



Do-it-yourself and regulatory aspects of transcranial stimulation

Anna Wexler

Introduction to tES in Neuropsychiatric Research
June 27, 2019



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

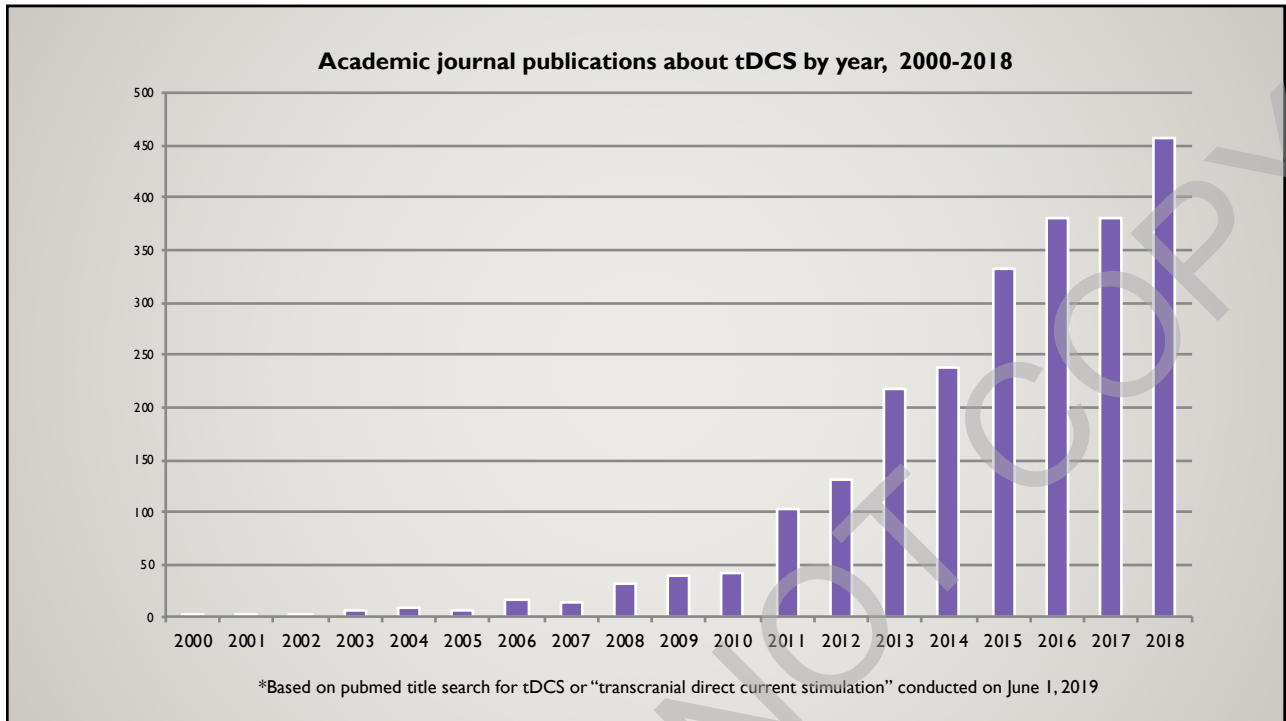
TALK OUTLINE

Do-it-yourself and direct-to-consumer tDCS

Who are home users, what devices do they use, how and why do they stimulate, and do they find tDCS effective?

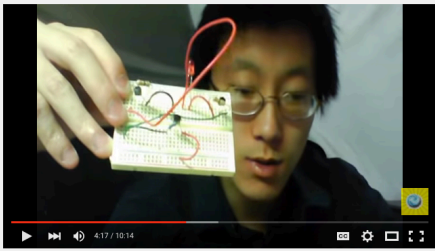
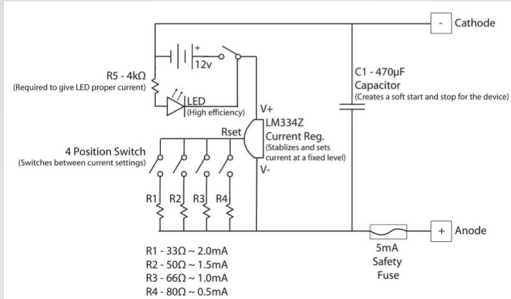
Regulation of tES devices in the US

FDA medical device law & tDCS devices

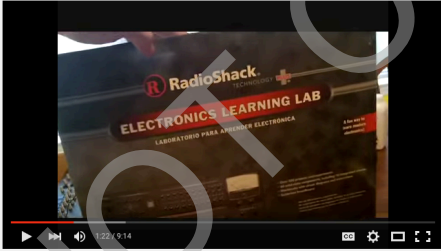


Rise of DIY tDCS

Do-it-Yourself Device



DIY How to make a tDCS Transcranial Direct Current Stimulation Device Tutorial



How to Build a Simple tDCS Device of Your Own (that you can use)

Repurpose an iontophoresis device



Chattanooga Ionto™



ActivaDose II



Current source/tDCS device



Super Specific Devices



Caputron Medical

tDCS Devices and "Device Kits"



Brain Stimulator



tDCS-Kit



PriorMind



Apex Type A



Cognitive Kit

Wearable Devices



halo
neuroscience



INDEMAND

PlatoWork brain stimulator

The world's first headset for boosting cognition: improve your memory, focus and creativity!

