Sparking Controversy: The Contested Use of Noninvasive Brain Stimulation

by

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Bachelor of Science
Massachusetts Institute of Technology, 2007

Submitted to the Program in Science, Technology and Society in Partial Fulfillment of the Requirements for the Degree of

Doctor of Philosophy in History, Anthropology, and Science, Technology and Society at the Massachusetts Institute of Technology

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Abstract: My dissertation examines the controversy over transcranial direct current stimulation (tDCS), a noninvasive form of brain stimulation that is thought to provide a constant low level of electrical current to the brain. Although scientists have been experimenting with tDCS in both healthy and clinical populations for the last fifteen years, in late 2011 a movement arose wherein "lay" individuals began constructing their own tDCS devices, or purchasing consumer devices, to stimulate their brains outside of academic or medical settings for self-improvement purposes. Not surprisingly, the lay use of tDCS has not been well received by researchers, who have termed it "fringe" or "unorthodox." This work studies the conflict over tDCS: what is tDCS, who gets to use it, and who studies it? What are the multiple social worlds that tDCS inhabits, how is the technology interpreted and utilized in each, and how does each group authorize or discredit the other's use?

My dissertation incorporates interviews, observations, an online survey, archival research, and legal analyses to probe aspects of the controversy from different angles. The first chapter introduces tDCS technology and chronicles the rise of the do-it-yourself movement and the subsequent emergence of direct-to-consumer devices. In the second chapter, I present an in-depth qualitative study of the practices of home users of tDCS; the third chapter offers a quantitative look at those who have purchased a consumer tDCS device, based on the results of an online survey. The fourth chapter addresses regulatory issues surrounding consumer tDCS devices, providing a comprehensive analysis of relevant legal doctrines and laws. The fifth chapter covers historical precedents for the home use of electrical stimulation, with a focus on uses of the medical battery between 1870 and 1920 in the United States. In the sixth chapter, I compare the medical battery to tDCS, arguing that the controversy over the home use of tDCS is not novel or even surprising, but rather the latest wave in a series of ongoing attempts by lay individuals to utilize electricity for therapeutic purposes.

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Table of Contents

Title.....1

Abstract.....3

Table of Contents.....4

Acknowledgements 5

Chapter 1: Introduction.....10

Chapter 2: The Practices of Do-it-yourself Brain Stimulation.....49

Chapter 3: Surveying Consumers of tDCS Devices.....80

Chapter 4: A Pragmatic Analysis:
The Regulation of Consumer tDCS Devices in the United States.....135

Chapter 5: The Medical Battery in the United States (1870-1920):
Electrotherapy at Home and in the Clinic.....173

Chapter 6: Recurrent Themes in the Home Use of Electrical Stimulation:
tDCS & the Medical Battery.....236

Chapter 7: Conclusion.....261

Appendix: Consumer tDCS Survey Supplementary Materials 272

References.....298

Acknowledgements

This dissertation has been a journey: an intellectual journey through the depths of anthropology, sociology, STS, history, law, philosophy, and bioethics; a digital journey, through the virtual spaces of the Internet and its message boards, blogs, and websites; an institutional journey, to hospitals, wellness clinics, research laboratories, museums, and regulatory agencies; and a physical journey, one that has taken me to more than a dozen cities across the United States. And it has been a journey through academia, one that is rendered invisible on these pages: taking classes, meeting with faculty and mentors, teaching undergraduate courses, studying for qualifying exams, applying to grants, and delivering presentations.

More than anything, this has been a personal journey: I began my Ph.D. as a writer and documentary filmmaker interested in studying the ethical, legal and social implications of brain-computer interfaces. I conclude it as a researcher about to embark on an academic career, whose area of expertise lies in how (neuro)science technology is being adopted and co-opted outside of mainstream science and medicine.

Though my name alone appears on this cover, I am indebted to a team of outstanding mentors, without whose guidance this work would not have been possible. Foremost among them is my advisor, Susan Silbey. Susan read and reviewed all of my chapter drafts, papers, grants, applications, and presentations; advised me on everything from job applications to how to craft responses to difficult reviewers; and always made time to meet with me, even when she was halfway across the world. Her edits sharpened my work and helped me articulate complex concepts. She was never shy of telling me what I did right or wrong; I could always turn to her for honest feedback and critique. She is a strong supporter of all her students, and I felt confident moving ahead knowing that she had my back. I am honored to call her my advisor, and hope I can one day emulate her academic abilities.

Two other female academic powerhouses round out my thesis committee. Natasha Schüll guided me on my early work when I was still struggling to find my research direction, and through classes, seminars, and conversations, helped me flesh out my ideas, often pointing out connections that I'd missed. (We miss her at MIT). Erica James taught me how to ask questions in new and thoughtful ways, and has encouraged me to engage with diverse bodies of literature. She is a phenomenal teacher who made an impact on me twelve years ago, when I took my first-ever social science class with her ("Violence, Human Rights, & Justice") as a young sophomore at MIT.

To the rest of the distinguished HASTS team, particularly Dave Kaiser, Christine Walley, Heather Paxson, Harriet Ritvo, Clapperton Mavhunga, and Stefan Helmreich: thank you for you incredible support, instruction, and guidance over these years. You have been committed mentors and exceptional teachers, and I have always felt comfortable turning to you for advice. To my fellow HASTS students—in particular, Ashawari, Lucas, Grace, Lauren, Peter, Beth, and Richard: your companionship on this journey has made this trip easier. Thank you for your ongoing comments and feedback. Looking back, it's amazing to see how even a brief five-minute conversation in the hallway can spark an entirely new research direction.

A special thanks goes to Karen Gardner, who deserves her own paragraph here. When things run smoothly—as they do at HASTS—it's easy to assume that that's just the natural order of things. But they only run smoothly because Karen puts in an enormous amount of behind-the-scenes effort. For the last five years, she has been approachable, responsive, and helpful in every way possible; she has kept me on track and has been my scheduling savior.

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Several other individuals merit acknowledgement for their assistance with particular chapters. Part of Chapter 2 was published in the *Journal of Medical Ethics*, and the work benefitted from the feedback of two anonymous reviewers. The survey in Chapter 3 was conducted in collaboration with Nicholas Fitz, a prolific researcher now at Duke University. Chapter 4 would not have been possible without the assistance of Harvard law professor Peter Barton Hutt, who graciously allowed me to audit his course on food and drug law: the class was so outstanding that I nearly decided to attend law school. Peter met with me outside of class to answer my many questions and reviewed several drafts of this chapter, which was ultimately published in the *Journal of Law and the Biosciences*. I thank the two anonymous reviewers at that journal for their comments, as well as the authors of four superb peer commentaries that were published alongside my manuscript.

Chapters 5 and 6 are based primarily on archival work conducted at the Bakken Museum (formerly known as The Bakken: A Library and Museum of Electricity in Life) in Minneapolis, Minnesota. The Bakken generously provided me with a travel fellowship to support my research, and the staff—particularly Rachel Howell, Adrian Fischer, Juliet Burba—went above and beyond in every respect, assisting me with everything from trip logistics to sourcing difficult material to helping me think about my overall research questions. Thanks, too, to Amber Dushman at the American Medical Association's (AMA) Historical Health Fraud Archives in Chicago, IL for helping to coordinate my last-minute visit and to locate relevant research materials. I am also grateful to Jeff Behary and Dean P. Currier, two extremely knowledgeable collectors of late-nineteenth century electrotherapeutic devices, for taking the time to answer my questions. Both chapters benefitted from extensive and thoughtful commentary from anonymous peer reviewers: parts of Chapter 5 were published in the *Journal of the History of Medicine and Allied Sciences*, and Chapter 6 was published in *Brain Stimulation*.

I owe a special acknowledgement to the entire do-it-yourself tDCS community (and consumer tDCS manufacturers) for putting their trust in me, and for opening up to me about their very personal experiences with brain stimulation. John Humphrey and Jennifer Dawson in particular have always been willing to answer my questions.

Two individuals were influential in shepherding me from my life as a writer to my life as an academic. Eilon Vaadia sparked my interest in brain-computer interfaces and continues to be a wonderful mentor and friend. Cathy Kerr, who unfortunately recently passed away, was a remarkable researcher and friend who encouraged me to pursue this doctoral degree; I feel her absence acutely as I embark on this next stage of my academic career. Both Eilon and Cathy have been inspiring role models: fearlessly pursuing their research passions, advocating on behalf of their students, and providing advice with frankness and candor.

Thank you to all of my family and friends—too many to list here—for being understanding when I had to miss all those events to "work." If you are reading this… See? This is what I was working on.

Most of all, I'd like to thank my super-human husband, Jonathan Reisman, who has offered his comments on every single page I've ever published. He has been my editor, advisor, sounding board, travel partner, and best friend. No one deserves to have to endure *years* of conversation about DIY brain stimulation, but Jon has borne it with patience, kindness, and (seemingly) genuine interest. Although his desire to practice off-the-grid medicine in far-flung corners of the earth has not always meshed with my research needs, we have somehow made it work—portions of this dissertation have been written in a remote Inuit hospital thirty miles north of the Arctic Circle and at a high-altitude medical clinic in the heart of the Himalayas. It's been a wild ride, full of adventure, and above all I am grateful to you, Jon, for your love and for your rock-solid, unfailing support.

