The Food and Drug Administration's (FDA's)
2015 ORSI Science Symposium
April 27, 2015
SPEAKER ABSTRACTS AND BIOGRAPHIES

Session 1: Centers for Excellence in Regulatory Science and Innovation (CERSIs) Presentations – 8:35-11:30 AM

Georgetown University CERSI

CERSI	**Georgetown University**
Speaker	**Ira Shoulson, MD**
Title and Location	**Professor of Neurology, Pharmacology, and Human Science** **Director, Program for Regulatory Science & Medicine** **Principal Investigator, Center of Excellence in Regulatory Science and Innovation (CERSI)** **Georgetown University, Washington, DC**
Biography	**Ira Shoulson, MD, is Professor of Neurology, Pharmacology, and Human Science, and Director of the Program for Regulatory Science and Medicine (PRSM) [http://regulatoryscience.georgetown.edu] at Georgetown University, Washington, DC. From 1990 until 2011, Dr. Shoulson was the Louis C. Lasagna Professor of Experimental Therapeutics and Professor of Neurology, Pharmacology and Medicine at the University of Rochester School of Medicine & Dentistry in Rochester, New York, where he currently holds adjunct appointments as Professor of Neurology, Pharmacology & Physiology. He received his MD degree (1971) and postdoctoral training in medicine (1971-73) and neurology (1975-77) at the University of Rochester and in experimental therapeutics at the National Institutes of Health (1973-75). Dr. Shoulson founded the Parkinson Study Group (www.parkinson-strudy-group.org) in 1985 and the Huntington Study Group (www.huntington-study-group.org) in 1994 -- international academic consortia devoted to research and development of treatments for Parkinson disease, Huntington disease, and related neurodegenerative and neurogenetic disorders. He was a key investigator in the US-Venezuela Collaborative Huntington Disease Project, which identified the gene responsible for this fatal hereditary disorder. Dr. Shoulson has served as principal investigator of the National Institutes of Health-sponsored trials, "Deprenyl and Tocopherol Antioxidative Therapy of Parkinsonism" (DATATOP), the "Prospective Huntington At Risk Observational Study" (PHAROS), and in the leadership of more than 35 other multi-center clinical research studies. He played an instrumental role in the development of 10 new drugs for neurological disorders, including seven for Parkinson disease (selegiline, lazabemide, pramipexole, entacapone, clozapine, rasagiline, rotigitine), two for Huntington disease (tetrabenazine, dutetetrabenazine), and one for attention deficit disorder (Concerta). He was formerly a health policy fellow in the U.S. Senate, a member of the National Institute of Neurological Disorders and Stroke Council, and president of the American Society for Experimental NeuroTherapeutics (ASENT). He is currently principal investigator of the FDA-Georgetown University Collaborating Center of Excellence in Regulatory Science and Innovation (CERSI - FD004319), associate editor of JAMA Neurology and an active elected member of the Institute of Medicine of the National Academy of Sciences. He has authored more than 300 scientific reports.**
Presentation Title	**Overcoming Challenges to Medical Product Innovation**
Presentation Abstract	**Georgetown University Center of Excellence in Regulatory Science and Innovation (CERSI) promotes and supports collaborative approaches to address current and emerging regulatory science decision-making challenges. Success of these efforts has been demonstrated through tangible value created in regulatory science research, education and training, and scientific exchange. In his brief remarks, Ira Shoulson, MD, will describe the key features of the Georgetown CERSI and highlight milestones achieved in the first four years of collaboration with the FDA.**