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SCIENCE AND REGULATION

Oversight of direct-to-consumer neurotechnologies

Efficacy of products is far from clear

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Marketed for the purpose of modulating cognition or a variety of affective and mental states, a growing ecosystem of neurotechnology products is being sold direct to consumers (DTC) without necessitating the physician as intermediary. Offering individuals the prospect of monitoring and manipulating a range of brain functions from memory to mental health, the major product categories are neuromonitoring devices, cognitive training applications, neurostimulation devices, and mental health apps. The market for these products is predicted to top $3 billion by 2020 (*1*). Yet there are good reasons to conclude that regulatory oversight of DTC neurotechnologies is insufficient. We suggest ways to provide systematic support for regulatory agencies, funding bodies, and a public that is thirsty for knowledge about the efficacy of DTC neurotechnology products.

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UNCLEAR EFFICACY, POTENTIAL HARMS

These products are neurotechnologies insofar as they appeal to the fruits of the brain and cognitive sciences; indeed, the imprimatur of science is often an integral part of their marketing. One overarching issue is whether DTC neurotechnologies work as advertised. The problem is threefold. First, many companies have conducted little to no original research on the effectiveness of their products. Second, many DTC neurotechnology companies sell products that are loosely based on scientific research, yet it is unclear whether data gathered in the laboratory are applicable to consumer-grade products. For example, consumer electroencephalography (EEG) devices are designed differently from research-grade EEG devices (e.g., they employ fewer electrodes) and are used in different ways (e.g., they require the individual himself or herself, not a trained technician, to position the EEG headset). Third, in many domains of DTC neurotechnology, there is a lack of scientific consensus with regard to efficacy: Questions have been raised about whether devices that deliver transcranial direct current stimulation (tDCS) can improve cognitive performance (*2*), whether cognitive

Direct-to-consumer marketing of neurotechnologies is on the rise.

gains from brain-training games are generalizable (*3*), and whether the behavioral effects of EEG neurofeedback (*4*) and mental health apps (*5*) are due to placebo.

tDCS devices present the possibility of overt harms such as skin burns, which are reported by a small portion of users (*6*). Also worth mentioning are the potential psychological harms from DTC neurotechnologies. For example, many consumer EEG devices purport to "read" one's emotional state (e.g., as stressed, meditative, or focused). Yet these devices have not been independently validated and may provide false information. If a consumer EEG device erroneously shows that an individual is in a stressed state, this may cause him or her to become stressed or to enact this stressed state, resulting in unwarranted psychological harm (*7*). Individuals may learn from a smartphone app that they have symptoms of depression—yet the diagnosis is provided without support structures that exist within the medical realm, such as a psychologist or mental health counselor.

PUBLIC UNDERSTANDING AND ETHICS

It is difficult for the public to assess the validity of claims made by DTC neurotechnology companies. Even those who are interested in developments in neurotechnology see navigating product claims as a key concern in the brain fitness field (*8*). Research has found that the public is unsure of which activities actually benefit their cognition. More than a quarter of adults age 40 and older believe that the best way to maintain or improve brain health is to play so-called "brain games" like Lumosity, even though there is little scientific evidence to support this notion (*9*).

No single DTC neurotechnology has yet demonstrated the kind of overwhelming efficacy that would result in widespread public adoption. However, if a new technology were to display the sort of efficacy that the field aspires to, a host of ethical concerns would arise. One common issue brought forward by neuroethicists is distributive justice: To the extent that cognitive ability influences socioeconomic status, premium pricing of cognitive enhancers could serve to exacerbate existing inequality gaps. Moreover, cognitive enhancement technologies hold particular appeal for populations such as the elderly, for whom cognitive decline is among the most frightening of prospects. The popularity of brain fitness software in the face of unproven efficacy is a testament to the appeal of this class of product.

REGULATORY INSUFFICIENCIES

One might imagine that DTC neurotechnologies would be classified as medical devices. But in much the same way that dietary supplements can avoid being classified as drugs by refraining from making claims about treating or diagnosing disease, so, too, do most DTC neurotechnologies avoid classification as medical devices by limiting their claims to wellness (e.g., "optimizing focus"). Indeed, a recent guidance from the U.S. Food and Drug Administration (FDA) clarified that the agency would not be enforcing medical device regulations for "low-isk" products marketed for wellness purposes (*10*). This guidance suggested that tDCS products would fall within the agency's jurisdiction, but the FDA has not taken public enforcement action against consumer tDCS products.