CHAPTER 1

Introduction

In 2002, two German neurophysiologists, Michael Nitsche and Walter Paulus, published a paper showing that passing a weak electrical current through the human skull caused subjects to perform better on a motor task.[1] In the years since the publication of their paper, over 1,000 studies that utilize what has come to be known as transcranial direct current stimulation (tDCS) have been published in academic journals, claiming that tDCS may have beneficial effects both in clinical populations, for treating a variety of physiological conditions and psychiatric disorders,[2] and in healthy individuals, for enhancing everything from creative problem solving to the acquisition of motor skills.[3]

In part because a tDCS device is relatively easy to make, in late 2011 a movement arose wherein lay individuals began stimulating their own brains for self-improvement with tDCS outside of research or medical settings. Although the movement began with individuals making devices in true do-it-yourself (DIY) fashion, soon many individuals purchased ready-made,

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[1] Michael A. Nitsche and Walter Paulus, "Excitability Changes Induced in the Human Motor Cortex by Weak Transcranial Direct Current Stimulation," *The Journal of Physiology* 527, no. 3 (September 1, 2000): 633–39.

[2] Min-Fang Kuo, Walter Paulus, and Michael A. Nitsche, "Therapeutic Effects of Non-Invasive Brain Stimulation with Direct Currents (tDCS) in Neuropsychiatric Diseases," *NeuroImage*, Neuro-enhancement, 85, Part 3 (January 15, 2014): 948–60.

[3] Brian A. Coffman, Vincent P. Clark, and Raja Parasuraman, "Battery Powered Thought: Enhancement of Attention, Learning, and Memory in Healthy Adults Using Transcranial Direct Current Stimulation," *NeuroImage*, Neuro-enhancement, 85, Part 3 (January 15, 2014): 895–908.

direct-to-consumer (DTC) devices. As the border between DIY and DTC tDCS has become somewhat muddled, in this dissertation I refer to those who use tDCS devices outside of professional research and medical settings as "home users."

The home use movement has given rise to a unique situation wherein there simultaneously exists two groups, professional researchers and lay individuals (home users), using the same technology in very different ways (**Table 1.1**). Researchers apply tDCS to experimental subjects in laboratory settings, with the primary goal of gaining a deeper understanding of brain function or discovering a new method of treating disease.[4] Researchers undergo training prior to being permitted to administer brain stimulation, and experiments are generally carried out in a dedicated space, utilizing tDCS equipment that can cost upwards of $10,000. Before using tDCS experimentally, researchers submit their detailed experimental protocol several weeks in advance to an Institutional Review Board (IRB) for an ethical and safety review. To maximize their chances of a timely approval from the IRB, most researchers adhere to stimulation parameters that have become established in previous studies. Thus, when carried out in laboratory settings, tDCS exists in a controlled environment, subject to both formal regulations and informal laboratory codes of conduct.

By contrast, home users utilize tDCS in the privacy of their own homes, free from the constraints that govern the laboratory uses. Users can stimulate for as long as they want, with whatever current levels they desire, and are not limited to established stimulation parameters. They can build a device for as little as forty dollars or purchase a ready-made device for a few hundred dollars. As I show in Chapters 2 and 3, most users administer stimulation to either self-treat what they describe as a mood disorder (such as depression) or to enhance their cognition.

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[4] Of course, researchers have many goals, including publishing articles, obtaining grants, earning recognition, achieving promotion, etc.

For home users, tDCS is a private endeavor that is motivated by a desire for repair or self-improvement.

Professional researchers	DIYers/home users
Use tDCS in the 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

Table 1.1. A comparison of the differential use of tDCS between professional researchers and home users.

Unsurprisingly, the home use of tDCS has not been well received by researchers and ethicists, who have warned against the practice in both media outlets and academic journals. There are likely a number of reasons why scientists have not looked favorably upon the home use of tDCS. First, they fear a diminished respect for their scientific enterprise if tDCS is conceptualized as a consumer product rather than a serious research tool. Indeed, in 2013, several tDCS researchers published a letter in *Nature* entitled "Transcranial devices are not playthings," writing: "Unorthodox technologies and applications must not be allowed to distort the long-term validation of tDCS."[5] Second, they have voiced concerns that incidents of lay individuals misusing the technology (especially if such incidents were to gain media attention) could result in decreased research funding and potentially cause Institutional Review Boards to

[5] Marom Bikson, Sven Bestmann, and Dylan Edwards, "Neuroscience: Transcranial Devices Are Not Playthings," *Nature* 501, no. 7466 (September 12, 2013): 167.

deny approval for further tDCS experiments. Indeed, at neuromodulation conferences, researchers have expressed fears that home users may "ruin it" for the entire tDCS field.[6] Third, researchers are concerned about potential risks to lay users: although no serious adverse events have been reported among the 10,000 subjects studied to-date,[7] researchers fear that tDCS may potentially have as-yet-unknown deleterious effects on cognition. Indeed, there have been a handful of studies suggesting that enhancing one domain of cognitive function with tDCS could result in impairments in another.[8]

For these reasons, in December 2015, the International Federation of Clinical Neurophysiology (IFCN) became the first professional organization to issue a formal position paper opposing the home use of tDCS, warning "against the use of DIY devices and methods unless they have shown both efficacy and safety."[9] In addition, many researchers and ethicists have suggested that there is a need for strict regulation to control the lay use of tDCS.[10] Indeed,

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[6] For example, according to the results of a questionnaire distributed at the 2015 New York City Neuromodulation Conference, researchers believe that one of the main issues facing the field over the next 15 years is the 'DIY community ruining it for the rest of us'. Conference Questionnaire Results, Presented on Jan. 11, 2015 at the New York City Neuromodulation Conference, New York, Jan. 9–11, 2015; http://neuromodec.com/events/nyc-neuromodulation-conference-2015/ (accessed Aug. 25, 2015)

[7] Felipe Fregni et al., "Regulatory Considerations for the Clinical and Research Use of Transcranial Direct Current Stimulation (tDCS): Review and Recommendations from an Expert Panel," *Clinical Research and Regulatory Affairs* 32, no. 1 (March 1, 2015): 22–35.

[8] Teresa Iuculano and Roi Cohen Kadosh, "The Mental Cost of Cognitive Enhancement," *The Journal of Neuroscience* 33, no. 10 (March 6, 2013): 4482–86; Anna-Katharine Brem et al., "Is Neuroenhancement by Noninvasive Brain Stimulation a Net Zero-Sum Proposition?," *NeuroImage*, Neuro-enhancement, 85, Part 3 (January 15, 2014): 1058–68; and Bruce Luber, "Neuroenhancement by Noninvasive Brain Stimulation Is Not a Net Zero-Sum Proposition," *Frontiers in Systems Neuroscience* 8 (2014).

[9] International Federation of Clinical Neurophysiology, "Position Statement: Transcranial Electric Stimulation in Do-It-Yourself Applications," December 13, 2015, http://www.ifcn.info/uploadfiles/documents/2015/Using_tES_devices_as_DIY_FINAL_13Dec15.pdf (accessed January 5, 2016).

[10] Veljko Dubljević, "Neurostimulation Devices for Cognitive Enhancement: Toward a Comprehensive Regulatory Framework," *Neuroethics*, November 12, 2014, 1–12; Hannah

in recent years the Food and Drug Administration (FDA), the Institute of Medicine, and the American Academy of Arts and Sciences have all held meetings to discuss the home use of brain stimulation and the possibility of regulating commercially available tDCS devices (see Chapter 4 for detailed discussion).

My initial interest in studying the home use movement was borne out of a realization that the ongoing debate over the home use of tDCS seemed entirely disconnected from the sociological phenomenon itself. In other words, though a major controversy was afoot, and though scientists, ethicists, and regulators were struggling with how to control the possible alternate uses of tDCS, there was a complete absence of consideration of any historical, regulatory, or social context within which to understand the phenomenon. Who were home users, what were their motivations for using tDCS, and what were their processes of stimulation? How were they drawing on scientific knowledge, if at all? How do their "ways of knowing" differ from those of scientists? Was the home use of tDCS an example of lay individuals trying to influence a research direction or political outcome[11] or was it merely another example of technological innovation provoking concerns about public health and safety? Did existing legal frameworks in the U.S. encompass the direct-to-consumer stimulation devices currently on the

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Maslen et al., "The Regulation of Cognitive Enhancement Devices: Extending the Medical Model," *Journal of Law and the Biosciences* 1, no. 1 (March 1, 2014): 68–93; Hannah Maslen et al., "Do-It-Yourself Brain Stimulation: A Regulatory Model," *Journal of Medical Ethics* 41, no. 5 (May 1, 2015): 413–14.

[11] See, e.g., Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (Berkeley, Calif.: University of California Press, 1996); M. Callon and V. Rabeharisoa, "Research 'in the Wild' and the Shaping of New Social Identities," *Technology in Society*, Studies in Science, Technology, and Society (STS) North and South, 25, no. 2 (April 2003): 193–204; and Hilary Arksey, "Expert and Lay Participation in the Construction of Medical Knowledge," *Sociology of Health & Illness* 16, no. 4 (September 1, 1994): 448–68.

market, and if so, how? Were there historical precedents for the home use of electrical medicine, and if so, could they help us understand the present phenomenon?

These are some of the questions that drove my research, which involved multiple methods of data collection and analysis (e.g. interviews, surveys, content analysis) to identify the practices of home users (Chapters 2 and 3), legal analyses of the regulatory frameworks that apply to consumer tDCS devices (Chapter 4), and archival work to situate the present phenomenon within the historical context of the home use of electrical stimulation (Chapters 5 and 6). Though this work was initially motivated by ongoing ethical and regulatory discussions, it was not conducted in the service of policy—no normative recommendations appear on these pages. At the same time, I believe this work provides an empirical foundation onto which ethical approaches and regulatory proposals can be based.[12] It was thus written to be accessible for those outside of the social sciences: policymakers, ethicists, researchers, neuroscientists, clinicians and scientists.

