From Do-It-Yourself to Direct-to-Consumer: the Regulation of Consumer Noninvasive Brain Stimulation Devices

Anna Wexler
Ph.D. Candidate, Department of Science, Technology, and Society, MIT
Visiting Scholar, Center for Neuroscience and Society and Society, University of Pennsylvania
Introduction

*tDCS and the rise of the DIY/home use movement*

Practices of do-it-yourself brain stimulation

*how do home users draw upon scientific knowledge?*

Regulation of consumer tDCS devices

*how do consumer tDCS devices fit into the existing US regulatory framework?*
Presentation Outline

Introduction

*tDCS and the rise of the DIY movement*

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*how do consumer tDCS devices fit into the existing US regulatory framework?*
Transcranial direct current stimulation (tDCS)!

Deep brain stimulation (DBS)!

Transcranial magnetic stimulation (TMS)!
Excitability changes induced in the human motor cortex by weak transcranial direct current stimulation

M. A. Nitsche and W. Paulus

Department of Clinical Neurophysiology, University of Goettingen, Robert Koch Strasse 40, 37075 Goettingen, Germany
tDCS Research

Clinical Populations
- Depression
- Schizophrenia
- Stroke
- Chronic pain
- Alzheimer’s
- Parkinson’s
- Anxiety
- Motor disorders
- Epilepsy
- and more…

Healthy Populations
- Memory
- Creativity
- Problem-solving
- Motor skills
- Language
- Mathematics
- Attention
- Perception
- Executive function
- and more…
Rise of DIY tDCS

Brain-O-Matic

Can a jolt from a nine-volt battery make you smarter? Happier? Medical researchers revive a discarded technology and set the standard for the 'brain pod.'

By PAGAN KENNEDY | February 7, 2007

DIY tDCS

Keeping Tabs Transcranial Direct Current

Still Zapping My Brain. DIY tDCS Volume Two.
Academic journal publications about tDCS by year, 2000-2014

Data obtained from PubMed.com title search for "transcranial direct current stimulation" or "tDCS" conducted on January 5, 2015
DIY/home use tDCS Demographics

- Mostly male

Figure 2. Age of respondents (year).

- Global

Jwa (2015)
Purpose of home stimulation

59% self-stimulate for cognitive enhancement

11% self-stimulate for treatment

24% self-stimulate for both enhancement and treatment

Figure 4. Types of cognitive enhancement purpose for which respondents use tDCS.

Figure 5. Types of medical condition for which respondents use tDCS.

Jwa (2015)
<table>
<thead>
<tr>
<th>Researchers</th>
<th>DIYers/home users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use tDCS in laboratory</td>
<td>Use tDCS at home</td>
</tr>
<tr>
<td>Apply tDCS to subjects</td>
<td>Apply tDCS to themselves</td>
</tr>
<tr>
<td>Primary purpose: research</td>
<td>Primary purpose: self-improvement</td>
</tr>
<tr>
<td>Controlled, regulated environment</td>
<td>Uncontrolled environment</td>
</tr>
</tbody>
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Conclusion
Making/Acquiring a Device

neuroConn

Soterix
<table>
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<tr>
<th>Types of tDCS devices that home users can make/acquire</th>
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</thead>
<tbody>
<tr>
<td><strong>SELF-BUILT</strong> ($30-50)</td>
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<tr>
<td><img src="image1" alt="SELF-BUILT" /></td>
</tr>
</tbody>
</table>
Applying tDCS

- link to scientific articles (when behind firewall, post unrestricted copies)

- use video tutorials on electrode positioning

- adhere (mostly) to certain scientific standards (10-20 placement system; conventional current maximum of 2 ma)
Applying tDCS

DIYers transform existing scientific literature into user-friendly indexes and guides geared towards their needs.
Applying tDCS

Where there are “unknowns” in scientific literature, DIYers experiment and share their knowledge

- session length/frequency

DIYers experiment with longer and more frequent sessions. One DIYer wrote on the subreddit that “most studies never measured ‘the point at which it [tDCS] stops working.’”

- other disorders

One user posted that he “extrapolated” from a scientific finding about tDCS on depression to self-treat his bipolar disorder. Another self-treated for seasonal affective disorder (SAD) and generalized anxiety disorder (GAD).
Practices of DIY Brain Stimulation

- Important for scientists to understand how their unintended “second audience” utilizes their research
- Scientists may find small kernels in value in how home users utilize tDCS and what obstacles they encounter in home use
- Proposing methods of engaging with DIYers/home users
- Assessing regulatory proposals
Types of tDCS devices that home users can make/acquire

