Summary: This panel will consider the complicated scientific, legal, and ethical issues posed by rapid advances in mobile neurotechnology such as transcranial direct current stimulation (tDCS) and electroencephalography (EEG).

The rapidly emerging field of neuroscience and law (“neurolaw”) is exploring how a myriad of advances in neuroscience may affect society and legal outcomes. The two advances most relevant to this proposed panel are the development of (1) consumer friendly transcranial direct-current stimulation (tDCS) devices, and (2) wearable electroencephalography (EEG) technology.

The last decade has seen the rise of wearable neurotechnology. While historically neuroscientific evaluation required a trip to a hospital or research facility, today consumers can purchase a transcranial direct current stimulation (tDCS) device to alter mood and potentially treat mental disorders. tDCS sends low voltage electrical currents into targeted areas of the brain. The targets of tDCS are specific for a given purpose. For instance, studies have examined the use of tDCS to treat depression. In the current marketplace, the Thync company markets to users that tDCS can de-stress and boost their energy.

In addition to tDCS, consumers can also use their smart phones, attached wirelessly to an electroencephalography (EEG) device placed on their head, to get real-time electrical brain activity data in order to modulate their thoughts. EEG, originally discovered in 1929, is a method of measuring electrical activity produced by the brain. Electrodes are placed on the subject’s scalp, and electrical activity is recorded. Neurofeedback using EEG is a method that encourages individuals to use their brain data to alter their mental states (for instance, going from anxious to calm).

Mobile neurotechnology such as this offers both promise and peril. On one hand, the technology may lead to improved mental health and enjoyment of life. On the other hand, the technology (and the data it collects) raises important questions concerning regulation, safety, efficacy, and privacy.

We thus propose a panel to address the scientific, legal, and ethical questions posed by mobile neurotechnology. Questions to be considered include:

- **Efficacy**: Does the technology provide the benefits it promises, and what is known about variation in efficacy across individuals?
- **Safety**: What are the known side effects, and how do they compare to other technologies?
- **Regulation**: How, if at all, should the FDA regulate this technology? In what ways is this distinguishable from, or analogous to, existing technologies (some of which are under FDA oversight and some of which are not)?
- **Privacy**: How is brain data being stored and used by the companies processing the data for consumers? What levels of access do users have to their own data?

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• **Legal:** The law regulates many types of brain modulation, for instance making it illegal to drive in certain brain states. In what ways should law account for brain changes brought on by neurofeedback and neurostimulation?

• **Ethical:** Does neurostimulation deserve special ethical attention as compared to other, more indirect, ways of modulating mental activity?

While academic dialogue about some of these questions has begun, the questions above have not been sufficiently explored. A Dupont Summit panel would kick-start an important conversation.

The proposed panelists provide the requisite expertise for such a dialogue. Dr. Marom Bikson is a world-leading expert on tDCS; Dr. James Giordano (who is nearby as Chief of the Neuroethics Studies Program in the Pellegrino Center for Clinical Bioethics at Georgetown) has written multiple books on the ethics of neurotechnology; and Dr. Francis Shen is a leader in the field of neurolaw, having co-authored the first Law and Neuroscience textbook.

Finally, it is worth noting that this year the proposed panel would be uniquely timely. On November 19-20, the FDA is hosting its first public workshop on “Neurodiagnostics and Non-Invasive Brain Stimulation.” A Dupont Summit panel would be an important extension of that FDA discussion, which is not likely to reach the many legal and ethical questions the technology raises. Moreover, given the Washington DC location, we expect that the panel would be well attended by those with an interest in the regulation of the technology.

In sum, we think that a Dupont Summit panel would provide an excellent opportunity for much needed interdisciplinary dialogue about rapidly developing policy being put in place to govern mobile neurotechnology.