Venture capitalists interested in financing neurotechnologies have publicly stated that it would be difficult for them to invest in devices that require a premarket approval path through the FDA (*11*). Although some companies, such as app developer Pear Therapeutics, have pursued FDA approval, there is incentive for companies to market products for wellness to avoid FDA regulation. The regulatory burden for DTC neurotechnologies has largely fallen to the Federal Trade Commission (FTC), which has authority to take action in cases of deceptive advertising. Although the FTC has filed complaints against companies marketing brain-training software, there are thousands of mental health apps on the market (*12*), as well as dozens of devices for cognitive enhancement, relaxation by entraining brain waves, improving motor function, and more.

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. In the United States, supplements are regulated by the FDA via the Dietary Supplement Health and Education Act (DSHEA) in a largely postmarket approach (*13*). Just as federal regulatory oversight from the FDA and FTC has been critiqued as being ill-suited to monitor the dietary supplement market (*14*), we suggest that similar concerns exist for DTC neurotechnologies: Given the sheer number of products, the dynamic nature of software applications that can change with each update, the flexibility required to oversee them, and the potential ethical issues involved, current regulatory oversight leaves much to be desired.

WHAT SHOULD WE DO?

Looking to the realm of supplements for guidance can be instructive, even if it does not provide a clear pathway forward. DSHEA mandated the creation of the National Institutes of Health (NIH) Office of Dietary Supplements, which conducts scientific research on dietary supplements and translates knowledge for the public and policy-makers. In addition, independent organizations provide evaluations and seals of approval for supplements (*14*).

In the realm of DTC neurotechnology, the analogous needs are twofold: for additional research into the safety and effectiveness of products, as well as how they are used by consumers; and for evaluations that can be made available to the public.

With regard to research, given that the DTC neurotechnology market is smaller than that of supplements and the concomitant public health risks are lower, we do not suggest the creation of a dedicated NIH body at the present time. However, inasmuch as DTC neurotechnology can be viewed as a downstream product of NIH-supported neuroscience research, we recommend that the NIH consider specifically funding research on DTC neurotechnologies, potentially under the umbrella of neuroethics research.

As for evaluation, two approaches exist for mental health apps but none for the remaining DTC neurotechnologies. At one end of the spectrum, the nonprofit organization Psyberguide provides consumer-oriented numerical ratings of individual mental health apps based on factors that include credibility, user experience, and transparency; at the other end of the spectrum, the American Psychiatric Association developed a framework that gives psychiatrists (but not consumers) tools to evaluate the safety, efficacy, and veracity of mental health apps.

We propose an approach that strikes a balance between the two: an independent working group that would survey the main domains of DTC neurotechnology and provide succinct appraisals of potential harms and probable efficacy. Rather than evaluating each and every product, which is resource-intensive, or providing overarching framing questions, the working group's appraisals would outline the evidence base and potential risks and identify gaps in current knowledge. Recent articles on the home use of brain stimulation (*15*) and consumer EEG devices (*7*) provide guidance and critiques without evaluating individual devices or claims and could serve as a model for the working group's appraisals.

The working group would be tasked with broadly circulating its appraisals to the public. Dissemination strategies would involve identifying and partnering with organizations such as the American Association of Retired Persons that are well positioned to communicate with key consumer groups, as well as sharing information with media outlets. The working group would serve as a clearinghouse for regulatory agencies such as the FDA and FTC, third-party organizations that monitor advertising claims, industry, social and medical scientists, funding agencies, and the public at large.

We envision the working group, which would be housed independently or within a reputable third-party organization, as drawing on the expertise of scientists, health professionals, consumer groups, industry representatives, ethicists, regulators, and funders. The working group would survey the current landscape, incorporating new domains of DTC neurotechnology and revising its appraisals. The group's mandate would include anticipating future developments, with an eye toward possible ethical concerns.

Given that government agencies and private enterprises are actively funding research into new methods of modulating brain function, the present generation of DTC neurotechnologies may be only the tip of the iceberg—making it all the more imperative to create an independent body to monitor developments in this domain. ■

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ACKNOWLEDGMENTS

This paper is informed by a 2018 meeting at the Banbury Center at Cold Spring Harbor that brought together regulators, scholars, and representatives from various professional organizations. A.W. acknowledges support from the Office of the Director, NIH, under Award Number DP5OD026420. P.B.R.'s funding derives from SSHRC grant 435-2018-0561. The content is solely the responsibility of the authors and does not represent the official views of funders.

10.1126/science.aav0223

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Science, 363 (6424), • DOI: 10.1126/science.aav0223