PROJECT OWNER

 PlatoScience Neurostimulation
Copenhagen, Denmark
1 Campaign | [More](#)

\$413,142 USD total funds raised
1457% funded on May 4, 2019



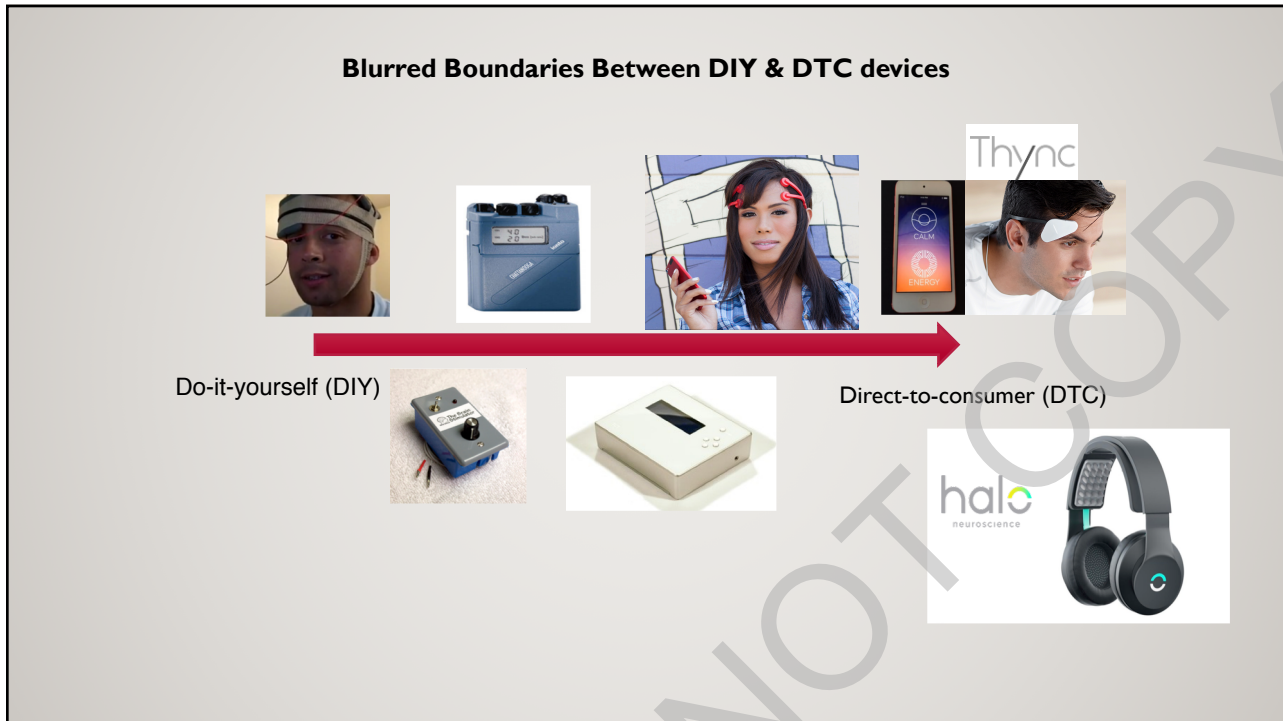
Medication-free depression treatment

[Order now](#)

- Easy to use at home: 30 min/day, 2-5 sessions/week
- Approved in the EU and UK (CE) for depression treatment
- 30-days return policy
- Made in Sweden

Requires access to an iOS device such as iPhone or iPad.
Consult a doctor or other healthcare professional before use.





Transcranial devices are not playthings

Controlled investigation of transcranial direct-current stimulation (tDCS) for treating neuropsychiatric disorders or for neurorehabilitation should not be confused with improvised devices or practices that apply electricity to the brain without reference to established protocols (see *Nature* 498, 271–272; 2013). Unorthodox technologies and applications must not be allowed to distort the long-term validation of tDCS.

Warning over electrical brain stimulation

COMMENTS (123)
 By Melissa Hogenboom
 Science reporter, BBC News

Neuroscience Researchers Caution Public About Hidden Risks of Self-administered Brain Stimulation

Warning over experimental brain boost

Thus, the IFCN warns against the use of DIY devices and methods unless they have shown both efficacy and safety.