The overarching theme connecting these chapters is the controversy between professionals (scientific researchers) and lay individuals (home users) over electrical brain stimulation: what is tDCS, who gets to use it, and who controls it? As one author put it, "controversies… provide a kind of natural laboratory for studying the operations of science and technology and their interactions with the surrounding society"[13] and can therefore be a fruitful area of research.[14]

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[12] Indeed, there has been a recent move to bring sociological considerations into the study of bioethics. See, e.g., John H. Evans, *The History and Future of Bioethics: A Sociological View* (Oxford University Press, 2012).

[13] Ronald N. Giere, "Dorothy Nelkin: 1988 Bernal Prize Recipient," *Science, Technology, & Human Values* 14, no. 3 (1989): 302–4.

[14] Dorothy Nelkin, *Controversy: Politics of Technical Decisions* (Beverly Hills: Sage Publications, 1979).

Each chapter of this dissertation engages with a different body of scholarly literature to understand the conflict over the home use of tDCS. In Chapter 2, I show how the home use of tDCS differs in a number ways from previous examples of lay interaction with scientific knowledge; most saliently, the main motivation of home users is self-improvement, not influencing the direction of medical research or achieving a political outcome. In Chapter 3, which describes the results of a survey of home users of consumer tDCS devices, I argue that while some concerns expressed in the bioethical literature regarding the home use of tDCS (such as those regarding safety and distributive justice) are empirically supported, there is little evidence to support others, namely those relating to autonomy and authenticity. The fourth chapter, which provides a comprehensive analysis of the regulation of consumer tDCS devices, argues that rather than there being a "regulatory gap" with regard to consumer tDCS devices (as some scholars have suggested), there are in fact multiple, distinct pathways by which consumer tDCS can be regulated in the United States. The fifth chapter centers on the history of a portable shock-producing device known as the "medical battery" between 1870 and 1920; though companies marketed medical batteries primarily to either consumers or physicians, I argue that the lines between what was considered a consumer product and a medical device were often muddled. The sixth chapter compares the present-day home use of tDCS to uses of the medical battery, arguing that while many themes are recurrent (a do-it-yourself movement, anti-medical establishment themes, and tensions between professional and users), many seem unique to the present day, such as focus on the head (and brain) instead of body, the dominant discourse of safety and risk, and uses for cognitive enhancement purposes. Finally, in the conclusion, I highlight how this dissertation adds to the existing body of literature on electricity and medicine: while previous work has largely focused on how electrical medicine practitioners have struggled

for credibility in the broader medical world or have fended off encroachment from irregular practitioners, here I have focused on "incursions" by lay individuals: a dispersed, informal set of individuals that have no formal relationship with one another.

In the remainder of this introductory chapter, I provide background on tDCS technology and its use in laboratory settings. Next, I chronicle the rise of DIY tDCS and the shift to direct-to-consumer tDCS devices. I then situate the home use of brain stimulation within broader social and cultural contexts, focusing on four main themes: "neurohacking" and the drive for brain optimization; the self-tracking movement; DIY biology and citizen science initiatives; and DIY medical endeavors. Finally, I describe my research methodology, and present detailed outlines of each chapter.

I. tDCS in the laboratory

At its core, a tDCS device is a simple contraption: there is a current-providing component (such as a 9V battery), wires that carry the current, and electrodes that interface between the wire and the head (**Fig 1.1**). When both electrodes are connected to the scalp, the electrical circuit closes, and the device is thought to deliver a current to the brain. The placement of the wires is of utmost importance: when the anodal (positive) electrode is placed over a specific brain area, current is thought to flow into that region and stimulate neuronal activity. The cathodal (negative) electrode is the "exit" point for current, and is thought to inhibit neuronal activity.

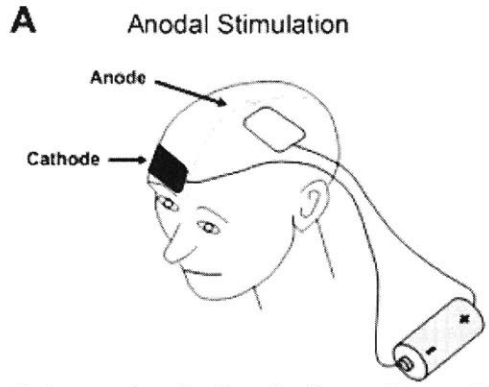


Figure 1.1. Schematic of stimulation with a tDCS device.

Importantly, tDCS is not a whole-brain procedure: rather, the specific placement of electrodes over targeted brain areas can modify brain activity in different ways. Since scientists are interested in replicable, commensurable effects across studies, electrodes are carefully positioned on the skull according to the International 10-20 system (**Fig 1.2**), which standardizes placement across individuals. A common electrode configuration (known as a "montage") for depression, for example, involves stimulating the left dorsolateral prefrontal cortex and having the cathode rest a few inches above the right eyebrow.

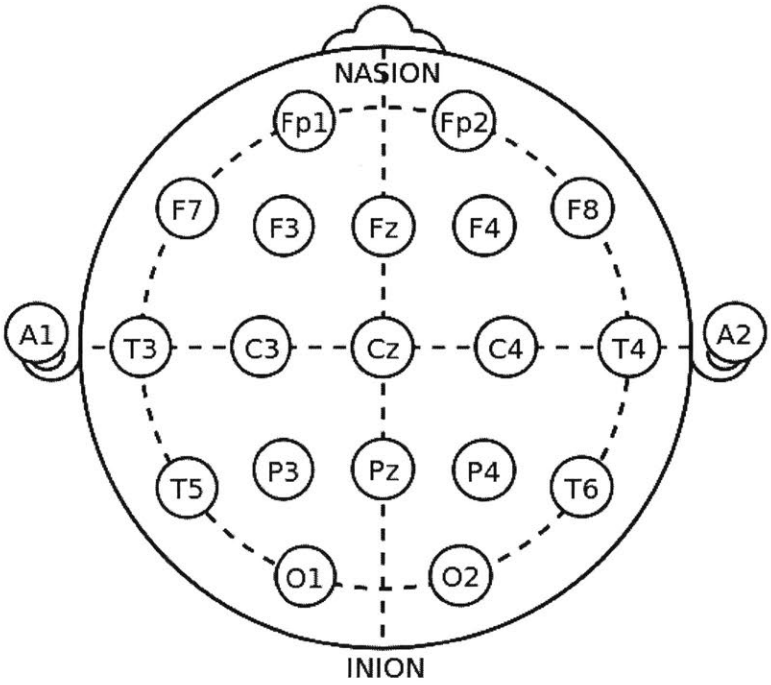


Figure 1.2. Diagram of the International 10-20 system for electrode placement on the head.

Although there are other methods of stimulating the brain with electricity or magnetism, tDCS is unique in that the stimulation device is both "noninvasive" (i.e., no surgical implantation is required) and relatively inexpensive to acquire or create. By comparison, deep brain stimulation (DBS), an FDA-approved treatment for Parkinson's disease that provides electrical stimulation to the brain, requires neurosurgery to implant a stimulation device. Transcranial magnetic stimulation (TMS), an FDA-approved treatment for certain kinds of depression, is noninvasive, but the stimulation device is not easy to replicate. Compared to other techniques that stimulate the brain with electricity, such as electroconvulsive therapy (ECT), the level of current used in tDCS is relatively low: most tDCS studies use .5 to 2 milliamps, whereas ECT utilizes 500-900 milliamps.[15]

As noted in the introductory paragraph, there have been over 1,000 peer-reviewed studies utilizing tDCS published in the past decade, most of which have been published in the last five years (**Fig 1.3**). There are two main lines of tDCS research. The first comprises studies in clinical populations that have claimed to show the beneficial effects of tDCS for treating a variety of diseases and disorders, such as schizophrenia, depression, chronic pain, stroke, Parkinson's disease and even eating disorders.[16] Such studies are often conducted by clinical researchers, most commonly neurologists and psychiatrists. The second line of tDCS research is comprised of studies claiming to show that tDCS can enhance learning and cognition in healthy individuals, on tasks requiring working memory, motor skills, mathematical ability, motor dexterity, perception,

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[15] *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging*, 2nd ed. (American Psychiatric Association, 2001).

[16] Andre Russowsky Brunoni et al., "Clinical Research with Transcranial Direct Current Stimulation (tDCS): Challenges and Future Directions," *Brain Stimulation* 5, no. 3 (July 2012): 175–95.

and creative problem solving.[17] These studies are mostly conducted by neuroscientists (not clinicians) who are interested in understanding the underlying mechanisms of brain function, particularly regarding learning, memory and attention. As experiments on learning, by their nature, are often short—researchers try to isolate and measure the acquisition of specific task or skill—tDCS is often administered just once in these studies.

