



FOR IMMEDIATE RELEASE
November 13, 2019

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FDA's Theresa Mullin, Compassionate Use Advisory Committee, and Cystic Fibrosis Foundation to be Honored with Innovations in Regulatory Science Awards

Honorees to be recognized on December 11 in Washington, DC

Washington, DC - The Reagan-Udall Foundation for the FDA will present 2019 Innovations in Regulatory Science Awards to Theresa M. Mullin, PhD, of the FDA's Center for Drug Evaluation and Research; the Compassionate Use Advisory Committee, a collaborative program of Johnson & Johnson and New York University; and the Cystic Fibrosis Foundation.

The awards will be presented at the [Reagan-Udall Foundation for the FDA's](#) annual Innovations in Regulatory Science Awards Dinner on Wednesday, December 11, at the Mayflower Hotel in Washington, D.C.

"We are extremely proud to recognize these leaders, innovators, and advocates who are making a meaningful impact in regulatory science," says Garry Neil, MD, Chair of the Awards Committee and a member of the Foundation's Board of Directors. "Not only have this year's slate of honorees helped advance science, they have also made a profound difference in the lives of patients."

The Foundation's **Leadership Award** recognizes the enduring contributions of **Dr. Theresa Mullin's** two-decade tenure with the FDA. Her career in public service demonstrates her persistent leadership and unwavering commitment to patient care, the drug development process, and public safety. As Associate Director for Strategic Initiatives at the Center for Drug Evaluation and Research (CDER), Dr. Mullin leads and facilitates FDA's Patient-Focused Drug Development initiative, ensuring that patient perspectives are integrated into drug development and evaluation using scientific methodologies. Dr. Mullin is at the forefront of a cultural shift in how regulators and researchers utilize patient input and data. Previously, as the Director of CDER's Office of Strategic Programs, Dr. Mullin was a critical leader in modernizing drug regulatory operations and in spearheading FDA negotiations to support the 2017 reauthorization of the Prescription Drug User Fee Act and Biosimilar User Fee Act.

The **Compassionate Use Advisory Committee (CompAC)**, winner of the **Innovation Award**, is a public-private partnership formed by New York University and Johnson & Johnson that is helping to transform how expanded access requests are evaluated by drug developers. By requesting expanded access, also known as compassionate use, patients may gain access to

investigational therapies outside of clinical trials. CompAC utilizes an external, independent group of physicians, bioethicists, and patient representatives to review and inform both the compassionate use strategy for emerging products as well as individual requests based on established criteria. The result is a consistent, transparent, and equitable means to navigate the challenges of pre-approval access. The CompAC model is now being shared to help other companies address their own approach to expanded access.

The **Cystic Fibrosis Foundation** (CFF) receives the Foundation's inaugural **Advocacy/Policy Award**, which recognizes significant policy achievements that advance regulatory science and have a direct impact on the public. CFF's mission is to cure Cystic Fibrosis and to provide those living with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialty care. CFF has worked with FDA to support the modernization of clinical trial design for patients with rare diseases, and nearly every Cystic Fibrosis-specific drug available today was supported financially by CFF. Influencing public policy at all levels, CFF rallies the Cystic Fibrosis community nationwide to educate policymakers on the need for more research, more therapies, and more access.

"Our 2019 honorees truly represent the spirit of the Innovations in Regulatory Science Awards," says Ellen V. Sigal, PhD, Chair of the Reagan-Udall Foundation for the FDA's Board of Directors. "Their groundbreaking and enduring work moves science forward, and, hopefully, will inform and inspire the next generation of regulatory scientists and leaders."

The 2019 Innovations in Regulatory Science Awards Dinner is supported by presenting sponsor Alexandria Real Estate Equities, Inc. and more than 20 other organizational donors.

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) organization created by Congress to advance regulatory science in support the U.S. Food and Drug Administration's mission. For additional information about the Foundation, please visit <https://reaganudall.org>.

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