



September 17, 2018

Reagan-Udall Foundation for the FDA Selects Three Honorees for 2018 Innovations in Regulatory Science Awards

Washington, DC – The Reagan-Udall Foundation for the FDA will honor two longtime U.S. Food and Drug Administration leaders and an independent public-private partnership as the 2018 recipients of the Innovations in Regulatory Science Awards. This year’s Leadership Award recipient is Richard Pazdur, M.D., Director of the FDA's Oncology Center of Excellence (OCE), and the two recipients of the Innovations Award are Robert T. O’Neill, Ph.D., former Senior Statistical Advisor in the Office of Translational Sciences (OTS) in the FDA’s Center for Drug Evaluation and Research (CDER) and the Clinical Trials Transformation Initiative (CTTI), a public-private partnership cofounded by Duke University and the FDA.

The awards will be presented at one of [Reagan-Udall Foundation for the FDA’s](#) signature events, the Innovations in Regulatory Science Awards Dinner celebrating advances in regulatory science on December 4th, 2018 in Washington DC. The congressionally chartered Foundation brings an array of resources and perspectives to bear on high priority FDA regulatory science projects and facilitates engagement between FDA and external stakeholders through public-private partnerships.

“We hope by recognizing leaders and innovators in our field, we will inspire the next generation of researchers, innovators and regulators to address emerging challenges in regulatory science,” said June Wasser, Executive Director of the Foundation. “We are delighted to recognize three outstanding honorees for their invaluable contributions to advance regulatory science.”

Dr. Pazdur’s nearly 20 years with the FDA demonstrates transformative leadership and commitment to improve cancer care. He has worked tirelessly to dramatically reduce the amount of time to review new products and to increase the number of safe and effective oncology products available to cancer patients today. He is a prominent thought leader in oncology drug development who has embraced the use of novel trial designs, endpoints and biomarkers to help realize the promise of precision medicine and the impact of immunotherapy for cancer.

“His remarkable success and dedication to improving the future of cancer care is consistently demonstrated through his crucial role in promoting regulatory science innovation and the science of precision medicine to benefit patients. This will undoubtedly improve patient outcomes far into the future,” said Dr. Garry Neil, member of the Foundation Board of Directors and the Awards Committee Chair. “That’s why we are honored to present this Leadership Award to Dr. Richard Pazdur.”

Dr. Robert O’Neill, an Innovations Award honoree, recently retired after 47 years of service to the FDA during which he was at the forefront of regulatory statistical science and instrumental in the development of standards for well-designed clinical trials as a Senior Statistical Advisor in the CDER’s OTS at FDA.

“Dr. O’Neill is an exemplary statistician whose leadership, expertise, and advice profoundly shifted the regulatory landscape and elevated the quality of clinical trials designed to support drug approval. In so doing he helped to insure that safe and effective drugs are available to the American people,” said Dr. Richard Schilsky, Vice Chair of the Foundation Board of Directors. “This award recognizes his inspired intellectual leadership, and his profound impact on drug safety and the field of biostatistics.”

CTTI’s Innovation Award recognizes their groundbreaking work in transforming clinical trials. CTTI is a public-private partnership cofounded by Duke University and the FDA with a mission to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. CTTI’s inclusive, collaborative, and evidence-based approach now comprises more than 80 organizations including government agencies, industry, patient advocacy groups, investigators and academic institutions.

“The Clinical Trials Transformation Initiative’s evidence-based approach to transforming clinical trials has been significant,” said Dr. Neil. “As CTTI celebrates its 10th anniversary, it seems only fitting that we recognize their ability to bring together all participants in the clinical trials enterprise and develop comprehensive and actionable programs that have changed the way we conduct clinical trials.”

FDA Commissioner, Scott Gottlieb, M.D. will be a featured speaker at the event, which will be held from 6:00pm – 9:00pm at the Kaiser Permanente Center for Total Health in Washington DC on Tuesday, December 4, 2018.

The presenting sponsor of the Awards Dinner is Johnson & Johnson, and other contributing sponsors include Merck & Company Inc., Teva Pharmaceutical Industries Ltd., Eli Lilly and Company, EMD Serono Inc., Friends of Cancer Research, Pharmaceutical Research and Manufacturers of America, and Ultragenyx Pharmaceutical.

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress for the purpose of advancing regulatory science to support the FDA’s mission. For additional information about the Foundation, please visit <https://reaganudall.org/>.

###

Media Contact Information (not for publication)

For questions about the Innovations in Regulatory Science Awards Dinner or the Reagan-Udall Foundation for the FDA, contact Patricia Enright Kaplan, Director of Marketing and Communications by email pkaplan@reaganudall.org or phone (202)-849-2071.

(202) 849-2075

1900 L Street NW, Suite 835, Washington, DC. 20036

www.reaganudall.org