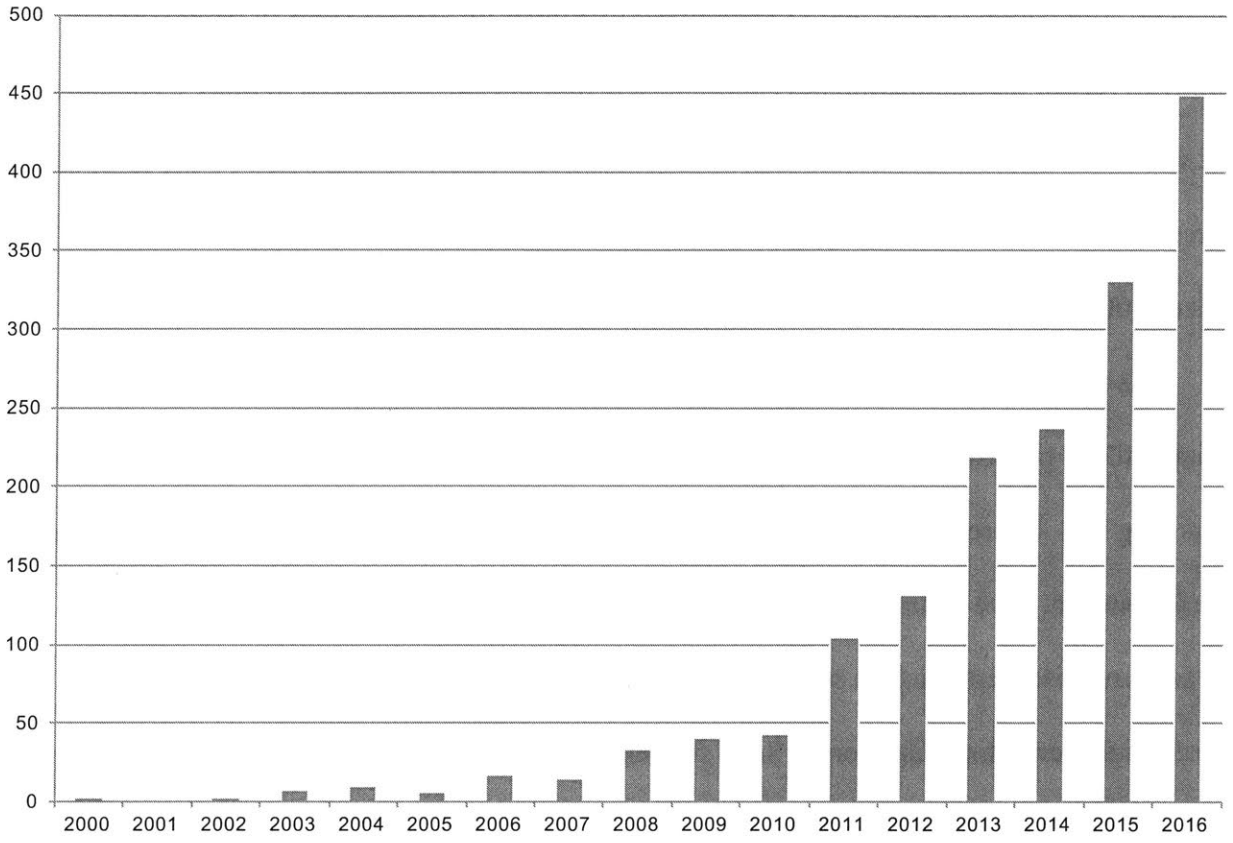


Figure 1.3. Number of academic journal publications about tDCS by year, 2000-2016. (Based on PubMed.com title search for "transcranial direct current stimulation" or "tDCS" conducted on January 10, 2017.)

[17] Brian A. Coffman, Vincent P. Clark, and Raja Parasuraman, "Battery Powered Thought: Enhancement of Attention, Learning, and Memory in Healthy Adults Using Transcranial Direct Current Stimulation," *NeuroImage*, Neuro-enhancement, 85, Part 3 (January 15, 2014): 895–908.

In both studies on clinical and healthy populations, stimulation is generally applied for ten to thirty minutes (though on occasion, clinical studies will utilize longer sessions of up to an hour). Almost all tDCS studies make use of "sham" stimulation, which is the tDCS equivalent of a placebo, wherein a subject is set up for a regular tDCS session, but no current is passed through the device (except for up to a minute at the beginning of the session to mimic the sensation of a real session). Some studies are "single-blind," where only the subjects are unaware if they received the stimulation or the sham, whereas others are "double-blind," wherein both the subject and experimenter administering tDCS are not aware of who received the stimulation and the sham. Some clinical studies use a treatment group instead of a sham group, and compare the results of standard treatment to the results of tDCS. Others studies have within-subject designs, where, for example, a single individual is given both sham and tDCS at different sessions, and their performance is measured on a given task. Although studies often incorporate more complex variations on these designs, an experimental control is crucial to establishing the validity of all professional tDCS research.

Recently, however, questions have been raised about the replicability of the effects of tDCS, with researchers criticizing the proliferation of small sample-size studies and the lack of larger, longitudinal studies.[18] The debate has been most heated with regard to studies of tDCS in healthy populations (i.e., those claiming to show that tDCS has cognitive enhancement effects): in January 2015 several researchers published a meta-analysis of single-session tDCS studies for cognitive enhancement, finding that the claimed beneficial effects washed out (e.g., for every

[18] See, e.g., Tamas Minarik et al., "The Importance of Sample Size for Reproducibility of tDCS Effects," *Frontiers in Human Neuroscience* 10 (2016), doi:10.3389/fnhum.2016.00453.

paper claiming memory enhancement, there was another that found no effect).[19] However, other researchers responded by criticizing the methodology used in the meta-analysis,[20] and several additional meta-analyses have since been published with mixed results.[21] Though criticisms have also been raised—to a lesser degree—with regard to clinical studies of tDCS, the current consensus seems to be that tDCS has "probable efficacy" for treating depression, fibromyalgia, and addiction/craving.[22] Thus, the question of whether tDCS is merely hype—or whether it is premised on a "true" effect, perhaps one has been exaggerated—is an issue that tDCS researchers are actively confronting and debating in the brain stimulation literature.

Despite the recent questions over efficacy, tDCS remains a popular research technique in the field of neuromodulation, which encompasses other brain stimulation techniques such as TMS, ECT, DBS, repetitive TMS (rTMS), transcranial alternating current stimulation (tACS), transcranial random noise stimulation (tRNS), and transcutaneous vagal nerve stimulation (tVNS), among others. For example, at the most recent international conference on noninvasive transcranial brain stimulation, which took place over four days in September 2016,

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[19] Jared Cooney Horvath, Jason D. Forte, and Olivia Carter, "Quantitative Review Finds No Evidence of Cognitive Effects in Healthy Populations From Single-Session Transcranial Direct Current Stimulation (tDCS)," *Brain Stimulation* 8 no. 3 (2015): 535–50.

[20] Amy R. Price and Roy H. Hamilton, "A Re-Evaluation of the Cognitive Effects From Single-Session Transcranial Direct Current Stimulation," *Brain Stimulation* 8, no. 3 (2015): 663–65.

[21] See, e.g., L. E. Mancuso et al., "Does Transcranial Direct Current Stimulation Improve Healthy Working Memory?: A Meta-Analytic Review," *Journal of Cognitive Neuroscience* 28, no. 8 (August 2016): 1063–89; Aron T. Hill, Paul B. Fitzgerald, and Kate E. Hoy, "Effects of Anodal Transcranial Direct Current Stimulation on Working Memory: A Systematic Review and Meta-Analysis of Findings From Healthy and Neuropsychiatric Populations," *Brain Stimulation* 9, no. 2 (2016): 197–208, doi:10.1016/j.brs.2015.10.006.

[22] Jean-Pascal Lefaucheur et al., "Evidence-Based Guidelines on the Therapeutic Use of Transcranial Direct Current Stimulation (tDCS)," Clinical Neurophysiology 128, no. 1 (January 2017): 56–92, doi:10.1016/j.clinph.2016.10.087.

approximately one-third of all posters centered on tDCS,[23] and the technique is being utilized at top research institutions worldwide. Researchers publish both in general neuroscience journals and in specialized journals such as *Brain Stimulation* and *Clinical Neurophysiology*. Funding for tDCS research is provided both by the National Institute of Health (NIH) and the National Science Foundation (NSF), both directly and through the recently established BRAIN (Brain Research Through Advancing Innovative Neurotechnologies) initiative, which was launched by President Obama in 2013 to develop new technologies to record and influence brain function.[24]

II. The rise of DIY tDCS and the shift to direct-to-consumer devices

The earliest mentions I have found of non-professional tDCS use are from 2007, in the form of a posting on the Longecity.org forum (website tag line: "advocacy and research for unlimited lifespans") and an article in the *Boston Phoenix,* which described how one individual tried to treat his depression using a tDCS device he constructed by modifying a Radio Shack Electronics Learning Lab.[25] However, non-professional use of tDCS seems to have remained isolated until the middle of 2011, when a Yahoo group and a Reddit forum (called a "subreddit") dedicated to DIY tDCS were formed.

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[23] 6th International Conference on Transcranial Brain Stimulation, September, 7-10, 2016, Göttingen, Germany. By my own count, 99 of 315 posters were about tDCS. See http://www.tbs-conference.de/programme/scientific-programme/ (accessed February 17, 2017).

[24] BRAIN Initiative, https://www.whitehouse.gov/brain and NIH - Brain Initiative, https://braininitiative.nih.gov (accessed November 1, 2016) .

[25] "Attaching a batter to your head," *Longecity*, 2007. http://www.longecity.org/forum/topic/19346-attaching-a-battery-to-your-head/; Pagan Kennedy, "Brain-O-Matic," *The Phoenix*, February 7, 2007, http://thephoenix.com/boston/life/33313-brain-o-matic (accessed March 8, 2015).

By early 2012, there were a number of blogs and sites dedicated exclusively to the topic.[26] As of the time of writing (April 2017), the most active tDCS forum is the subreddit (http://www.reddit.com/r/tDCS/), which averages several posts a day. tDCS tutorial videos on YouTube have racked up tens of thousands of views. The appearance of the movement corresponds to the increase in popularity of tDCS in scientific journals: in 2011, there were over 130 peer-reviewed articles about tDCS, more than double that of the previous year.

