Direct-to-consumer neurotechnology: ethical and regulatory challenges

Anna Wexler[1] and Peter B. Reiner[2]

[1] Department of Medical Ethics & Health Policy, Perelman School of Medicine, University of Pennsylvania
[2] Department of Psychiatry and the Neuroethics Collective, University of British Columbia

There exists a growing ecosystem of direct-to-consumer (DTC) neurotechnology products. Offering individuals the prospect of monitoring and manipulating a range of brain functions from memory to mental health, the major product categories are brainwave recording devices, brain training games, brain stimulation devices, and smartphone apps for mental health conditions. What distinguishes these products as *neuro*technologies is their appeal to the fruits of the brain and cognitive sciences; indeed the imprimatur of science is an integral part of their marketing. Because manufacturers of these technologies often limit their claims to improving general "wellness," they are able to skirt Food and Drug Agency (FDA) medical device laws. As a result, there is no more regulation applied to DTC neurotechnologies than to consumer products such as pedometers and bathroom scales. In this talk, I will identify and elaborate upon several areas of concern surrounding DTC neurotechnology: unclear efficacy, potential physical and psychological harms, lack of consumer understanding, and marketing to vulnerable populations. I will discuss how the challenges of regulating DTC neurotechnologies are in many ways similar to those facing dietary supplements: in both cases, the safety and efficacy of products have not been well established, there are no industry-wide standards, and the market is flooded with companies advertising and selling products directly to consumers with dubious health claims. Finally, I will propose a soft regulatory solution that reduces the potential for harm to the public without being onerous: the establishment of an independent oversight committee – distinct from existing regulatory regimes – whose mandate would be to evaluate the DTC neurotechnology market and disseminate information to the public and regulators.

Email: awex@pennmedicine.upenn.edu
Phone: 215.898.8274
Mailing Address: Blockley Hall, 423 Guardian Drive, Room 1431, University of Pennsylvania
Philadelphia, PA 19104

Acknowledgements: This study was supported by the Office of the Director, National Institutes of Health (NIH), grant number DP5OD026420.