Researchers	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

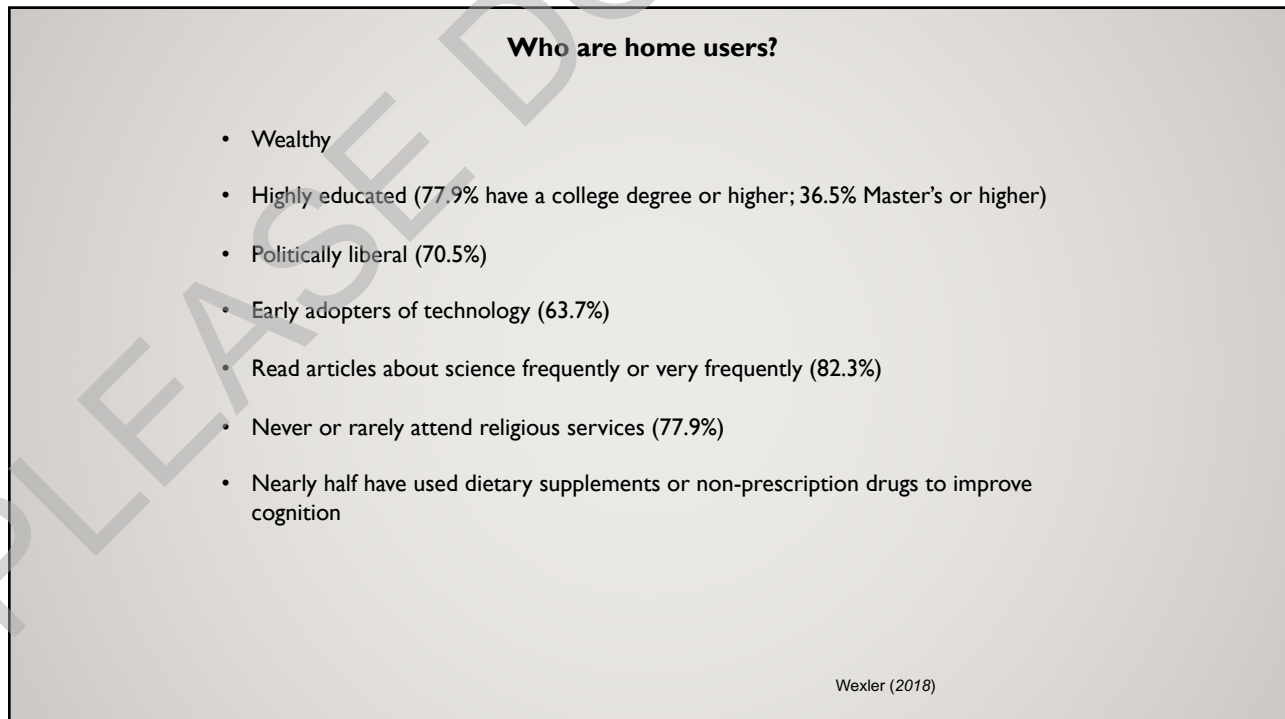
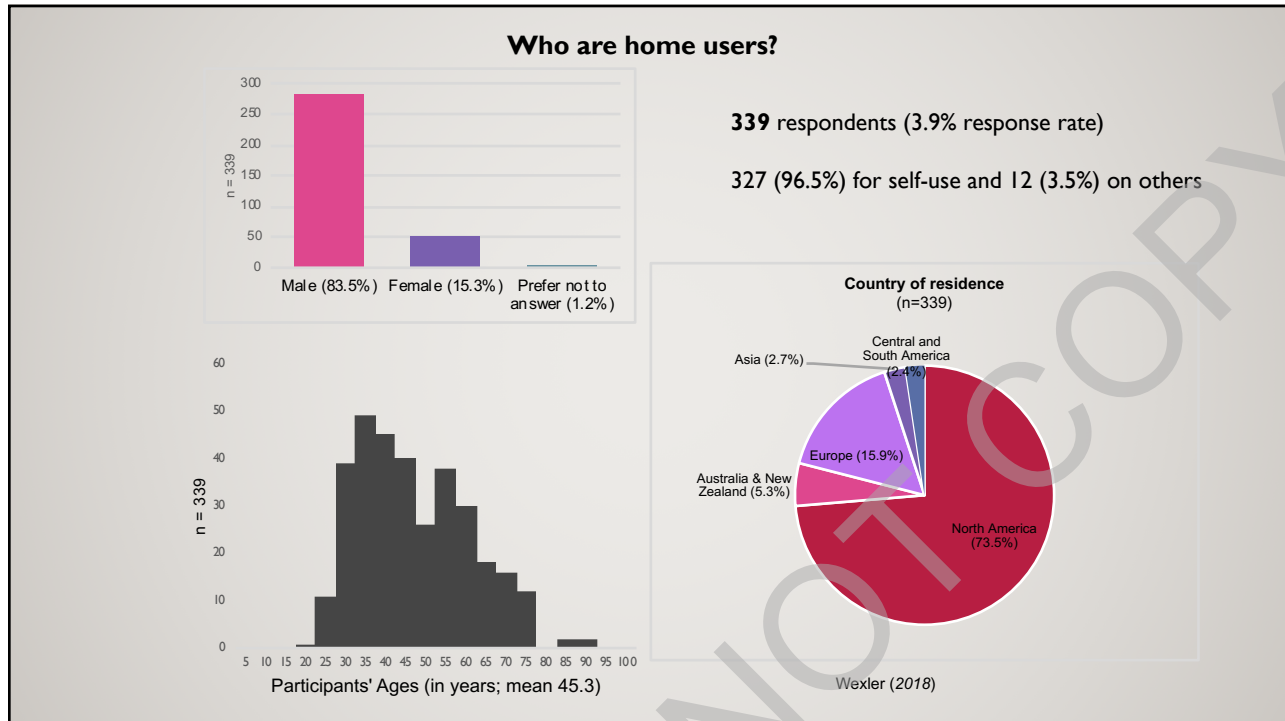
Studying home users of tDCS