The notion of a ready-to-wear consumer tDCS headset first emerged in the spring of 2012, when two undergraduates from the University of Michigan, Matt Sornson and Nick Woodhams, built a prototype of a tDCS device called the GoFlow ("the world's first tDCS kit") and promised to sell it for $99.[27] Various press outlets picked up on the story, enthusiastically describing the initiative with headlines such as "Buy a DIY Brain Supercharger for $100" and "Transcranial direct current stimulation works, and you can try it at home."[28] Two months later, in May 2012, the company announced that they were being delayed due to FDA concerns,[29] and in early 2013 the co-founders made the decision to abandon plans for the headset.[30] Rumors

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[26] "[modpost] A wild FAQ appeared!," 2012, *Reddit /r/tDCS*. http://www.reddit.com/r/tDCS/comments/1jn8um/modpost_a_wild_faq_appeared/ ; Note that the Yahoo group contained a considerable number of medical professionals who were interested in using tDCS to treat patients.

[27] *GoFlow*, http://www.flowstateengaged.com (last visited March 3, 2012) archive available at http://web.archive.org/web/20120314201106/http://flowstateengaged.com/

[28] Ashlee Vance, "Buy a DIY Brain Supercharger for $100," *Bloomberg.com*, March 21, 2012, https://www.bloomberg.com/news/articles/2012-03-21/buy-a-diy-brain-supercharger-for-100; Christopher Mims, "DIY Kit Overclocks Your Brain With Direct Current," *MIT Technology Review*, March 9, 2012, https://www.technologyreview.com/s/427177/diy-kit-overclocks-your-brain-with-direct-current/.

[29] "Go Flow Kickstarter Campaign Denied," DIYTDCS, http://www.diytdcs.com/2012/05/goflow-kickstarter-campaign-denied/ (accessed December 14, 2013).

[30] Interview with Matt Sornson, co-developer of GoFlow, (February 14, 2014).

swirled online that the GoFlow team "ran into some problems" with the FDA.[31] But Sornson had not been contacted by the FDA; rather, he and Woodhams abandoned the GoFlow for personal reasons, though potential future complications with the FDA were also a factor in their decision.[32] The company quietly sold their mailing list and domain name to a firm building a consumer tDCS device called the Foc.us,[33] and in June 2013 announced that they would not be moving forward with the project.[34]

In the year between Sornson's and Woodham's start up and shut-down announcements, a number of other consumer tDCS devices appeared on the market: Hong Kong-based TCT Technologies[35] began selling a $379 device, and at least three other websites offered more affordable tDCS device "kits."[36] The kits varied in both price and level of sophistication, but usually consisted of a nine-volt battery enclosure (or a snap connector that the battery attached to), wires, electrodes, and a headband to facilitate electrode placement. They were seemingly geared to those who had knowledge of tDCS but lacked the necessary soldering skills to build their own device from scratch. Some home users, like scientists, began purchasing and

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[31] Longecity Forum, http://www.longecity.org/forum/topic/57869-increased-cognition-with-9v-battery/ (accessed December 24, 2013).

[32] E-mail from Matt Sornson, co-developer of GoFlow, to Anna Wexler, (December 15, 2013), on file with author.

[33] Interview with Matt Sornson, co-developer of GoFlow, (February 14, 2014).

[34] Ibid., and "News from GoFlow! Good and Bad," DIYTDCS, http://www.diytdcs.com/2013/06/news-from-goflow-good-and-bad/ (accessed December 14, 2013).

[35] TCT Technologies, http://www.trans-cranial.com/ (accessed December 14, 2013); note that the company is currently conducting business as TCT Research Limited.

[36] See www.biocurrentkit.com, www.tdcs-kit.com, and www.tDCSdevicekit.com, accessed between Dec 2012 and April 2013, archived versions available at http://web.archive.org

repurposing iontophoresis devices, which legally require a prescription but in practice are widely available online.[37]

The Foc.us device, which was released in the summer of 2013, was arguably the first true direct-to-consumer tDCS device (**Fig 1.4**).[38] With its sleek, ready-to-wear headset design, it looked more like Google Glass than a cobbled-together DIY device. The company's website, advertising campaign (featuring photos of an attractive woman wearing the device), and promised smartphone integration made it clear that the product was a step up from the kits sold by small-scale vendors. Though the Foc.us device was ostensibly marketed to gamers, its release thrust the DIY tDCS movement into the spotlight and brought the debate over the regulation of cognitive enhancement devices to public attention.[39]



Figure 1.4. The Foc.us v1 headset, which was released in 2013.

[37] See, e.g., http://www.amazon.com/DSS-Chattanooga-Ionto/dp/B00FC2SRMY and http://www.isokineticsinc.com (accessed December 3, 2014).

[38] Foc.us, "Transcranial direct current stimulation for gamers," http://www.foc.us/ (accessed July 8, 2013), archive available at: http://web.archive.org/web/20130708144009/http://www.foc.us/

[39] See, e.g., Kate Murphy, "Jump-Starter Kits for the Mind," *The New York Times*, October 28, 2013, https://www.nytimes.com/2013/10/29/science/jump-starter-kits-for-the-mind.html; and Nick Statt, "When Wearable Tech Makes You Smarter -- by Zapping Your Brain," *CNET*, August 9, 2013, https://www.cnet.com/news/when-wearable-tech-makes-you-smarter-by-zapping-your-brain/ (accessed December 4, 2014).

Since 2013, thousands of Foc.us devices have been sold[40] and the company has released a second generation of products; it currently has a headset specially designed for exercise.[41] New consumer tDCS devices are constantly appearing on the market, most often manufactured in small runs by individuals interested in, or involved with, the DIY tDCS movement. Though the prospect of regulation looms large for many of these manufacturers, the only legal action to date has come at a state level, from the California Department of Public Health, which effectively halted sales from tdcsdevicekit.com in May 2013 (see Chapter 4 for an in-depth discussion).

In 2014, two Silicon Valley start-ups announced that they were entering the consumer brain stimulation device market. One company, Thync, announced via an October 2014 press release that it had raised $13 million in venture capital funding.[42] In June 2015, the company released the first version of its device ($299), which is controlled via smartphone and provides a form of non-invasive brain stimulation for mood alteration (either a "calm vibe" or an "energy vibe").[43] The company has reportedly tested thousands of subjects, both on its own and in collaboration with tDCS researchers, and has posted some of its results online.[44] However, in early 2016 the company struggled to raise additional investor funding, and was forced to lay off

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[40] Although sales data for the Foc.us device are not public, the company sold out its first production run of 3,000 within a month (ibid.) and has since had several production runs.

[41] Foc.us edge tDCS headset, http://www.foc.us/edge-tdcs-headset (accessed January 25, 2015).

[42] Brad Stone, "Thync Lets You Give Your Mind a Jolt," *Bloomberg.com*, October 8, 2014, https://www.bloomberg.com/news/articles/2014-10-08/thync-raises-13-million-for-its-brain-stimulating-electrodes (accessed December 4, 2014).

[43] Ibid., and Thync.com.

[44] The safety section of Thync's website states: "Thync Vibes were safely tested on several thousand individuals under a variety of conditions to optimize their performance and comfort." Thync – Safety, http://www.thync.com/science-and-technology (accessed June 25, 2015). See also Tyler et al., "Transdermal Neuromodulation of Noradrenergic Activity Suppresses Psychophysiological and Biochemical Stress Responses."

three-quarters of its staff.[45] The company is currently re-focusing its strategy as it continues to market the same device, for the lower price of $199.

Halo Neuroscience, the other Silicon Valley start-up, issued a press release in May 2014 noting that it had received $1.5 million in venture capital funding and was developing "wearable technology that boosts brain function."[46] The company's board includes well-known names such as Reed Hundt, former chairman of the Federal Communications Commission.[47] In 2016, Halo Neuroscience released its first product, HaloSport, a tDCS stimulator marketed for athletic enhancement. Because HaloSport only claims to stimulate the motor cortex—which, conveniently for the company, lies beneath the area of the head where a pair of headphones might sit—the product does not utilize stray wires or a futuristic headset, but instead takes the recognizable shape of headphones. The device currently retails for $749 and is marketed almost exclusively to professional and amateur athletes, though in late 2016 the company began early efforts to market its product to musicians. The company has also partnered with the Pentagon's Defense Innovation Unit Experimental (DIUx) to test the product's military applications.[48]

Although Thync and Halo Neuroscience have been the most prominent start-ups to enter the direct-to-consumer electrical stimulation market, several other investor-backed companies, such as Nervana, have been manufacturing newer versions of consumer electrostimulation

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[45] Ellen Huet, "How Thync, Startup Behind Brain-Zapping Gadget, Almost Died," *Bloomberg.com*, accessed May 29, 2016, http://www.bloomberg.com/news/articles/2016-05-23/how-thync-startup-behind-brain-zapping-gadget-almost-died.

[46] Halo Neuroscience, "Press Release" (May 28, 2014) http://haloneuro.com/press/ (accessed January 25, 2015).

[47] Halo Neuroscience, http://haloneuro.com/ (accessed January 25, 2015).

[48] Corey Dickstein, "Brain Stimulator Used by Athletes among Tech Devices Touted for Troops," Stars and Stripes, July 26, 2016, http://www.stripes.com/news/brain-stimulator-used-by-athletes-among-tech-devices-touted-for-troops-1.421070 (accessed January 30, 2017).

products.[49] Thus, what began as do-it-yourself brain stimulation is being dwarfed by direct-to-consumer brain stimulation. At present, however, the border between do-it-yourself and direct-to-consumer still remains muddled. As I show in Chapter 2, while some individuals build their own devices, others acquire a wide range of devices, from device "kits" (which require assembly) and iontophoresis devices (which require repurposing) to the Foc.us headset.[50] Indeed, the range of devices has blurred the meaning of "DIY" tDCS: some use the term in reference to the hands-on construction of a stimulation device, while others use it more broadly to refer to the self-directed nature of the stimulation itself. Here, I adopt the former definition, using DIY to refer to the actual assembling of the device, and "home use" to refer to the general phenomenon of self-stimulation outside of academic or medical settings.

