

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



Anthony Lee; Photo credit, David Yellen (IEEE Spectrum, 3/14/14)

Anna Wexler

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Presentation Outline

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

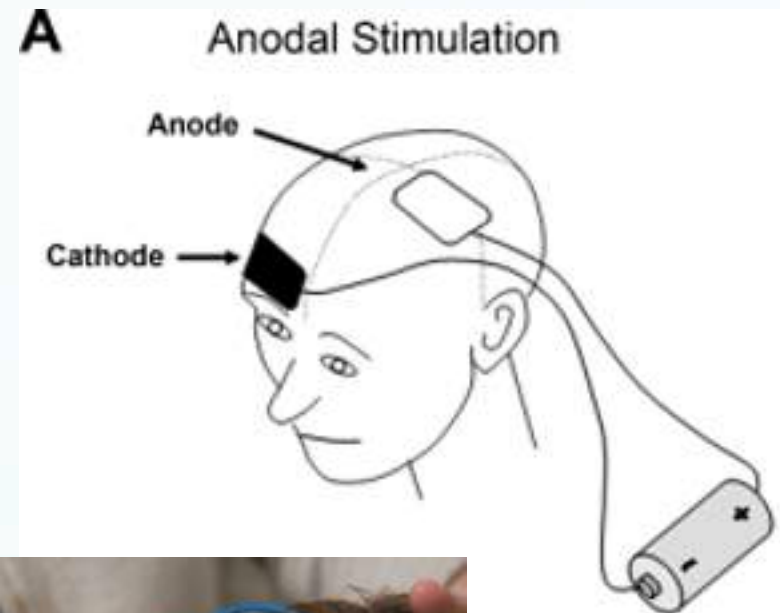
Practices of do-it-yourself brain stimulation

how do home users draw upon scientific knowledge?

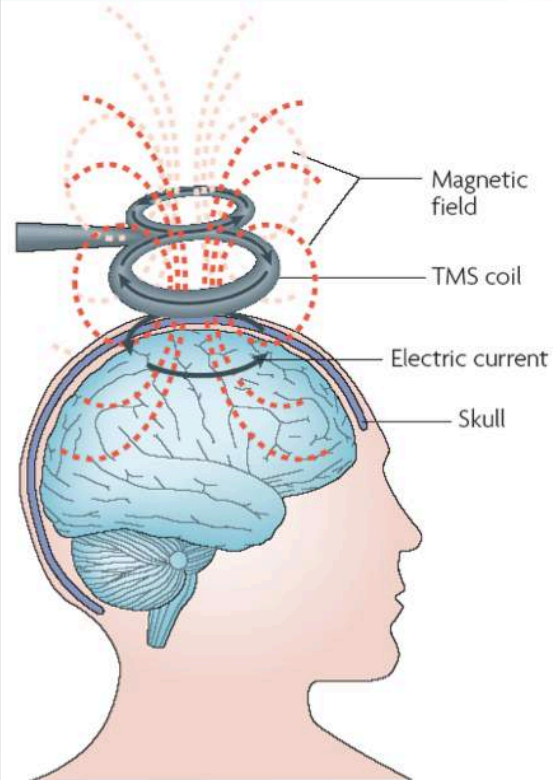
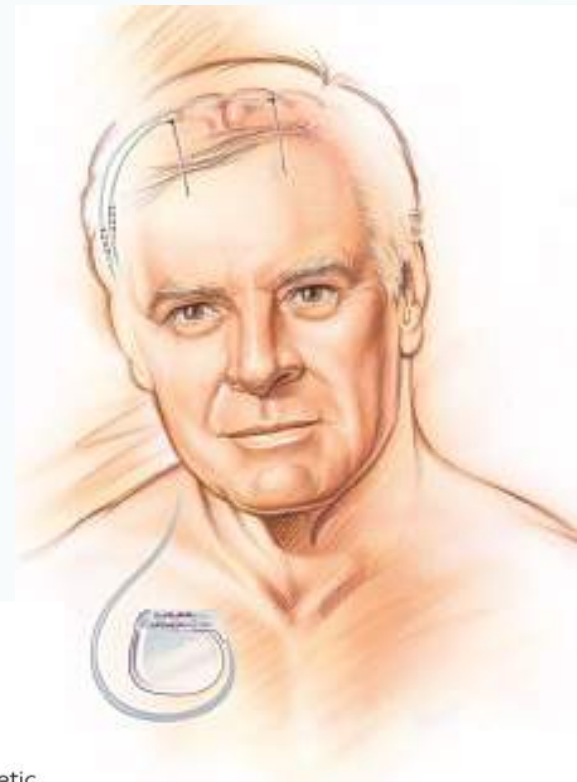
Regulation of consumer tDCS devices

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

Transcranial direct current stimulation (tDCS)



Deep brain stimulation (DBS)



Transcranial magnetic stimulation (TMS)