Ethnography of home users (*Wexler 2016*)

- Analysis of DIY tDCS websites, forums and blogs
- Semi-structured interviews with home users

Survey of consumers of tDCS devices (*Wexler 2018*)

- 7 companies agreed to participate on the condition of anonymity; emails sent to companies' customer lists with link to online survey
- Quantitative and open-ended qualitative questions about tDCS device(s), use practices, beliefs, attitudes, and demographics



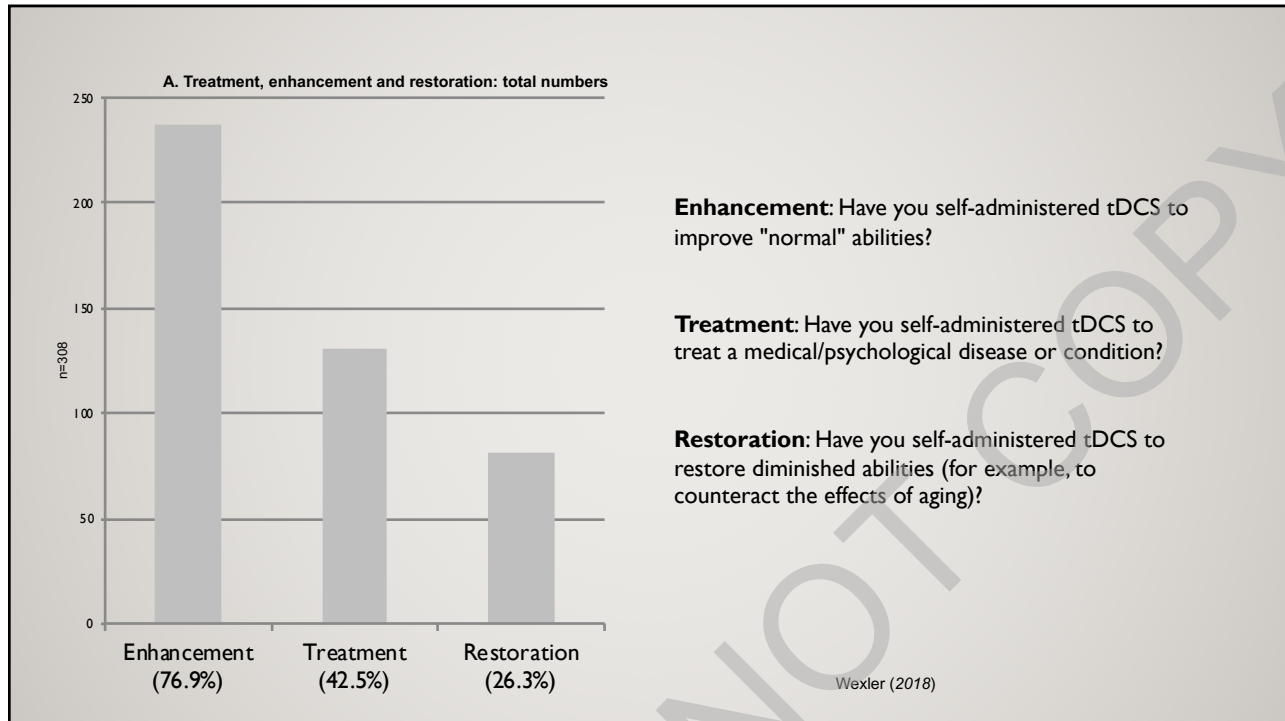
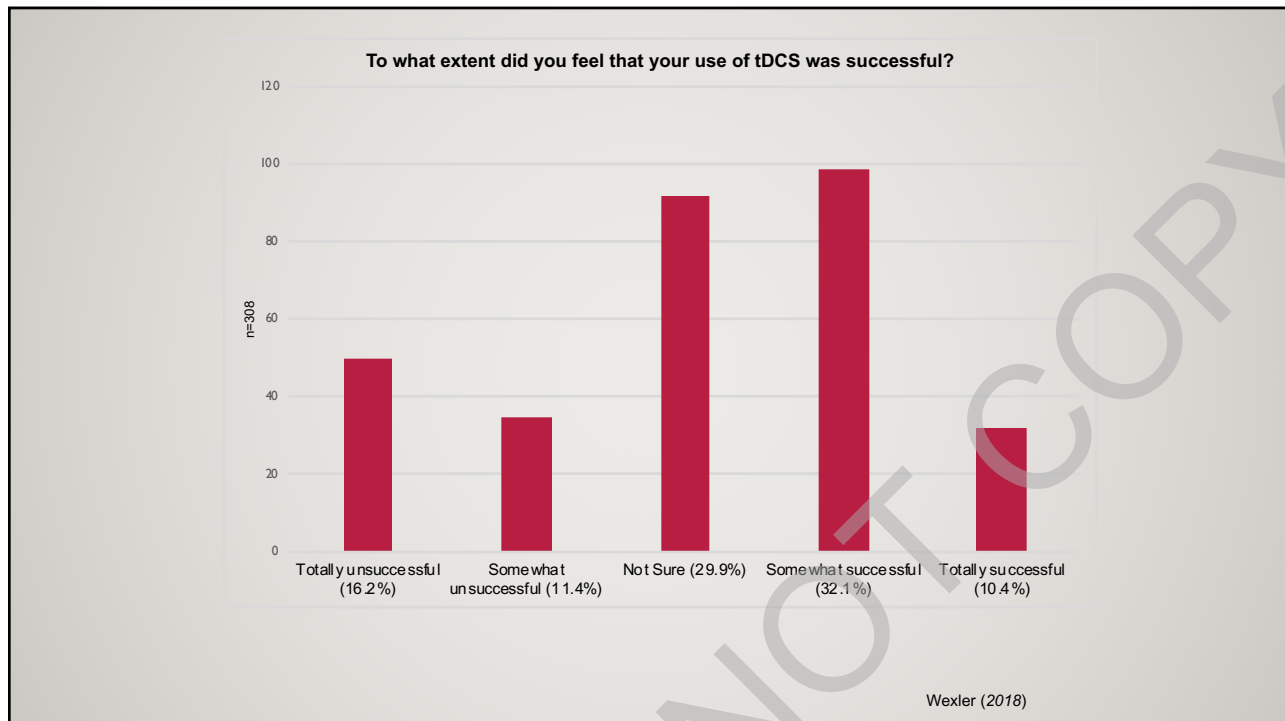