III. Social and Cultural Contexts

The previous two sections focused narrowly on tDCS technology and the rise of the home use movement. However, social phenomena do not exist in isolation: they sit in relation to other phenomena, and cultural memes circulate across domains. Thus, it is crucial to locate the home use of brain stimulation within its overall social and cultural contexts. Seen in this broader light, the home use of brain stimulation is only a small part of the "neurohacking" movement, which is comprised of individuals attempting to optimize their brains to achieve enhanced performance. Neurohacking itself is related to the "quantified self" movement, in which individuals self-track

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[49] Experience Nervana, https://experiencenervana.com (accessed January 22, 2017).

[50] Anita Jwa, "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, no. 2 (July 13, 2015): 292–335; Anna Wexler, "The Practices of Do-It-Yourself Brain Stimulation: Implications for Ethical Considerations and Regulatory Proposals," *Journal of Medical Ethics* 42, no. 4 (2016): 211–15.

minute aspects of their daily lives in order to enhance productivity or performance. Additionally, the home use of brain stimulation is in many ways parallel both to DIY biology and citizen science initiatives, which seek to democratize tools of scientific experimentation, and to DIY medical endeavors, wherein patients who are frustrated with the slow pace of medicine administer experimental interventions to themselves outside of medical settings.

Neurohacking

Since the turn of the 21st century, neuroscience has had an increasing place in the public realm.[51] In the early 2000s a flood of popular science books, such as *The Brain that Changes Itself*, helped catapult neuroscience into the self-help arena, and the neuroscience concept of "plasticity" was co-opted into a mantra for personal growth and spirituality. Rather than a passive organ that exists as an immutable part of our bodies, the brain has been increasingly conceptualized (by both the media and the public) as something to be exercised, re-shaped, and maximized.[52] Indeed, a study of brain-related articles published in six United Kingdom newspapers between 2000 and 2010 found that 43% characterized the brain as a "resource to be optimized,"[53] and sociologists such as Nikolas Rose have written extensively about how we have become "neurochemical selves."[54]

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[51] See, e.g., Cliodhna O'Connor, "The Brain in Society: Public Engagement with Neuroscience" (University College London, 2013); Nikolas Rose and Joelle M. Abi-Rached, *Neuro: The New Brain Sciences and the Management of the Mind* (Princeton, N.J: Princeton University Press, 2013); Davi Johnson Thornton, *Brain Culture: Neuroscience and Popular Media* (Rutgers University Press, 2011).

[52] Cliodhna O'Connor and Helene Joffe, "How the Public Engages With Brain Optimization: The Media-Mind Relationship," *Science, Technology, & Human Values* 40, no. 5 (2015): 712–43

[53] Cliodhna O'Connor, Geraint Rees, and Helene Joffe, "Neuroscience in the Public Sphere," *Neuron* 74, no. 2 (April 26, 2012): 220–26.

[54] Nikolas Rose, "Neurochemical Selves," *Society* 41, no. 1 (November 1, 2003): 46–59.

In an effort to capitalize on the brain optimization trend, in the mid-2000s a number of companies—such as Lumosity, PositScience, and CogniFit—began selling brain-training software games. The products emphasized the idea of brain fitness, and were marketed to those wanting to stave off age-related cognitive decline or even dementia. Even without training, the brain has come to be viewed as something that can be enhanced—via drugs (both legal and illegal), dietary supplements, food, drinks, and even chewing gum. Websites and forums have sprung up dedicated to the world of "nootropics," a term used to describe "smart drugs" and dietary supplements that supposedly improve one's intelligence or cognitive ability. More recently, Silicon Valley start-ups like Nootrobox (tagline: "nootropics for everyone") have sought to bring brain-boosting supplements to the mainstream.

In parallel to the commercialization of "brain optimization" games and nootropics, a number of companies began developing pared-down versions of neuroscience tools—such as electroencephalography (EEG) devices—and marketing them directly to consumers. Although some direct-to-consumer EEG products initially focused on mind-control applications, such as the ability to move a computer cursor using one's thoughts, today the majority are geared toward brain optimization and wellness. Reflecting the rise of what has become known as "neurotechnology," a variety of industry groups, independent market research, and non-profit organizations now hold conferences and meetings related both to direct-to-consumer and clinical applications of neurotechnology.[55]

The rise of brain training, the increasing availability of brain-enhancing drugs and supplements, and the commercialization of neuroscience tools all set the foundation for the

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[55] See, e.g., Neurotechnology Industry Organization (https://www.neurotechindustry.org/); NeuroInsights (https://www.neuroinsights.com/), NeuroTechX (http://neurotechx.com/). See also SharpBrains (http://sharpbrains.com/).

emergence of DIY and direct-to-consumer brain stimulation. Viewed myopically, the home use of brain stimulation can be perceived as individuals merely adapting scientific techniques for use on themselves. But considered more broadly, the movement is part-and-parcel of the "neurohacking" movement, and cannot be fully comprehended without understanding the overall drive for brain enhancement.

Yet compared to other "neurohacking" techniques, the lay use of brain stimulation represents only a very small piece of the terrain: the Reddit forum on nootropics has ten times the number of subscribers as its tDCS counterpart; and there are dozens, if not hundreds, of companies selling brain-boosting nootropics, compared to roughly a dozen direct-to-consumer tDCS companies (the majority of which are individuals building and selling devices from home in their spare time). Although there are no official measures of the size of the consumer brain stimulation market, in Chapter 3 I estimate that the total number of consumer devices sold has been in the low five figures (and active users likely comprise only a small proportion of that figure). By comparison, a single brain-training company, Lumosity, reported having 70 million subscribers in 2015.[56]

Self-tracking and Quantified Self

Although individuals have been tracking aspects of themselves for hundreds of years,[57] the movement known as "quantified self" (QS) cohered in 2008.[58] Melanie Swan defines "the

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[56] Lumosity, "Let's Celebrate - This Month Lumosity Added Our 70 Millionth Member!," January 10, 2015, https://plus.google.com/+lumosity/posts/KtXta3S5zdi.

[57] Kate Crawford, Jessa Lingel, and Tero Karppi, "Our Metrics, Ourselves: A Hundred Years of Self-Tracking from the Weight Scale to the Wrist Wearable Device," *European Journal of Cultural Studies* 18, no. 4–5 (August 1, 2015): 479–96.

[58] Melanie Swan, "The Quantified Self: Fundamental Disruption in Big Data Science and Biological Discovery," *Big Data* 1, no. 2 (June 1, 2013): 86.

quantified self" as "any individual engaged in the self-tracking of any kind of biological, physical, behavioral or environmental information."[59] Like home users of brain stimulation, those who identify with the QS movement have the ultimate goal of enhancing themselves; they track various aspects of their lives in order to improve (or "hack") them.[60] Such individuals—sometimes known as "life hackers" or QSers—place a high value both on the collection of such information and its analysis; data is thought to illuminate knowledge of the self.

Self-trackers frequently engage in forms of self-experimentation. For example, they may hypothesize about which factors affect their cognition or mood: does drinking coffee after 3 pm cause them to stay up late, and does eating Bleu cheese make them more alert?[61] Self-trackers test such hypotheses, often plotting the resulting data on graphs and attempting to derive meaning from them. When it comes to data analysis, they struggle with the same issues as home users of brain stimulation: namely, the methodological limitations of a sample size of one. To date, self-trackers have not published aggregated data on their experiments in a peer-reviewed journal.

As a whole, self-trackers are a more coherent and organized group than home users of brain stimulation. In addition to annual international and regional "quantified self" conferences, there are over 200 groups in more than 30 different countries where individuals meet to share the results of their self-experimentation data, presenting what they did, how they did it, and what

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[59] Ibid., 85.

[60] Ibid; Deborah Lupton, "The Digitally Engaged Patient: Self-Monitoring and Self-Care in the Digital Health Era," *Social Theory & Health* 11, no. 3 (June 19, 2013): 256–70; Stefan Selke, ed., *Lifelogging*, Digital Self-Tracking and Lifelogging – between Disruptive Technology and Cultural Transformation (Wiesbaden: Springer Fachmedien Wiesbaden, 2016).

[61] Seth Roberts, "Self-Experimentation as a Source of New Ideas: Ten Examples about Sleep, Mood, Health, and Weight," *Behavioral and Brain Sciences*, October 7, 2004, 227–88; Seth Roberts, "The Unreasonable Effectiveness of My Self-Experimentation," *Medical Hypotheses* 75, no. 6 (December 1, 2010): 482–89.

they learned.[62] By contrast, as I show in Chapter 2, home users of brain stimulation have never coalesced into a formal group, and there has been no official gathering of any kind.

Yet home users of brain stimulation share some of the same ethos as self-trackers: namely, they experiment on themselves, report their methods, and share their results (albeit on pseudonymous Internet forums, rather than in-person gatherings). However, home users focus narrowly on two forms of self-improvement—cognitive enhancement and/or self-treatment—using a single intervention, that of noninvasive brain neurostimulation. Self-trackers are interested more broadly in productivity, mood and performance. For them, an intervention is not always required—often insight can be gained merely by analyzing self-tracking data. There is likely overlap between the groups, and at least some self-trackers have also tried brain stimulation: Dave Asprey, a prominent figure in the lifehacking movement, included a direct-to-consumer brain stimulation device in a recent shipment to subscribers of his quarterly productivity package.[63]

DIY Biology & Citizen Science

A number of scholars and authors have written about do-it-yourself (DIY) biology, which is a movement of makers and tinkerers doing biology in kitchens and garages.[64] Alessandro

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[62] Kristen Barta and Gina Neff, "Technologies for Sharing: Lessons from Quantified Self about the Political Economy of Platforms," *Information, Communication & Society* 19, no. 4 (January 11, 2016): 518–31; Dawn Nafus and Jamie Sherman, "Big Data, Big Questions| This One Does Not Go Up To 11: The Quantified Self Movement as an Alternative Big Data Practice," *International Journal of Communication* 8, (June 16, 2014): 11.