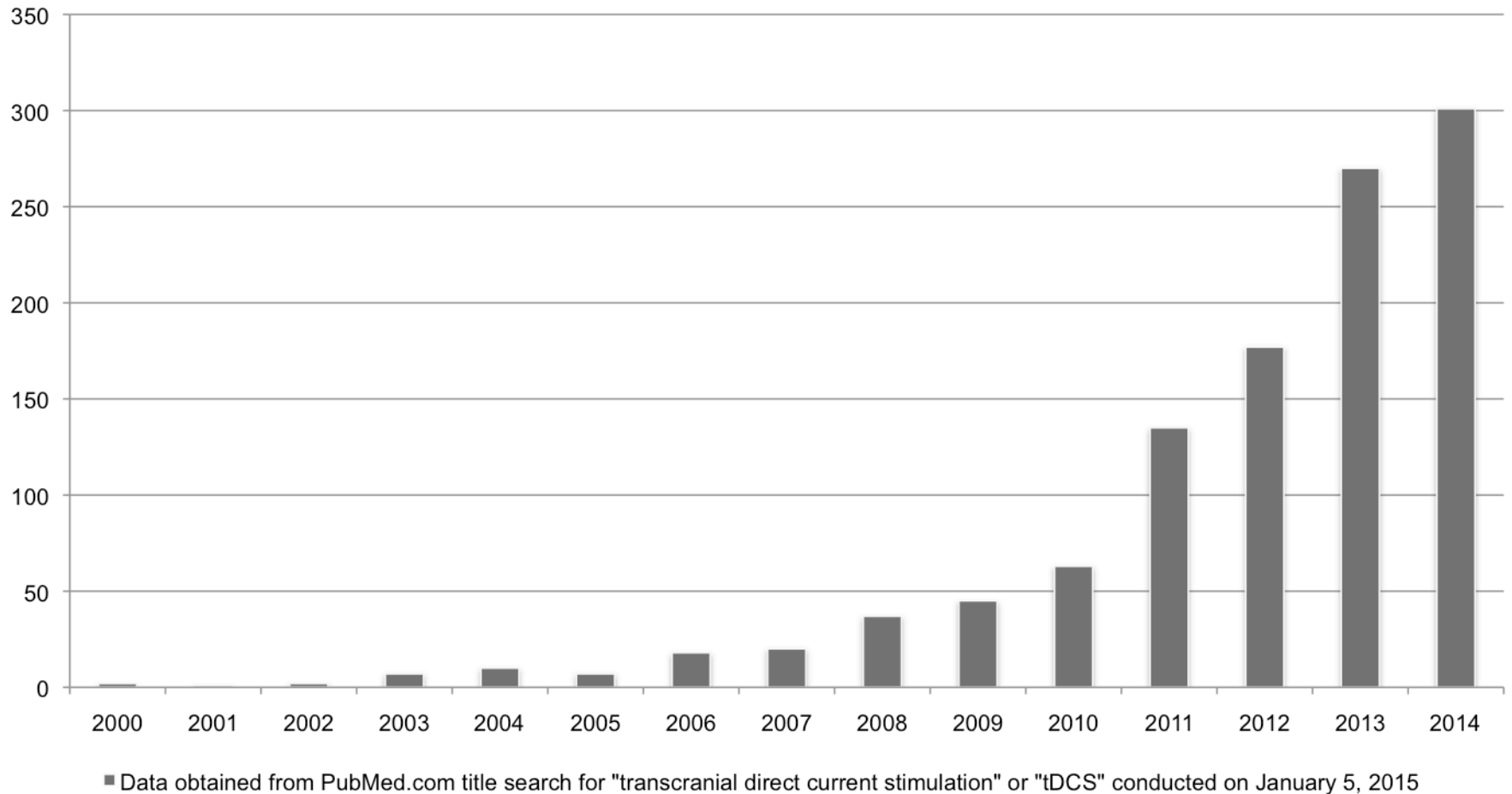
Journal of Physiology (2000), 527.3, pp.633–639

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*

Academic journal publications about tDCS by year, 2000-2014



Wexler, A. (2015). "Understanding the practices of the do-it-yourself brain stimulation community: implications for regulatory proposals and ethical discussions." *Journal of Medical Ethics*, doi:10.1136/medethics-2015-102704.