Table 4. Detailed usage indications for treaters, enhancers, and restorers*

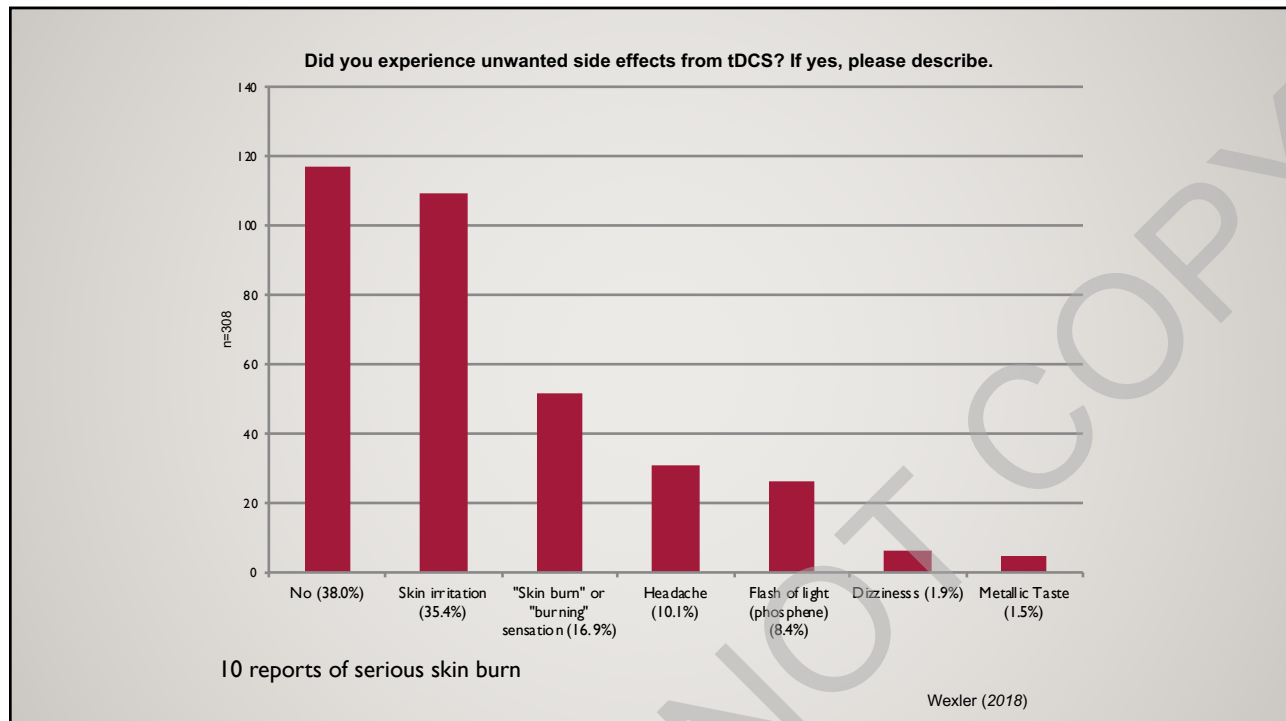
	n	%
Treatment (n=131)		
Depression	97	74.0%
Anxiety	55	42.0%
ADD/ADHD	35	26.7%
Chronic pain	12	9.2%
Bipolar disorder	7	5.3%
Migraine	7	5.3%
Tinnitus	6	4.6%
Addiction	5	3.8%
Enhancement (n=237)		
Focus/concentration	100	42.2%
Memory	61	25.7%
Learning	57	24.1%
General Enhancement	56	23.6%
Mood/emotion	26	11.0%
Physical abilities	25	10.5%
Speed/reaction time	23	9.7%
Creativity	14	5.9%
Restoration (n=81)		
Memory	31	38.3%
Focus/concentration	21	25.9%
General enhancement	19	23.5%
Problem solving	12	14.8%
Mood/emotion	9	11.1%
Other	8	9.9%
Learning	7	8.6%
Speed/reaction time	4	4.9%
Physical abilities	4	4.9%



