Neuromodulation with Subthreshold Electrical Stimulation: Mechanisms, Safety, and Seeking Proof of Effectiveness

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Most of the information integration in the central nervous system involves subthreshold events that involve biochemical changes that result in electrical changes. This information through electrical modulation is integrated temporally and spatially to cause or alter the rate of nerve impulses (action potentials). The talk by Dr. Krauthamer will be in three parts. The first will outline some of the physiological mechanisms used by devices to modulate neural function with electrical stimulation from DC to kilohertz. The second will discuss some of the research on assessing safety. The third will discuss the quest to demonstrate efficacy.

Biography: I am a physiologist by training and practice. My PhD degree was in neuroscience from SUNY at Buffalo, NY with a postdoctoral fellow at New York Medical College, NY, and I am a former faculty member in physiology at Nova Southeastern University, FL. I have been a research scientist at FDA for nearly 28 years and direct the Division of Biomedical Physics in the CDRH Office of Science and Engineering Labs.

My Division of Biomedical Physics has witnessed a revolution in medical devices within our regulatory research domains. These include a “wireless revolution”, the use of magnetic resonance for imaging and functional measures, innovative optical techniques, devices to treat neurological and psychiatric disorders, and the use of computational methods to help evaluate device effects in humans. In addition, there is a new recognition of the role of the human-device interface in the safe and effective use of medical devices along with the need for medical devices to be useful for patients and practitioners with disabilities. As the director of this division, I am moving into the future with laboratory programs that encompass innovative technologies and present-day device areas of device concern. Our strategy is one of engagement with the CDRH regulatory staff, academic centers, other federal agencies and industry so that our programs contribute our overall mission of public health. My personal goal is to be a leader in applied research and regulation through excellence in science.