<table>
<thead>
<tr>
<th>SELF-BUILT ($30-50)</th>
<th>TDCS DEVICE “KITS” ($40-180)</th>
<th>CURRENT SOURCE DEVICE</th>
<th>IONTOPHORESIS DEVICE ($300-400)</th>
<th>DEVICE DESIGNED FOR TDCS ($379)</th>
<th>DIRECT-TO-CONSUMER HEADSET ($249-300)</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.jpg" alt="Image" /></td>
<td><img src="image2.jpg" alt="Image" /></td>
<td><img src="image3.jpg" alt="Image" /></td>
<td><img src="image4.jpg" alt="Image" /></td>
<td><img src="image5.jpg" alt="Image" /></td>
<td><img src="image6.jpg" alt="Image" /></td>
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The Rising Tide of tDCS in the Media and Academic Literature

Veljko Dubljević,1,2,* Victoria Saigle,1 and Eric Racine1,2,3,4,*

1Neuroethics Research Unit, Institut de recherches cliniques de Montréal (IRCM), 110 Avenue des Pins Ouest, Montréal, QC H2W 1R7, Canada
2Department of Neurology and Neurosurgery, McGill University, 3801 University Street, Montréal, QC H3A 2B4, Canada
3Experimental Medicine & Biomedical Ethics Unit, McGill University, 1110 Avenue des Pins Ouest, Montréal, QC H3A 1A3, Canada
4Department of Medicine and Department of Social and Preventive Medicine, Université de Montréal, 2900, boul. Édouard-Montpetit, Montréal, QC H3T 1J4, Canada
*Correspondence: veljko.dubljevic@ircm.qc.ca (V.D.), eric.racine@ircm.qc.ca (E.R.)

http://dx.doi.org/10.1016/j.neuron.2014.05.003

Academic and public interest in tDCS has been fueled by strong claims of therapeutic and enhancement effects. We report a rising tide of tDCS coverage in the media, while regulatory action is lack and ethical issues need to be addressed.

The regulation of cognitive enhancement devices: extending the medical model

Hannah Maslen1, Thomas Douglas2, Roi Cohen Kadosh3, 1 and Julian Savulescu5,*

Do-it-yourself brain stimulation: a regulatory model

Hannah Maslen1, Tom Douglas2, Roi Cohen Kadosh3, Neil Levy4, Julian Savulescu5

Neurostimulation Devices for Cognitive Enhancement: Toward a Comprehensive Regulatory Framework

Veljko Dubljević
Definition of a Medical Device

Is a consumer non-invasive brain stimulation device a medical device?

According to Section 201(h) of the Food, Drug & Cosmetic (FD&C) Act, a medical device is:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
Definition of a Medical Device

How does the FDA establish intended use?

According to 21 C.F.R. § 801.4:

The words intended uses... refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.
# Importance of intended use

**Drug**  
“reduces wrinkles”  
sunscreen lotion

**Cosmetic**  
“reduces the appearances of wrinkles”  
suntan lotion
Dual Use Products

Regulated by the Food and Drug Administration (FDA)

Regulated by the Consumer Product Safety Commission (CPSC)
<table>
<thead>
<tr>
<th>Consumer tDCS Device</th>
<th>Marketing Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Brain Stimulator</td>
<td>“tDCS allows you to unlock your brain’s true potential”</td>
</tr>
<tr>
<td>Foc.us</td>
<td>“make your synapses fire faster,” “overclock your brain,” “take charge”</td>
</tr>
<tr>
<td>Cognitive Kit</td>
<td>“charge your mind”</td>
</tr>
<tr>
<td>Tdcs-kit.com</td>
<td>“power your mind”</td>
</tr>
<tr>
<td>TCT</td>
<td>“when only the best in tDCS therapy will do”</td>
</tr>
<tr>
<td>ApeX Type A</td>
<td>“Be happier. Be focused. Be smarter”</td>
</tr>
<tr>
<td>Thync</td>
<td>“quiet your mind,” “boost your workout”</td>
</tr>
<tr>
<td>PriorMind</td>
<td>“increase your attention span” “tDCS has been widely used to treat depression...”</td>
</tr>
<tr>
<td>SuperSpecificDevice</td>
<td>“personal tDCS device”</td>
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• **intended for** use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

• **intended to** affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.

Finally, there is drug free (DIY) method to increase Concentration as well as relief for Depression, Anxiety and Migraines.

CDPH Warns Consumers Not to Use TDCS Home Device Kit

Date: 6/28/2013
Number: 13-029
Contact: Anita Core, Heather Bourbeau (916) 440-7259
SACRAMENTO

The California Department of Public Health (CDPH) today warned consumers not to use the unapproved medical device sold on the Internet as a TDCS (Transcranial Direct Current Stimulation) Home Device Kit.

TDCS Device Kit, Inc. of Petaluma, Calif., is voluntarily recalling the TDCS Home Device Kits because the product has not been federally approved to market in the United States, and has not been determined to be safe and effective for their intended use. During a recent inspection, CDPH determined that the devices had not been manufactured in compliance with good manufacturing practices for medical devices. Also, the devices were found to be labeled without adequate directions for use and without adequate warnings against uses that may be dangerous to health.

