REAGAN-UDALL FOUNDATION for the Food and Drug Administration

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Independent Expert Panel Announced to Review FDA's Tobacco Program

Evaluation Launched September 21, 2022

*(*September 21, 2022*)* The Reagan-Udall Foundation today announced members of an Independent Expert Panel who will conduct the operational evaluation of the Food and Drug Administration's tobacco program. Lauren Silvis, JD, former FDA Chief of Staff, was named as Chair of the panel last month. Joining Silvis are Jane Axelrad, Keith Flanagan, Charlene Frizzera, and Alberto Gutierrez.

"The panel has been asked to evaluate regulatory processes and agency operations related to tobacco to help the Center address new challenges as it works to reduce death and disease from tobacco and achieve its public health mission," said Silvis. "We've put together a team with deep expertise in standing up programs and running regulatory organizations throughout FDA and HHS."

The evaluation, launched today, will address Center programs for regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders. The panel will not address tobacco policy issues, which are outside the scope of this evaluation. The report will be presented to FDA Commissioner Robert Califf in 60-business-days on December 19, 2022.

Charged with generating the recommendations, the Independent Expert Panel includes former FDA leaders and regulatory strategists as well as process improvement specialists:

- **Jane Axelrad, JD,** spent 25 years at FDA as the Associate Director for Policy at FDA's Center for Drug Evaluation and Research. She stood up the Center's Office of Regulatory Policy, providing strategic policy advice to the Center Director and other senior staff. Before retiring from FDA, she was the Agency lead responsible for developing a comprehensive program for the oversight of the evolving drug compounding industry. Today she is principal at Axelrad Solutions LLC.
- **Keith Flanagan, JD,** stood up two new offices within FDA's Center for Drug Evaluation and Research: the Office of New Drug Policy and the Office of Generic Drug Policy. Previously, as Senior Health Counsel to the U.S. Senate Health, Education, Labor & Pensions (HELP) Committee, he co-authored numerous FDA reform laws. He is the owner of Flanagan Strategies, LLC.

- **Charlene Frizzera** is President and Co-founder of CF Health Advisors following three decades at the Centers for Medicare and Medicaid Services, including roles as the Acting Administrator and Chief Operating Officer. She led the Agency's policy and operational aspects, including budget, information technology and systems, human resources, contracting, administration, and program integrity.
- **Alberto Gutierrez, PhD,** a Partner at NDA Partners, a ProPharma Group Company, spent 25 years at FDA gaining expertise in preclinical and clinical testing, premarket notifications of devices, applications for approval, and post-marketing surveillance and compliance. He retired in 2017 as the Director of In Vitro Diagnostics and Radiological Health in the Center for Devices and Radiological Health.

The Independent Expert Panel will consult as needed with tobacco and public health experts, including Georges Benjamin, MD, executive director of the American Public Health Association, and Andrew C. von Eschenbach, MD, 20th Commissioner of Food and Drugs, both members of the Reagan-Udall Foundation Board of Directors. The panel will also gather broad stakeholder input during the evaluation process.

A separate Independent Expert Panel for evaluation of FDA's human foods program was announced earlier this month.

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) created by Congress to advance regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The FDA Foundation works to improve health and safety through stakeholder engagement and public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and polices to keep pace with today's rapidly evolving science.

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