tDCS Research

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graph TD; A[tDCS Research] --> B[Clinical Populations]; A --> C[Healthy Populations]; B --> D["Depression<br/>Schizophrenia<br/>Stroke<br/>Chronic pain<br/>Alzheimer's<br/>Parkinson's<br/>Anxiety<br/>Motor disorders<br/>Epilepsy<br/>and more..."]; C --> E["Memory<br/>Creativity<br/>Problem-solving<br/>Motor skills<br/>Language<br/>Mathematics<br/>Attention<br/>Perception<br/>Executive function<br/>and more..."]
```

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 stage for the 'brain pod'

By PAGAN KENNEDY | February 7, 2007



MY SUBREDDITS FRONT - ALL - RANDOM | FUNNY

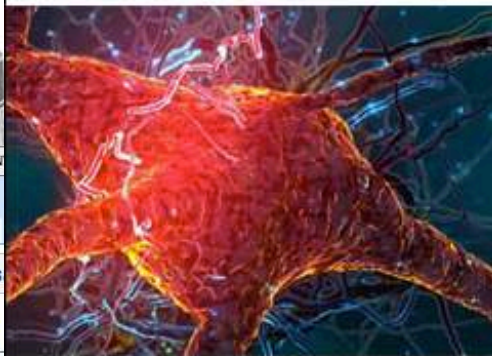
reddit tDCS hot new

Please read the FAQ | Potential side effects

- 1 3 **Electronics breadboards**
submitted 14 hours ago by dirk
1 comment share Sun May 11
- 2 3 **Stimulate Corpus callosum**
submitted 16 hours ago by From
5 comments share save hide report
- 3 7 **Strange effect** (self.tDCS)
submitted 1 day ago by max119
9 comments share save hide report
- 4 1 **Numerous articles starting**
(scienceindex.com)
submitted 23 hours ago by mrdmrd
comment share save hide report
- 5 0 **I feel this question will answer**
submitted 23 hours ago by mrdmrd
comment share save hide report

DIY tDCS

Keeping Tabs Transcranial Direct Current



Home About

FEATURED

DIY tDCS Start Here

New to DIYtDCS? This is the 'start here' collection of articles and posts.

1. Become a tDCS expert in only a few hours! [Davis tDCS Summit 9/5/13.](#)
2. [Morm Bikson Presentation on State of the Art tDCS 8/13](#)

YouTube



0:04 / 1:39

Still Zapping My Brain. DIY tDCS Volume Two.



anthonymlee · 42 videos



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7,484

23 3

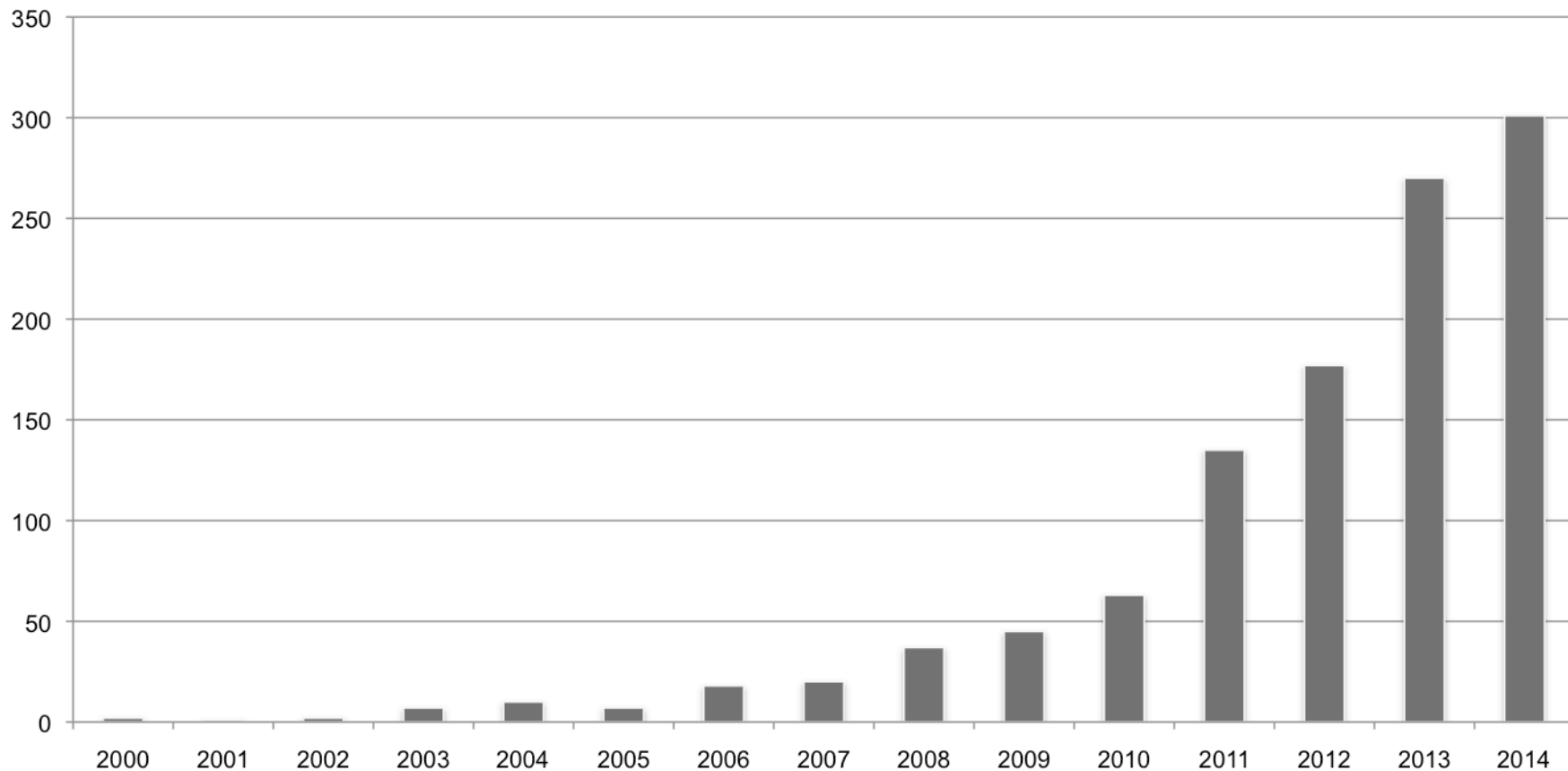
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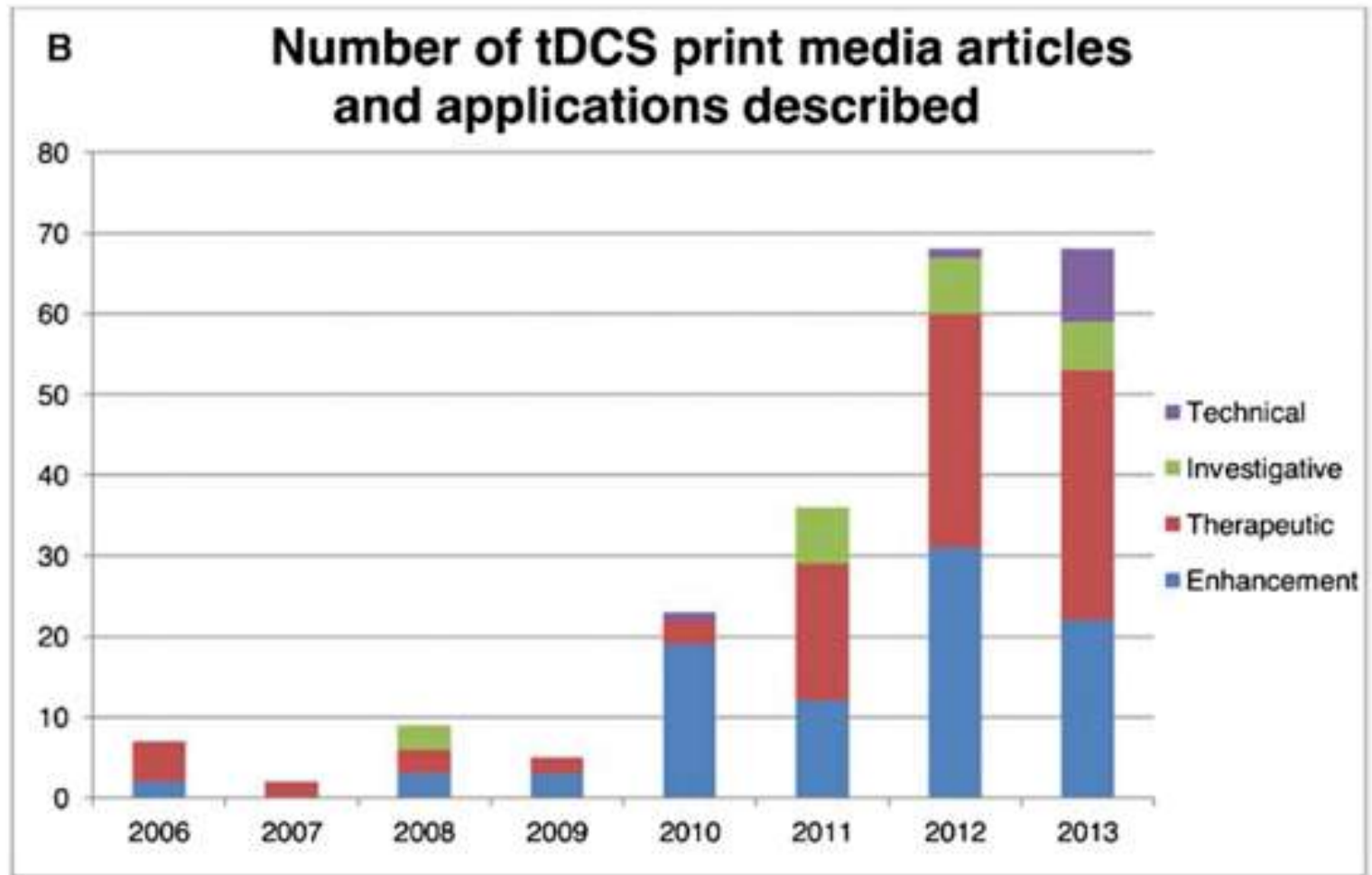
RECENT POSTS

• [tDCS clinical research -](#)

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



Dubljevic V, Saigle V, & Racine E. (2014). "The Rising Tide of tDCS in the Media and Academic Literature," *Neuron* (82)731-736, DOI:10.1016/j.neuron.2014.05.003