[63] Dave Asprey, "The Fifth Biohacking Box - #BIO05," *Bulletproof*, February 2, 2016, https://blog.bulletproof.com/the-fifth-quarterly-biohacking-box-bio05/ (accessed December 29, 2016).

[64] See e.g., Sophia Roosth, "Crafting Life: A Sensory Ethnography of Fabricated Biologies" (Massachusetts Institute of Technology, 2010); Marcus Wohlsen, *Biopunk: Solving Biotech's Biggest Problems in Kitchens and Garages* (New York: Current Trade,

Delfanti describes the community, which cohered in 2008, as "not a formal organisation but rather an open brand that anyone can use for citizen science projects, coupled with a global mailing list where most discussions are conducted and decisions taken."[65] Sophia Roosth writes that the DIY biology movement blurs the line between academics and amateurs, as most individuals who do DIY biology are also part of an academic lab.[66] Others, such as Delfanti and Wohlsen, have characterized DIY biology as a more varied group, composed of artists, tinkerers, and scientists.[67]

In many ways, the home use of tDCS has much in common with DIY biology: both movements embody what has become known as the maker culture, which places a high value on tinkering, engineering, and creating things from scratch. For example, there are ongoing debates on the DIY biology list about what is considered "real" DIY: Roosth writes that once "an argument broke out about whether it was truly 'DIY' to order gel starter kits and other readymade products from biological supply companies."[68] Similar debates took place amongst home users of tDCS after the release of the first direct-to-consumer devices: those who purchased ready-made devices were derided for not doing sufficient "homework" to understand electrical circuitry.

2012).Alessandro Delfanti, *Biohackers: The Politics of Open Science* (London: Pluto Press, 2013); Heidi Ledford, "Garage Biotech: Life Hackers.," *Nature*, October 7, 2010, doi:10.1038/467650a; Ana Delgado, "DIYbio: Making Things and Making Futures," *Futures* 48 (April 1, 2013): 65–73; Morgan Meyer, "Domesticating and Democratizing Science: A Geography of Do-It-Yourself Biology," *Journal of Material Culture*, January 1, 2013, doi:10.1177/1359183513483912; Gabriela Alejandra Sanchez, "Exploring the Collective Identity of the DIYbio Movement" (Del University of Technology, 2014).

[65] Delfanti, *Biohackers,* 115.

[66] Roosth, C*rafting life.*

[67] Delfanti, *Biohackers*; Wohlsen, *Biopunk.*

[68] Roosth, C*rafting life*, 126-7.

But a deeper excavation of the underlying goals of each movement reveals fundamental differences. The primary goal of home users of brain stimulation, whether self-treating for depression or attempting to enhance their memory, is self-improvement. By contrast, the goal of DIY biology is more political in nature: DIY biologists talk about redistributing power and fundamentally revising the way that science is done.[69] A "biopunk manifesto" written by one DIY biologist asserts: "We the biopunks are dedicated to putting the tools of scientific investigation in the hands of anyone who wants them."[70] According to Delfanti, "right now citizen biology is not a site of research and innovation but rather of political, artistic, and educational experimentation."[71]

While in many ways the home use of brain stimulation is an inherently political act—against the scientific community's tendency to restrict knowledge and devices to a privileged few—the movement is characterized by a culture of deference and respect toward scientific institutions, as it is scientific knowledge that will ultimately help users achieve their self-improvement goals. But in DIY Biology, it is politics, not self-improvement, that takes center stage. As Roosth writes: "biohackers do not pursue or promote science as a path to personal improvement or refinement, but as a pleasure and a kind of political speech."[72] Thus while DIY biologists and home users of tDCS may appear rather similar at the surface level — in terms of what they talk about, how they talk about it, their reliance on science and their existence on the edges of it — their underlying goals are in fact quite different.

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[69] Ana Delgado and Blanca Callen, "Do-It-Yourself Biology and Electronic Waste Hacking: A Politics of Demonstration in Precarious Times," *Public Understanding of Science*, May 27, 2016, 1–16.

[70] Meredith L Patterson, "A Biopunk Manifesto," January 30, 2010, http://maradydd.livejournal.com/496085.html; quoted in Delfanti, *Biohackers,* 126.

[71] Delfanti, *Biohackers,* 115.

[72] Roosth, C*rafting life*, 112.

DIY Medicine

In recent years there has been an increase in grassroots do-it-yourself heath movements. DIY fecal transplants, for example, emerged when some patients learned of the promising results being reported in the scientific literature for using stool transplants to treat resistant *Clostridium difficile* (*C. Diff*) infections. Rather than waiting several years for this treatment to become FDA-approved, those who were suffering from *C. Diff* and other serious intestinal ailments began to conduct stool transplants at home.[73] Today, there are how-to websites, blogs, and videos related to the practice.[74]

Other examples of DIY medicine endeavors abound: for example, the "open pancreas project" began when tech-savvy parents who were frustrated with the lack of capabilities in their children's glucose monitors effectively "hacked" the devices to provide information wirelessly.[75] The "EpiPencil," which costs $35 to construct, was created by self-described "pharma hackers" in response to the dramatic price increase of the EpiPen in the fall of 2016; this same group has

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[73] William Kremer, "The Brave New World of DIY Faecal Transplant," *BBC News*, May 27, 2014, sec. Magazine, http://www.bbc.com/news/magazine-27503660; Arielle Duhaime-Ross, "In Search of a Healthy Gut, One Man Turned to an Extreme DIY Fecal Transplant," *The Verge*, May 4, 2016, http://www.theverge.com/2016/5/4/11581994/fmt-fecal-matter-transplant-josiah-zayner-microbiome-ibs-c-diff (accessed January 18, 2017).

[74] See, e.g., "Fecal Transplant At Home – DIY Instructions," *The Power of Poop*, accessed February 25, 2017, http://thepowerofpoop.com/epatients/fecal-transplant-instructions/ (accessed January 18, 2017).

[75] Joyce M. Lee, Emily Hirschfeld, and James Wedding, "A Patient-Designed Do-It-Yourself Mobile Technology System for Diabetes: Promise and Challenges for a New Era in Medicine," *JAMA* 315, no. 14 (April 12, 2016): 1447–48, doi:10.1001/jama.2016.1903; Kate Linebaugh, "Tech-Savvy Families Use Home-Built Diabetes Device," *Wall Street Journal*, May 9, 2016, http://www.wsj.com/articles/tech-savvy-families-use-home-built-diabetes-device-1462728637; Aaron Neinstein, "Diabetes Patients Design Their Own 'Artificial Pancreas,'" *Medscape*, April 21, 2016, http://www.medscape.com/viewarticle/862064 (accessed February 7, 2017).

also been championing the home synthesis of pharmaceutical drugs.[76] Although DIY medicine endeavors differ in their scope, they stem from growing societal frustration with the institutions of modern medicine, including the exorbitant price of pharmaceuticals and the glacial pace at which new therapies trickle down to patients.

As I show in Chapters 2 and 3, these sentiments characterize those who utilize tDCS for treatment. Indeed, one of the most striking findings of the survey reported in Chapter 3 was that nearly one-third of *all* survey respondents utilized tDCS to treat depression. Many of these individuals feel that modern medicine is out of touch with their needs, and they see in brain stimulation the promise of a cheap, readily available therapy that anyone can self-administer at home. Thus, in contrast to the "brain optimizers" who comprise roughly two-thirds of home users of tDCS, this population is utilizing tDCS at home because they are sick, have not found relief with medication, and harbor a deep-seated frustrated with modern medical institutions.

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Although here I have discussed neurohackers, biohackers, and lifehackers separately, it is important to note that there is fluidity amongst the terms: for example, some use "life hackers" and "biohackers" interchangeably to refer to DIY biology, whereas others use "biohackers" to refer only to those who physically modify their bodies for self-improvement purposes. Furthermore, those who use commercial wellness or self-tracking products—like the Muse EEG headset or a FitBit—may not self-identify with any kind of "hacking" movement.

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[76] "Meet the EpiPencil: The $30 DIY EpiPen Alternative Created By Pharma Hackers," *Tech Times*, September 22, 2016, http://www.techtimes.com/articles/178904/20160922/meet-the-epipencil-the-30-diy-epipen-alternative-created-by-pharma-hackers.htm; Anne-christine d'Adesky, "Was the EpiPen Hack Ethical?," *KQED Future of You*, accessed February 24, 2017, https://ww2.kqed.org/futureofyou/2017/01/23/was-the-epipen-hack-ethical/; "Our Mission," *Four Thieves Vinegar Collective*, https://fourthievesvinegar.org/our-mission (accessed February 14, 2017).

By providing context for the rise of the home use of brain stimulation and describing its parallels to concurrent cultural movements, this section has attempted to situate the phenomenon in its broader social milieu. Like "biohackers," home users source inexpensive versions of restricted laboratory tools for use at home; like "life hackers," they are primarily interested in self-improvement. Though the home use of noninvasive brain stimulation has received a significant amount of attention in both media outlets and scholarly journals, it remains a very small part of the overall "neurohacking" movement, wherein individuals aim to optimize their brain function. Thus, the home use of brain stimulation did not emerge from the ether, but rather arose from the confluence of DIY science and medical movements, neuroenhancement initiatives, and a culture of self-tracking.