Usage Characteristics

- Home users mostly adhere to established scientific protocols (e.g., current level & session duration) but depart regarding number of stimulation sessions
- When using non-pre-set devices, look to scientific literature and placement websites
- 35% of users quit using tDCS, approximately half due to lack of efficacy

Wexler (2018)



PRACTICES OF DIY BRAIN STIMULATION

- **Recognize** that home users are utilizing tDCS both for treatment and enhancement
- **Be aware** that an unintended "second audience" is utilizing published scientific research
- **Be prepared** for individuals to approach you for guidance
- Warning home users/DIYers of risks (Wurzman et al. 2016)

An Open Letter Concerning Do-It-Yourself Users of Transcranial Direct Current Stimulation

Wurzman et al. (2016)

- Stimulation affects more of the brain than a user may think.
- Enhancement of some cognitive abilities may come at the cost of others.
- Changes in brain activity (intended or not) may last longer than a user may think.
- Small differences in tDCS parameters can have a big effect.
- tDCS effects are highly variable across different people.

Regulation of direct-to-consumer tDCS Devices

Are consumer tDCS devices medical devices?



BREWSTER'S MEDICATED ELECTRICITY!

AN INFALLIBLE REMEDY FOR

**Headache, Neuralgia, Hay Fever,
Catarrh and Cold in the Head.**

NOT A SNUFF, PASTE, SALVE OR LIQUID, BUT
A PERFECT

ELECTRIC BATTERY,

Combined with Vegetable Compounds,
That generate a vapor which is a safe,
convenient, and speedy method of obtain-
ing relief from Nervous Headache, Catarrh, Hay
Fever, Neuralgia; also, Falling Eyesight and Deaf-
ness caused by Catarrh.

**NO MAN can weigh, measure, estimate or comprehend
the power of Electricity.** We do know that it flashes the zones of the day
from one part of the world to another, and the day is not far distant when
the propelling power of the sun, forests and ocean comers of the
world will be Electricity. Thus it is when this Great Power is used to pre-
vent the leading properties of the best remedies known for the above ailments
and disease, it is no wonder that the cure are truly magical. By
inhaling the Medicinal Vapor from the Battery, it will cure Headache in
one to three minutes, and will break up the most severe Cold in the Head,
Throat or Lungs in a few hours.



TRADE MARK

NEW YORK AND LONDON ELECTRIC ASSOCIATION

Improved Electro-Magnetic Hair Brush and Comb

..PRICE, \$3.00..

This Brush can be relied upon to im-
mediately **CURE** Nervous or Bilious
Headaches and Neuralgia. Prevents
Dandruff and falling out of the
hair. Cures and Prevents Dis-
tract and all diseases of the
Scalp. Outside of its medical
properties, which are truly
marvelous, this Brush is
full value for the money,
being made of the very
best materials, and posses-
sing *Pure Bristles*
not Wire, which we
guarantee not to come
out and to stand water.
The Brush is perma-
nently charged with
Electro-Magnetism in
manufacture, which can
be always tested by
a silvered compass
which accompanies
each Brush. This in-
struction is a fac-
simile of Brush,
which is the
lightest and
handiest
one now
on the mar-
ket.



The Brush is
tastefully
boxed.

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SEND FOR
TERMS...

AN OFFER—We give away **FREE** with
every Brush a **DEMI-
TIC COMB**. Beware of Imitations. See that our
name is on each Brush. If you cannot secure this
Brush in your town from our Agent, write direct to
our office, remitting price, and the Brush will be
promptly mailed to you *post paid*, we guarantee safe
delivery, and if not entirely as represented, it may be re-
turned, and money will be cheerfully refunded.

We receive constantly from all parts of the World
numerous Testimonials of their efficacy and durability.

SENT POST-PAID ON RECEIPT OF PRICE.

Brush & Comb, P. O. Stamp Order, or remittance
in Registered Letter, at our risk, payable to

New York and London Electric Association,
529 WALNUT ST., KANSAS CITY, MO.

THE ELECTRICPATENT SOCKS.

FOR CREATING A CONSTANT ELECTRIC CURRENT AND PRODUCING A HIGH DEGREE
OF WARMTH.

Testimonials. Testimonials.

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AN ABSOLUTE
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SCIATICA &
RHEUMATISM

POSITIVE
REMEDY

For CHILBLAINS and COLD FEET.



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

Food & Drugs Act (1906)

- Prohibited misbranded & adulterated food and drugs



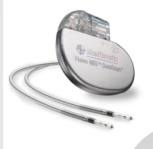
Federal Food Drug & Cosmetic Act (1938)

- Granted FDA *limited* jurisdiction over medical devices

Medical Device Amendments (1976)

- Device manufacturers required to notify FDA of medical device prior to marketing

RISK-BASED CLASSIFICATION FRAMEWORK

Class I Low risk	Class II Moderate risk	Class III High risk
		
<p>Most products exempt from pre-market notification</p>	<p>Pre-market notification (PMN) required via 510(k). Devices are “cleared.”</p>	<p>Pre-market approval (PMA)— must demonstrate safety & efficacy</p>

FDA APPROVED/CLEARED STIMULATION DEVICES

Class I Low risk	Class II Moderate risk	Class III High risk
	<p>TENS (pain/headache)</p> <p>rTMS (treatment-resistant MDD)</p> <p>TMS (headache)</p> <p>tVNS (cluster headache)</p> <p>ECT (catatonia + depression)¹</p>	<p>DBS (Parkinson’s related)</p> <p>VNS (epilepsy-related)</p> <p>CES (depression, insomnia² & anxiety²)</p> <p>ECT (all other indications)</p>
<p>1. severe major depressive episode associated with major depressive disorder or bipolar disorder</p> <p>2. Proposed reclassifying in 2016 to Class II</p>		



DEFINITION OF 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.