DIY/home use tDCS Demographics

- Mostly male

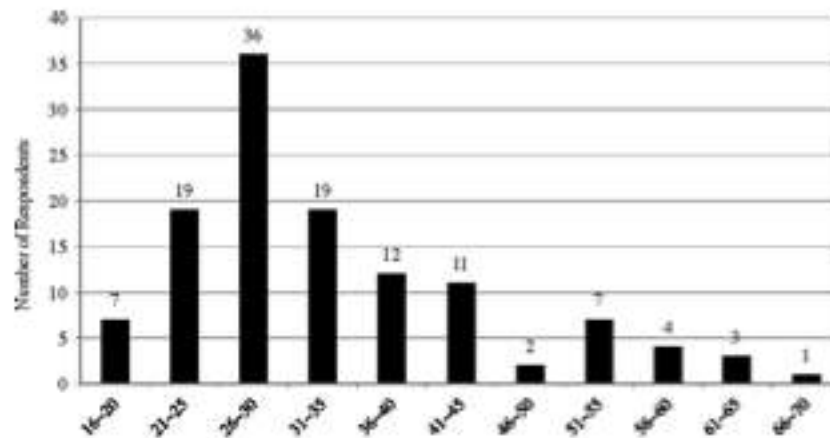



Figure 2. Age of respondents (year).

Jwa (2015)

- Global



ELSEVIER

Brain Stimulation

journal homepage: www.brainstimjrn1.com

Letter to the Editor

Neuroscientists Do Not Use Non-invasive Brain Stimulation on Themselves for Neural Enhancement

Dear Editor:

research (the question about the engagement was put as the first one), and 30 invalid or incomplete responses. The following discussion is based on the resulting 287 complete responses.

First of all, relatively few (23 researchers, 8%) had used NIBS on themselves as a tool for neuroenhancement, although a substantial number of researchers consider transcranial stimulation to be potentially useful for a real-life application of neural enhancement in a healthy population (112 positive answers, 39%). The reasons for not performing NIBS on themselves are wide-ranging. Half of the

Purpose of home stimulation

59% self-stimulate for cognitive enhancement

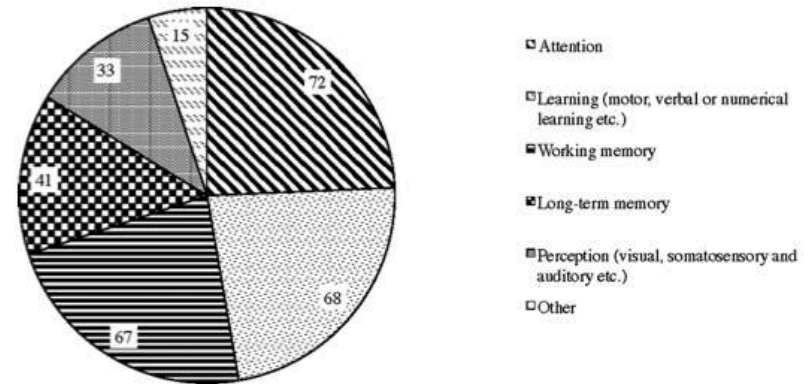


Figure 4. Types of cognitive enhancement purpose for which respondents use tDCS.

11% self-stimulate for treatment

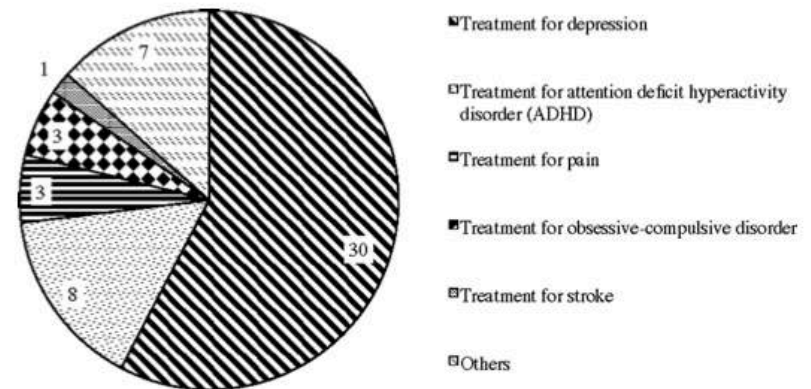


Figure 5. Types of medical condition for which respondents use tDCS.

24% self-stimulate for both enhancement and treatment

Researchers	DIYers/home users
Use tDCS in laboratory	Use tDCS at home
Apply tDCS to subjects	Apply tDCS to themselves
Primary purpose: research	Primary purpose: self-improvement
Controlled, regulated environment	Uncontrolled environment

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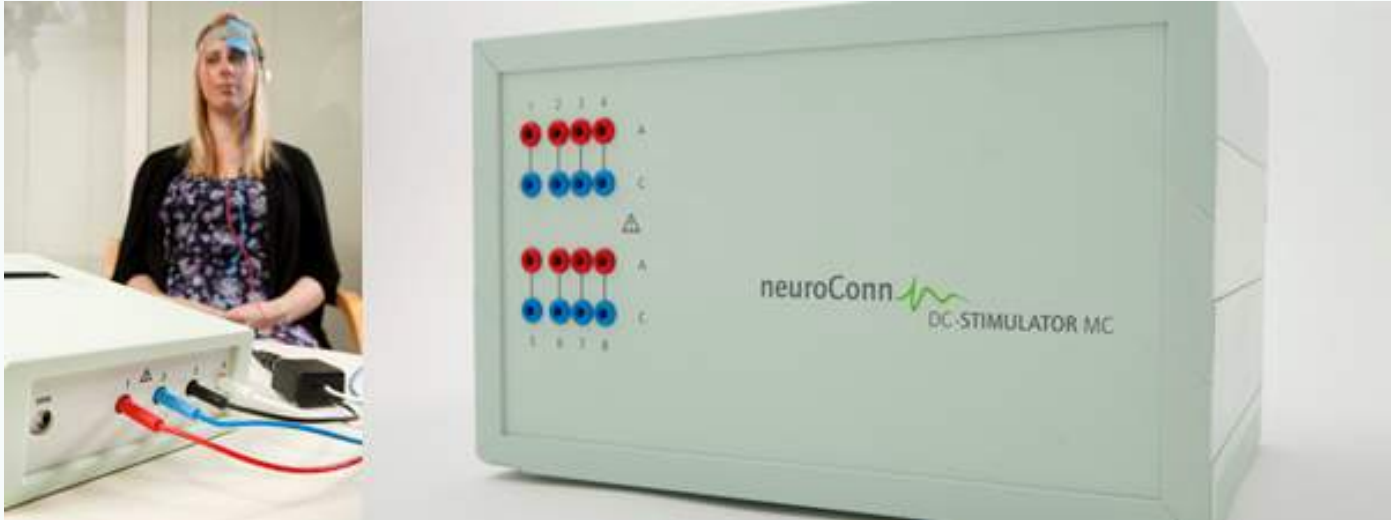
Regulation of consumer tDCS devices

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

Conclusion

Making/Acquiring a Device

neuroConn



Soterix



Types of tDCS devices that home users can make/acquire

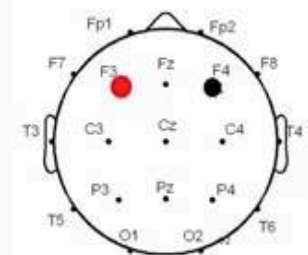
SELF-BUILT (\$30-50)	TDCS DEVICES & "KITS" (\$40-180)	CURRENT SOURCE DEVICE	IONTOPHORESIS DEVICE (\$300-400)	DEVICE DESIGNED FOR TDCS (\$379)	DIRECT-TO- CONSUMER HEADSET (\$249-300)
		 12 VOLT			
					
					
					

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



