



**FDA's Dr. Peter Marks, The COVID-19 Research Database, and Rep. Patrick Kennedy  
Recognized with  
*Innovations in Regulatory Science Awards***

*Honorees to be celebrated by FDA Foundation on December 14*

(September 27, 2021) The Reagan-Udall Foundation for the FDA will present 2021 [Innovations in Regulatory Science Awards](#) to Peter Marks, MD, PhD, The COVID-19 Research Database, and former U.S. Representative Patrick J. Kennedy.

Recipients will be honored at the Foundation's fifth annual *Innovations in Regulatory Science Awards* celebration which will take place virtually on Tuesday, December 14, at 6pm ET. The awards recognize outstanding contributions to regulatory science and public health in three categories: Leadership, Innovation, and Advocacy/Policy.

"The work of each of this year's honorees has made a substantial, positive impact on the health of the American public," says Garry Neil, MD, Chair of the Awards Committee, and a member of the Foundation's Board of Directors. "We're proud to celebrate their contributions to the field of regulatory science."

This year, the Foundation's Leadership Award honors **Peter Marks**, MD, PhD, for his exemplary achievements and lifelong public service commitment. As the director of FDA's Center for Biologics Evaluation and Research (CBER), Dr. Marks played an essential role in establishing the program formerly known as Operation Warp Speed, the partnership between the federal government and various private companies to develop COVID-19 treatments and vaccines. As CBER director, Dr. Marks oversees the FDA's work ensuring the safety and effectiveness of biological products, including vaccines, allergenic products, blood products, and cellular, tissue and gene therapies. He has demonstrated superior understanding of the importance of regulatory and manufacturing frameworks that can streamline the development of these treatments, bringing life-saving therapies to patients in a timelier manner.

In April of 2020, a consortium of leading public and private healthcare organizations came together to launch the **COVID-19 Research Database**, a secure repository of data sets made available at no cost to researchers, enabling them to conduct large-scale studies while protecting patient privacy. This year's Innovation honoree, the Research Database enabled access to real-world data to better understand and combat the COVID-19 pandemic. The Research Database is a cross-industry collaborative, composed of institutions donating technology services, healthcare expertise, and de-identified data. It has unlocked 85 billion records covering over 250 million unique individuals now available to a research community

conducting critical research in epidemiology, pharmacoepidemiology, population health and more.

**Former U.S. Rep. Patrick J. Kennedy** is this year's recipient of the Advocacy/Policy award for his dedication to increasing access to mental health and addiction care for all Americans. He founded The Kennedy Forum, a nonprofit that brings together advocates, business leaders, and government agencies to advance evidence-based practices, policies, and programming in mental health and addiction. He is a co-founder of the Kennedy-Satcher Center for Mental Health Equity as well as other nonprofit organizations that are changing the lives of people with mental illness, addiction, and other brain diseases in the U.S. and around the world. While in Congress, Kennedy was a lead author of the Mental Health Parity and Addiction Equity Act, which requires insurers to cover treatment for mental health and substance use disorders no more restrictively than treatment for illnesses of the body. Additionally, Kennedy authored and co-sponsored dozens of bipartisan bills to increase the understanding and treatment of neurological and psychiatric disorders.

"We applaud the remarkable accomplishments of this year's awardees," says Susan C. Winckler, RPh, Esq., CEO of the Reagan-Udall Foundation for the FDA. "Their vision and their dedication are an inspiration to all of us working to advance regulatory science and improve public health."

The 2021 Innovations in Regulatory Science Awards event is supported by presenting sponsor Alexandria Real Estate Equities, Inc./Alexandria Venture Investments along with other organizational and individual donors.

#### **About the Reagan-Udall Foundation for the FDA**

The [Reagan-Udall Foundation for the FDA](https://www.reaganudall.org) (FDA Foundation) 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 policies to keep pace with today's rapidly evolving science.