
- "Making American Healthy Again" through nutrition and education,
- Developing biomarkers for rare diseases,
- Repurposing drugs for new uses,
- Understanding patient outcomes using real world evidence,
- Maintaining its Expanded Access Navigator that provides resources for single-patient expanded access products to physicians, patients, and caregivers,
- Utilizing digital tools for better health and identifying the "snake oil",
- Reaching a "Goldilocks" number of opioids without fueling a new opioid crisis, and
- Helping to manage new public health crises such as the New World Screwworm.

Finally, Diamantas discussed how the Foundation's partnership with FDA can help with developing data-driven decision making and address the four pillars. In this context, Diamantas mentioned as some examples:

- Developing new natural food colors over petroleum-based products,
- Removing harmful chemicals from the food supply,
- Reforming new dietary ingredient reviews,
- Removing restrictions on laboratory-developed tests,
- Developing new preclinical tests to replace animal tests, and
- Modernizing drug reviews to assist with treatments for ultra-rare diseases including gene therapies – without sacrificing safety and maintaining FDA as the global gold standard.

Key Takeaways

Despite the recent change in FDA leadership (as reported here), organizations such as the Foundation can help FDA achieve its public health goals. Companies,

moreover, may be able to leverage the combined resources of FDA and the Foundation to find opportunities for new products to treat rare and ultra rare diseases or preclinical tests to replace animal tests like organ on a chip.

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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