tDCS Placements

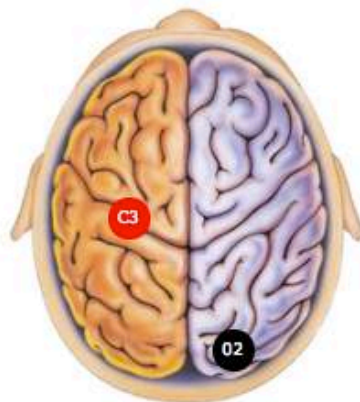
transcranial Direct Current Stimulation.

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Placements

[Home](#) \ [Placements](#)

Here is a list of the placements we have documented. Clicking on the title will take you to a more detailed page of the placements. Red dots stand for anodes while black dots represent cathodes.

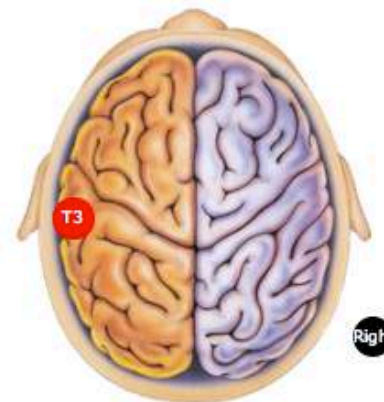


Anode & Cathode Placement

Enhancing Motor Ability and Reducing Pain

Sing your heart out

There are many motor strip studies showing that anodal stimulation at C3 or C4, with a contralateral orbit reference, enhances fine motor control, while cathodal stimulation impairs it. A motor-strip study of stroke patients by Lindenberg, et al., (2010), found that by placing the anode over the motor-strip lesion and the cathode over the contralate...

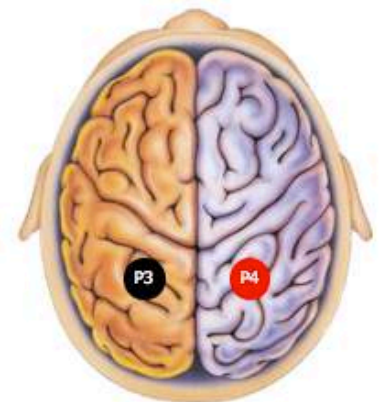


Anode & Cathode Placement

Improving Visual Audio-Pitch Discrimination

Sing your heart out

The electrode placement for improved auditory processing and pitch discrimination. (So you just might sing better in the choir.) Cathode on right shoulder. [Read more](#)



Anode & Cathode Placement

Increasing Math Ability

Girls love a guy who can do math.

A study by Kadosh (2010) showed that anodal stimulation at P4, with the cathode at P3, improved math ability, but did not test to see if the cathode caused verbal impairments. [Read more](#)

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

SELF-BUILT (\$30-50)	TDCS DEVICE "KITS" (\$40-180)	CURRENT SOURCE DEVICE	IONTOPHORESIS DEVICE (\$300-400)	DEVICE DESIGNED FOR TDCS (\$379)	DIRECT-TO- CONSUMER HEADSET (\$249-300)
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The Rising Tide of tDCS in the Media and Academic Literature

Veljko Dubljević,^{1,2,*} Victoria Saigle,¹ and Eric Racine^{1,2,3,4,*}

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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 lacking and ethical issues need to be addressed.

The regulation of cognitive enhancement devices: extending the medical model