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**PANEL BIOGRAPHIES**

**Marom Bikson - City College of New York & City University of New York**

**Dr. Marom Bikson**, Ph.D. is a Cattell Professor of Biomedical Engineering at The City College of New York (CCNY) of the City University of New York (CUNY) and co-Director of the Neural Engineering Group at the New York Center for Biomedical Engineering. The translational R&D activity of his group spans pre-clinical studies, computational models, device design and fabrication, regulatory activities, and clinical trials. Technologies developed by his group are in clinical trials in over 100 medical centers and include neuromodulation interventions for neuropsychiatric disorders, intra- and post-operative sensors, patient compliance tools, and surgeon training simulators. Dr. Bikson has published over 200 papers and book-chapters and is inventor on over 30 patent applications. He is known for his work on brain targeting with electrical stimulation, cellular physiology of electric effects, and electrical safety. Dr. Bikson co-invented High-Definition transcranial Direct Current Stimulation (HD-tDCS), the first non-invasive, targeted, and low-intensity neuromodulation technology. Dr. Bikson consults for medical technology companies and regulatory agencies on the design, validation, and certification of medical instrumentation. Dr. Bikson is co-founder of Soterix Medical Inc. and WiPOX LLC. Prior to becoming faculty at CUNY, Dr. Bikson was a research fellow at the University of Birmingham Medical School, UK and a Research Associate at Sontra Medical LLC, in Cambridge Mass. Dr. Bikson received a Ph.D. in Biomedical Engineering from Case Western Reserve University, in Cleveland OH, and a B.S. in Biomedical Engineering from Johns Hopkins University, Baltimore MD.

**Francis X. Shen - University of Minnesota**

**Dr. Francis X. Shen**, JD, PhD., is a McKnight Land-Grant Professor and Associate Professor of Law at the University of Minnesota, where he directs the Shen Neurolaw Lab. The Lab is currently exploring the legal implications of mobile neurotechnology. Dr. Shen also serves as Executive Director of Education and Outreach for the MacArthur Foundation Research Network on Law and Neuroscience. Dr. Shen received his B.A. from the University of Chicago, his J.D. from Harvard Law School, and his Ph.D. from Harvard University. During graduate school he was a doctoral fellow in the Harvard University Multidisciplinary Program in Inequality & Social Policy, supported by the National Science Foundation. Dr. Shen conducts empirical and legal research at the intersection of law and neuroscience. He recently co-authored the first *Law and Neuroscience* textbook, and has published on a range of neurolaw topics, including memory, lie detection, mental health, neurolegislation, criminal law, and tort law. At the University of Minnesota Law School, he teaches Criminal Law, Evidence, Law and Neuroscience, and Education Law. Previous to Minnesota, he taught at Tulane Law School, Vanderbilt Law School, and Harvard University.

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Dr. James Giordano, PhD, is Chief of the Neuroethics Studies Program in the Pellegrino Center for Clinical Bioethics, and a professor in the Department of Neurology, and Graduate Liberal Studies Program at Georgetown University, Washington, DC, USA. He is Clark Faculty Fellow of Neurosciences and Ethics at the Human Science Center of Ludwig Maximilians Universität, Munich, Germany, where he previously was JW Fulbright Foundation Visiting Professor. Dr. Giordano is William H. and Ruth Crane Schaefer Distinguished Visiting Professor of Neuroethics at Gallaudet University, Washington, DC; is appointed to the Neuroethics, Legal, and Social Issues Advisory Panel of the Defense Advanced Research Projects Agency (DARPA), and is a Fellow of the Center for National Preparedness at the University of Pittsburgh, PA. His ongoing research focuses upon the use of advanced neurotechnologies to explore the neurobiology of pain and other neuropsychiatric spectrum disorders; the neuroscience of moral decision-making, and the neuroethical issues arising from the use of neuroscience and neurotechnology in research, clinical medicine, public life, international relations and policy, and national security and defense (for additional information, see: www.neurobioethics.org). The author of over 200 peer-reviewed papers, and 7 books in neuroscience and neuroethics, Dr. Giordano is Editor-in-Chief of the journal Philosophy, Ethics and Humanities in Medicine; Associate Editor for the journal Neuroethics; and Executive Editor-in-Chief of the book series Advances in Neurotechnology: Ethical, Legal and Social Issues (published by CRC Press).