Regulated by the Food and Drug Administration (FDA)



Regulated by the Consumer Product Safety Commission (CPSC)

IMPORTANCE OF INTENDED USE

Drug

vs.

Cosmetic

“reduces wrinkles”

“reduces the appearances of wrinkles”

sunscreen lotion

suntan lotion



Direct-to-consumer tDCS Devices

Power Your Mind!



tDCS Provides a Learning Boost

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

RECHARGE YOUR BRAIN

tDCS allows you to unlock your brain's true potential!



Reducing Depression



Reducing pain



tDCS for Medical Use

tDCS had been widely applied to treat Depression, also in Chronic Pain, Amblyopia, Alzheimer's disease, Migraine, Parkinsonism, Tinnitus, Stroke and etc.

tDCS has also been documented as having impressive potential to treat depression, anxiety, PTSD, as well as chronic pain.

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

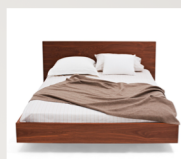


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 - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - **intended to affect the structure or any function of the body of man** or other animals, 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 to affect the structure or any function of the body of man or other animals...



Three wrinkle-remover cream cases:

United States v. An Article ... Sudden Change, 409 F.2d 734 (2d Cir. 1969)
United States v. An Article ... Helene Curtis Magic Secret, 331 F.Supp. 912 (D. Md. 1971)
United States v. An Article ... Line Away, 415 F.2d 369 (3d Cir. 1969)

“intended to affect the structure or function of the body” [*in some medical or drug-type fashion*]

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

21 USC § 393: “promote the public health... protect the public health”

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”

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

**Draft Guidance for Industry and
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Staff**

DRAFT GUIDANCE

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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?



**General Wellness:
Policy for Low Risk Devices
Guidance for Industry and
Food and Drug Administration Staff**

Document issued on: July 29, 2016.

The following are examples of products that would not be considered “low risk” as described in this guidance:

- A neurostimulation product that claims to improve memory, due to the risks to a user’s safety from electrical stimulation.



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



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS



CONSUMER PRODUCT SAFETY COMMISSION

(1) to protect the public against unreasonable risks of injury associated with consumer products;

(2) to assist consumers in evaluating the comparative safety of consumer products;

(3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and

(4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

What is a consumer product?

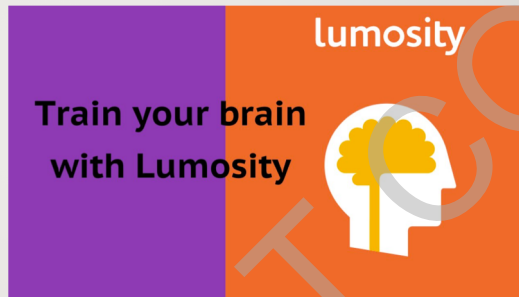
any article, or component part thereof, produced or distributed (i) **for sale to a consumer** for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) **for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence**, a school, in recreation, or otherwise;



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FEDERAL TRADE COMMISSION

Section 5 of the FTC Act prohibits “unfair or deceptive acts or practices” in commerce



STATE AUTHORITIES

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.



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



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION**



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS



TAKE-AWAY POINTS

- FDA definition of a medical device is based on “intended use” not mechanism of action
- Most recent actions demonstrate that FDA is monitoring the sphere and does not view tDCS as completely low-risk
- Unclear whether cognitive enhancement devices marketed for “wellness” fit the structure/function clause of FDA definition of a medical device
- Even absent FDA regulations, other regulatory agencies might play a role

Direct-to-consumer neurotechnology

- the set of products (devices, software, applications) that are marketed to modulate or affect brain function
- sold **directly to consumers** (i.e., bypassing the physician)
- appeal to the fruits of brain and cognitive science