Hannah Maslen¹, Thomas Douglas², Roi Cohen Kadosh³,
⁴ and Julian Savulescu^{5,*}

Do-it-yourself brain stimulation: a regulatory model

Hannah Maslen,¹ Tom Douglas,² Roi Cohen Kadosh,³ Neil Levy,⁴
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

vs.

Cosmetic

“reduces wrinkles”

sunscreen lotion



“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)

Consumer tDCS Device		Marketing Language
The Brain Stimulator		"tDCS allows you to unlock your brain's true potential"
Foc.us		"make your synapses fire faster," "overclock your brain," "take charge"
Cognitive Kit		"charge your mind"
Tdcs-kit.com		"power your mind"
TCT		"when only the best in tDCS therapy will do"
ApeX Type A		"Be happier. Be focused. Be smarter"
Thync		"quiet your mind," "boost your workout"
PriorMind		"increase your attention span" "tDCS has been widely used to treat depression..."
SuperSpecificDevice		"personal tDCS device"

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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

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 Gore, 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 otic 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

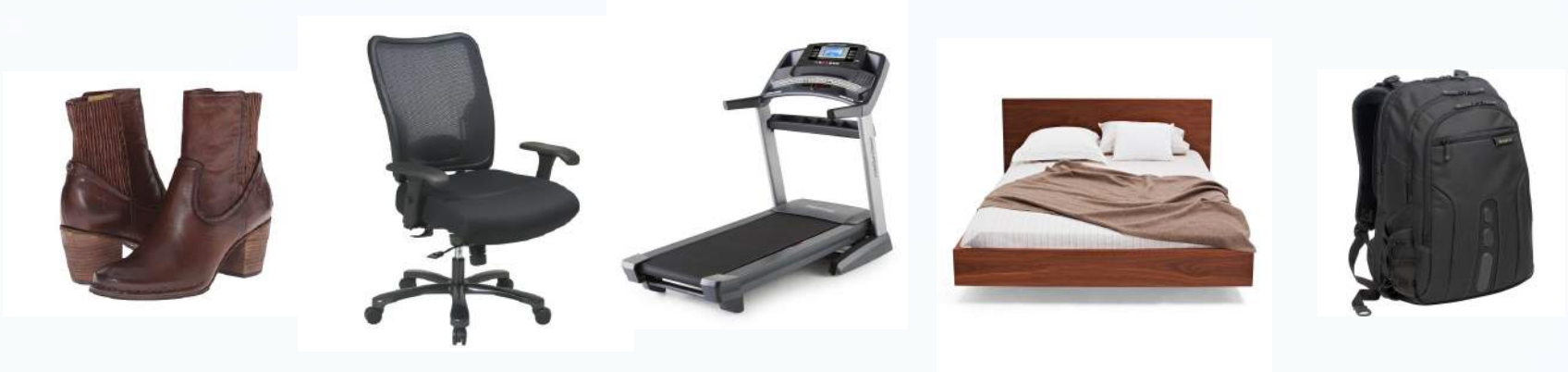
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intended to affect the structure or any function of the body of man or other animals...



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]”

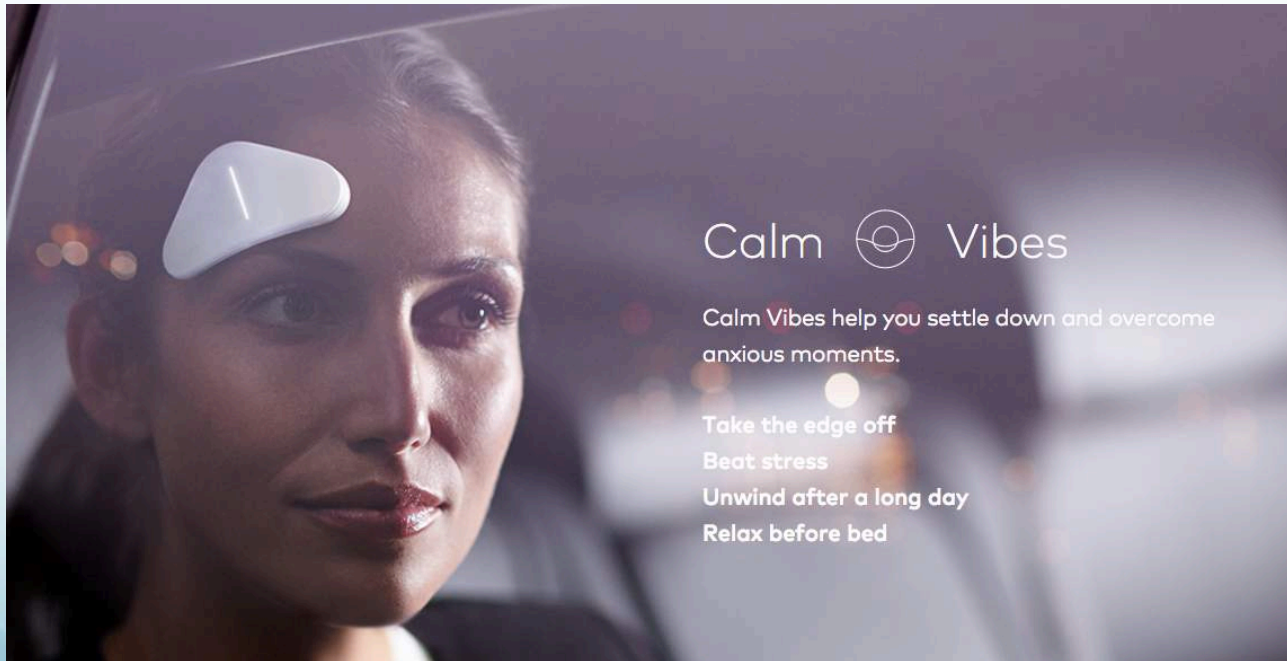
Verichip




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?

Power Your Mind!



Calm  Vibes

Calm Vibes help you settle down and overcome anxious moments.

- Take the edge off
- Beat stress
- Unwind after a long day
- Relax before bed



Increased Plasticity

Increase your brains plasticity



tDCS Provides a Learning Boost

Increase your attention span and stimulate your neurons to improve math skills, language abilities, creativity, and visual association.

**General Wellness:
Policy for Low Risk Devices**

**Draft Guidance for Industry and
Food and Drug Administration
Staff**

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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”