Use of the device could pose a health risk including, but not limited to: epileptic seizures, cardiac arrhythmias, cardiac arrest, optic and olfactory nerve injuries, skin irritation, headaches, blurred vision, and dizziness. No illnesses or injuries have been reported at this time.

Recalled TDCS Device Kits were manufactured and distributed worldwide from November 2012 through April 2013. The devices have no identifying control numbers (e.g. lot codes, serial numbers, or production dates) printed either on the packaging, or the units themselves, but would have been received by mail from TDCS Device Kit, Inc.

Clinical therapy using TDCS may be the most promising application of this technique. There have been therapeutic effects shown in clinical trials involving Parkinson's disease, tinnitus, fibromyalgia, and post-stroke motor deficits. In a recent study, stroke patients with speech difficulties displayed great improvement through a TDCS based therapy, with the improvement lasting past the one week retest. Stimulation therapy could also be developed into effective therapy for various psychological disorders such as depression, anxiety disorders, and schizophrenia. Some researchers are investigating potential applications such as the improvement of focus and concentration.
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**intended to** affect the structure or any function of the body of man or other animals…

Three wrinkle-remover court cases in the 1960s:

“*intended to affect the structure or function of the body*” [for some kind of medical or therapeutic purpose”]

Verichip

Accordingly, assuming that no medical claims are made for the personal ID\security VeriChip, and the product marketed for that purpose contains no health information. FDA can confirm that it is not a medical device.
Are “cognitive enhancement” claims structure/function or medical claims?
general wellness products presenting a low risk to safety will *not* be regulated as medical devices by the FDA.

A **general wellness product** is one that makes claims related to “maintaining or encouraging a general state of health” without references to diseases or conditions.

Examples of acceptable wellness claims are those relating to:

- “mental acuity”
- “concentration”
- “problem-solving”
- “relaxation and stress management”
general wellness products presenting a low risk to safety will *not* be regulated as medical devices by the FDA

A product is *not* a low-risk device if “it involves an intervention or technology that may pose a risk to a user’s safety if device controls are not applied.”

Are consumer non-invasive brain stimulation device low-risk devices?
Definition of a Medical Device

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Various cases have shown that the courts are often willing to allow the FDA significant leeway in its statutory interpretation.


The majority was of the opinion that the FD&C Act “is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health”
Caputron High Precision Direct Current Source

Model CDCCS01
Condition New
Ultra Low Noise High Precision Direct Current Source
13 Items

Write a review
Send to a friend

Add to cart

Quantity
1
Size
.01 mA Accuracy

$749
However...

The FDA can use a variety of factors when determining intended use

According to 21 C.F.R. § 801.4:

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Caputron High Precision Direct Current Source

Model CDCCS01
Condition New
Ultra Low Noise High Precision Direct Current Source

13 items

$749

Quantity
1

Size
.01 mA Accuracy

Add to cart

Send to a friend

View Larger
“Forseeable” Use

Can “actual” or “forseeable” use stand in for intended use?

• *Action on Smoking and Health (ASH) v. Harris* (1980)

To demonstrate intention based on consumer use, must show that product is used “nearly exclusively” for given intention. Congress surely did not mean for there to be a broad reading of “intended use.”

Letter from FDA Chief Counsel Daniel Troy (2002):  

*Foreseeability by the manufacturer does not suffice to establish intended use. Rather, there must be "objective intent" in the form of marketing claims.*
Just to recap...

1. If a product makes, in its advertising or marketing:

   explicit disease claims
   structure/function claims that are medically related
   implied medical claims

   *clearly within FDA jurisdiction as a medical device*

2. If a product makes only wellness claims or no claims at all:

   Unusual, but FDA can look at “circumstances surrounding distribution” or other factors to establish intended use
   Can (maybe) appeal to statutory mandate to protect public health
Multiple Regulatory Authorities that Regulate Consumer Devices
- Long-term unknowns
- Cognitive trade-offs
- Use on children
- Interaction with drugs & conditions

Regulation regulates the device, not the user
What to do?

- Guidelines to DIY/home use community
- Studies to monitor potential long-term safety issues
- Enforcement clarity: FDA, FTC, CPSC?
- Grounded perspective
- Multiple methods of analysis
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W. R. Warren, 4, 47 and 49 William Street, N. Y.

Frank Leslie's Illus. Newspaper
October 22, 1881

This picture shows the way in which the new Cerebral Centralizer of the Vitalizer is worn for the Treatment of Deafness.
A full description of this appliance will be found on page 50.

All images courtesy of the Bakken
Thank you!

Acknowledgements: Thanks to Peter Barton Hutt & Susan Silbey for guidance and feedback.


Anna Wexler
annaw@mit.edu

Ph.D. Candidate, Department of Science, Technology, and Society, MIT
Visiting Scholar, Center for Neuroscience and Society, University of Pennsylvania