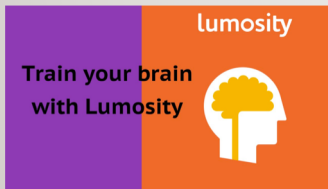


Table 1. Claims by Category

Category	Claim	Frequency	Percent of total	Example
Wellness	Relieve stress/anxiety	17	10%	"MyBrain Technologies built a new drug-free, easy-to-use, and perfectly safe solution to stress" (MyBrain Technologies MeloMind)
	Improve sleep quality	17	10%	"Because the Sleep Shepherd lets you directly control your brain rolls, you can naturally build a better, healthier sleep cycle that allows you to fall asleep faster, stay asleep longer, and have more energy during the day" (Sleep Shepherd Blue)
	Improve general wellness	16	9%	"Versus provides a path to wellness through brain exercises" (Versus)
	Augment meditation/relaxation	11	6%	"Muse: the brain sensing headset will elevate your meditation experience. It gently guides your meditation through changing sounds of weather based on the real-time state of your brain" (Intention Muse)
	Increase self-awareness	9	5%	"Introducing LowDown Focus Brain Sensing Eyewear™ with the Smith Focus App to help you develop a heightened sense of self-awareness" (Smith LowDown Focus)
	Improve mood	4	2%	"If you want to improve your mood... Omni is for you" (Omni)
	Lose weight	1	0.6%	"Modus (our neuro) technology to make weight loss easier by reducing your appetite and cravings" (Modus)
Enhancement	Assist with self-regulation/neurofeedback	19	11%	"The FocusBand headset and app provides neurofeedback, a proven method to train the brain" (FocusBand)
	Increase concentration/focus	15	9%	"The drug free way to learn to focus" (Naris)
	Improve general cognition	13	8%	"A smart headset helps you to achieve peak mental fitness" (Brainlink)
	Increase efficiency/productivity	9	5%	"Mindset can give suggestions on how to improve your productivity: schedule emails during your downtime, and save your best hours for your deep work sessions" (Mindset)
	Support learning/training	7	4%	"Halo Sport accelerates how fast people learn skills like golf, piano, trathlon, clarinet, and CrossFit" (Halo Sport)
	Boost physical performance	5	3%	"Enhance your mental/physical performance with photobiomodulation" (Vielight)
	Enhance Memory	5	3%	"Enhance your memory, logic and other cognitive skills" (Neuro's SenseBrain)
Practical Applications	Perform research	7	4%	"NeuroDEV offers neurotechnology that extends beyond hospitals and research facilities, giving developers and professionals the opportunity to access affordable brainwave technology and integrate it with their own applications for the purpose of research, monitoring brain waves and improving brain health" (Vielight Neuro Alpha)
	Control technology	4	2%	"Control machines with the power of your mind and make science fiction a reality today" (Emotiv)
	Create art	2	1%	"Whether commanding drones or wheelchairs, creating music or art, or adapting digital experiences to real time emotions, the interface between the brain and computer has never been easier" (Emotiv Insight)
	Promote safety	1	0.6%	"Our wearable technology prevents microsleeps by providing accurate alertness measurements in real-time to operators and drivers so they can take charge when it comes to safety" (SmartCap Technologies)
Health	Improve a medical condition	5	3%	"Some conditions where Bellabee has been used include: Anxiety problems, Sleep disorders, Stress-related issues, Concentration problems, ADD and ADHD issues (attention deficit disorders), PTSD (post-traumatic stress disorder)" (Bellabee)
	Promote autonomy after disability	4	2%	"The proof of concept software connects a wearable display with an EMOTIV Insight Brainware headset to show how a person with severe mobility restrictions, such as amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases, could regain more independence" (Emotiv Insight)
Total		171	100	

Owning Ethical Innovation: Claims about Commercial Wearable Brain Technologies

Iris Coates McCall,¹ Chloe Lau,¹ Nicole Minielly,¹ and Judy Illes^{1,*}
¹Neuroethics Canada, Division of Neurology, Department of Medicine, University of British Columbia, Vancouver, BC, Canada

Mind-Reading or Misleading? Assessing Direct-to-Consumer Electroencephalography (EEG) Devices Marketed for Wellness and Their Ethical and Regulatory Implications

Anna Wexler¹ · Robert Thibault^{2,3}

Table 1 Number of direct-to consumer EEG devices, out of the 18 included in our dataset, making claims relating to improving behavior, mental states, or well-being

	<i>n</i>
Improves focus/concentration	12
Reduces stress & promotes relaxation	12
Improves meditation	9
Improves sleep	9
Optimizes cognitive performance	8
Improves athletic performance	9
Optimizes learning	5
Improves memory	3

What should we do?

- Independent working group
 - Evaluate the main domains of neurotechnology & provide appraisals of potential harm and probable efficacy
 - Disseminate information to key consumer groups (e.g., AARP), media outlets, etc.
 - Identify areas for future research
 - Serve as a clearinghouse for regulatory agencies, third-party organizations that monitor advertising claims, industry, funding agencies

POLICY FORUM



SCIENCE AND REGULATION

Oversight of direct-to-consumer neurotechnologies

Efficacy of products is far from clear

Wexler & Reiner 2019



Thank you!

Jwa, Anita. (2015). Early adopters of the magical thinking cap: a study on do-it-yourself (DIY) transcranial direct current stimulation (tDCS) user community. *Journal of Law and the Biosciences*, 2(2):292-335.

Wexler, A. (2016). "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.

Wexler, A. (2015). "A Pragmatic Analysis of the Regulation of Consumer Transcranial Direct Current Stimulation (tDCS) Devices in the United States." *Journal of Law and the Biosciences*, doi:10.1093/jlb/lsv039

Wexler, A. (2018). "Who uses direct-to-consumer brain stimulation products, and why? A study of home users of tDCS devices." *Journal of Cognitive Enhancement*, 2(1): 114-134.

awex@upenn.edu