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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?

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FDA and public health risk



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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

- *United States v. An Article of Drug... Bacto-Unidisk (1969)*

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

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However...

The FDA can use a variety of factors when determining 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.



Caputron High Precision Direct Current Source

Model CDCCS01

Condition New

Ultra Low Noise High Precision Direct Current Source

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\$749

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.01 mA Accuracy



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“Foreseeable” Use



Can “actual” or “foreseeable” 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



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Supplement Marketers Will Relinquish \$1.4 Million to Settle FTC Deceptive Advertising Charges

Ads Claimed ProCera AVH Would Restore 10 to 15 Years of Memory Loss

FOR RELEASE

July 8, 2015



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION**



**Federal
Communications
Commission**



Better Business Bureau®



- Long-term unknowns
- Cognitive trade-offs
- Use on children
- Interaction with drugs & conditions



Regulation regulates the device, not the user

What to do?

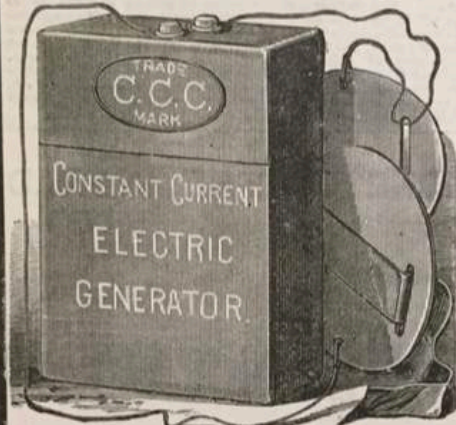
- Guidelines to DIY/home use community
- Studies to monitor potential long-term safety issues
- Enforcement clarity: FDA, FTC, CPSC?
- Grounded perspective
- Multiple methods of analysis

THE CONSTANT ELECTRIC CURRENT,

FROM OUR ELECTRIC GENERATOR,

CURES Headache, Neuralgia, Rheumatism, Pains in the Back, Loins, Limbs and Kidneys, Female Weakness, Nervousness, Incipient Consumption, Piles, Malarial Aches and Pains, Indigestion, Sleeplessness, Debility, Premature Decline in Man, Liver Complaint, and all other diseases requiring the peculiar stimulation afforded by a constant electric current. This gentle stimulation of the affected part induces nutrition in that region, and gives nature the aid required to set all of the repairing agencies actively at work. This powerful yet simple and compact generator develops a continuous, mild electric current, capable of passing entirely through the human body, affecting every organ, nerve and tissue, producing marked curative effects. The current, although so subtle and permeating, is not perceptible to the senses, yet it will operate a galvanometer through a resistance of 5,000 ohms, equal to a telegraph line over 300 miles long. *This truly scientific instrument is indorsed by physicians and electricians, and will cure when all other things fail.*

The CONSTANT CURRENT ELECTRIC GENERATOR with full instructions for use, is sent by mail, on receipt of the price, \$3.00, or by express, C. O. D., with collection charges added, with the privilege of examination. We guarantee safe delivery of the Generator by mail. All remittances should be by Postal Money Order, Draft, or Registered Letter.



ONE-HALF SIZE.
PRICE \$3.

Fine hard rubber case. Nickel plated binding posts and electrodes. Thoroughly well made and complete. It never gets out of order. No acids, no liquids, no trouble.

CONSTANT CURRENT CURE CO.,

(Incorporated under the laws of the State of New York.)

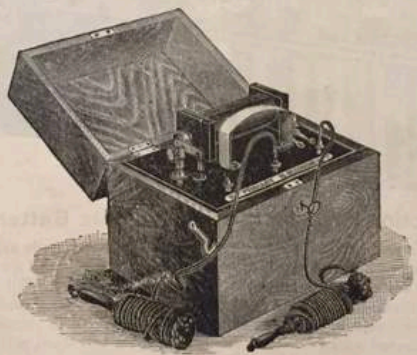
207 Main St., Buffalo, N. Y.

TO THE CONSTANT CURRENT CURE COMPANY, 207 Main Street, Buffalo, N. Y.

SIRS: Your Constant Current Electric Generator, which I have used for several weeks, has entirely cured me of rheumatism, and has proved extremely beneficial in other ways. With it I have counteracted the debilitating effects of overwork and warm weather, and have been invigorated and imbued with fresh vitality. Three of my friends, to whom I loaned my generator, have each ordered one from you.

W. R. WARREN, 45, 47 and 49 William Street, N. Y.

Frank Leslie's Illus. Newspaper
October 22, 1881



McIntosh Family Faradic Battery.



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!

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