IV. Research Methodology

My research methods included observations and interviews, content/document analyses, a survey, legal research, and archival work. Over the course of this dissertation, I also attended (and sometimes participated in) over a dozen meetings and conferences related to brain stimulation. My observations and interviews were focused primarily on home users of tDCS and neuromodulation researchers. I have also interviewed other groups of actors who have a stake in the controversy over tDCS, such as manufacturers of consumer tDCS devices, regulators, ethicists and policymakers. Recruitment of home users took place via email or direct message on the most active forum for tDCS home users. For interviews with manufacturers, ethicists, and scientists, I recruited them directly, most often via email. Most interviews took place via Skype

or phone, although several occurred in-person: at cafes, in the offices of device manufacturers, and in scientists' laboratories.

In addition to interviews and observations of tDCS home users, I analyzed forums, websites, blogs, and videos related to the home use of tDCS. Home users communicate pseudonymously on a Reddit forum, and there are several websites and blogs run by prominent home users. Thus, online content represented a rich repository for analysis, helping me understand the emergence of the tDCS home use movement and the progression from do-it-yourself devices to direct-to-consumer ones. As tDCS is very much a private endeavor, I did not have the opportunity to observe home users utilizing tDCS "in the wild." Although I have observed home users demonstrating the use of tDCS, they have done so in public spaces, and thus the act felt removed from the actual practice of stimulation. However, some of my most informative glimpses into the home use of tDCS have come from YouTube videos where individuals recorded themselves, in their own homes, applying tDCS; such videos afforded a deeply personal look into the private practices of stimulation.

To compliment interviews and content analyses, and to provide a demographic, statistical picture of the home use movement, my colleague Nicholas Fitz and I partnered with consumer tDCS device manufacturers to directly survey their use base. Seven companies who sell tDCS devices directly to consumers agreed to participate in the study on the condition of anonymity. In June 2016, emails were sent to companies' customer lists with a link to the online survey; a reminder email was sent after three weeks. Participants responded to between 40-80 measures about their tDCS device(s), use practices, beliefs, attitudes, and sociodemographics. The survey contained a mix of closed and open-ended responses. Three hundred and thirty-nine respondents completed the survey (and met inclusion criteria).

Although I do not have formal legal training, over the course of my graduate studies I took (and taught) several classes related to law, technology, and policy, and completed a reading seminar in law and science. To prepare for the specific analyses involved in medical device law, in January 2015 I audited Harvard Law School's "Food and Drug Law" class, which covered laws and regulations related to medical devices. In my resulting legal analyses (Chapter 4), I studied how both the FDA and courts have understood the FDA's jurisdiction over medical devices in cases where the definition of a "medical device" has been challenged. My research for the chapter also included interviews with numerous federal government officials (from the FDA and Consumer Product Safety Commission) as well as with state officials from the California Department of Public Health (CDPH), who forced a company to recall several hundred consumer tDCS devices in June 2013. In addition to these interviews, I obtained government reports via formal requests for information—such as a Freedom of Information Act (FOIA) request from the FDA—and informal inquiries to state officials.

My historical research on the home use of electrical brain stimulation devices in the late 1800s and early 1900s was comprised of several components. As a significant amount of literature related to electrical medicine and electrotherapy during that time period has been digitized, I conducted historical research online. I also made frequent use of the Google News Archive, which contains searchable magazines and documents about electricity from the late nineteenth and early twentieth century, as well as other sources, such as the Medical Heritage Library (http://www.medicalheritage.org/) and the Internet Archive (http://www.archive.org), which contain fully scanned books and catalogues related to electrotherapy in the late nineteenth century. In addition, I drew heavily on secondary sources, and reached out to several scholars to discuss my research.

The primary research for my historical chapters was conducted at two archives: the Bakken Museum (formerly known as The Bakken: A Library and Museum of Electricity in Life), in Minneapolis, Minnesota, and the American Medical Association's Historical Health Fraud Archives in Chicago, IL. The Bakken has an extensive collection of electro-medical trade catalogues from the late nineteenth and early twentieth century as well as a vault containing hundreds of historical electrotherapeutic devices. I spent three weeks at these archives, and will never forget the excitement of leafing through stacks of fragile, yellowed documents, and donning gloves to open century-old medical batteries. My time at the American Medical Association's Historical Health Fraud Archives was spent immersed in their extensive collection related to "medical quackery" in the early 1900s.

Over the course of my dissertation research, I participated in scientific tDCS meetings, consumer neurotechnology conferences, neuroethics and bioethics meetings, regulatory meetings, and policy workshops. I also attended (and received certification from) a two-day tDCS training session led by researchers. In addition, I spent one year as a visitor at the cognitive science department at the University of Pennsylvania, where my desk was located down the hall from several tDCS researchers. My regular interactions with tDCS researchers afforded me a deeper understanding of tDCS technology, experimental practices, and current debates within the tDCS literature.

In conducting this research, I have been something of a participant-observer, both presenting my ongoing research (on the home use of brain stimulation) to the broader academic community, but also continuously reflecting upon the very conferences and meetings that I have been attending. Over time, I have also earned a certain measure credibility amongst home users

of tDCS, which in turn allowed me to study them further (e.g., by partnering with consumer tDCS companies to survey their user base).

V. Chapter Outline

Chapter 2. The Practices of Do-it-yourself Brain Stimulation. Previous literature has highlighted the importance of two central themes for understanding the interaction between scientific professionals and lay individuals: (a) how ordinary members of the public engage with professional scientific researchers and interpret expert knowledge; and (b) the different ways of knowing between lay individuals and professional researchers. This chapter explores the practices of the home use of tDCS, addressing a series of questions related to these themes: How do home users of tDCS produce knowledge? How do they view, and interact with, existing scientific literature? What are their methods of analysis and "ways of knowing," and how do they cope with the methodological limitations inherent in self-experimentation? In this chapter, I show that when making or acquiring a device, home users of tDCS produce, document, and share their own body knowledge, through online forums, blogs, videos and personal communications. When it comes to using the device, home users of tDCS draw heavily on existing scientific knowledge, posting links to academic journal articles and scientific resources, and adopting the standardized electrode placement system used by scientists. They sometimes co-opt scientific knowledge and modify it by creating their own manuals and guides based on published papers. Interestingly, where there are "gaps" in scientific literature, home users of tDCS experiment and extrapolate; they create, document, and share a new body of self-produced knowledge, much like they do in the making/acquiring stage. Finally, when it comes to measuring the effects of tDCS,

home users interested solely in treatment seem to accept subject self-assessment (i.e., their "feelings") as validation, but there are others—mostly those who use tDCS for cognitive enhancement—who strive for some measure of validity: they want evidence of causality. These users often create their own "tests" of validity, which are personal, contested, and vary widely across the community.

Chapter 3. Surveying Consumers of tDCS Devices. Though the home use of noninvasive brain stimulation has been a subject of much discussion in the bioethics literature, many of the ethical concerns raised rely on unsubstantiated factual assumptions (Voarino et al. 2017), particularly regarding prevalence, efficacy, and safety. In this empirical study, my collaborator Nicholas Fitz and I found that while some issues identified in the bioethics literature—such as threats to autonomy due to the potential coerced used of tDCS, and issues related to authenticity—are less relevant and highly speculative, others, such as concerns about potential harm to home users and worries about distributive justice, are empirically supported. We found that home users who utilize tDCS for treatment rate it as significantly more effective than those who use it for enhancement/restoration, even though enhancement uses have comprised the main focus of debates in the bioethics literature. With regard to safety, we identified two primary concerns—skin burns and the unknown effects of the chronic use of tDCS—that should be the target of future research.

Chapter 4. A Pragmatic Analysis: The Regulation of Consumer tDCS Devices in the United States. In the ongoing debate in the bioethics and policy literature regarding the home use of tDCS, several scientists and neuroethicists have argued that there is a need for additional

regulation to cover consumer tDCS devices.[77] Missing from this literature advocating government regulation, however, are accounts that consider the practicalities of the law and how it would apply to existing and foreseeable consumer brain stimulation devices. Though an idealized albeit naive model of the law may envision all regulations as being consistently and equally enforced, a more realistic view takes into account the resource-constrained nature of government bodies, who must formally, and sometimes informally, prioritize regulatory enforcement and often do so in unclear or idiosyncratic ways. Thus, before calling for additional regulation or concluding that there is a "regulatory gap," as some authors claim, it must first be determined that the problem is the lack of regulation, not the lack of enforcement of existing state and federal law.

This chapter contributes to the literature on the regulation of consumer brain stimulation devices in the US by providing an empirical analysis of the consumer tDCS market and relevant laws and regulations. In the four main sections of this chapter I take into account (a) the statutory language of the Federal Food, Drug and Cosmetic Act and how the definition of a medical device—which focuses on the intended use of the device rather than its mechanism of action—is of paramount importance for discussions of consumer tDCS device regulation; (b) how both the Food and Drug Administration (FDA) and courts have understood the FDA's jurisdiction over medical devices in cases where the meaning of 'intended use' has been challenged; (c) an analysis of consumer tDCS regulatory enforcement action to-date; and (d) the multiple US authorities, other than the FDA, that can regulate consumer brain stimulation devices. Taken

[77] Veljko Dubljević, "Neurostimulation Devices for Cognitive Enhancement: Toward a Comprehensive Regulatory Framework," *Neuroethics*, November 12, 2014, 1–12; Hannah Maslen et al., "The Regulation of Cognitive Enhancement Devices: Extending the Medical Model," *Journal of Law and the Biosciences* 1, no. 1 (2014): 68–93.

together, this chapter demonstrates that rather than a "regulatory gap," there are multiple, distinct pathways by which consumer tDCS can be regulated in the United States.

Chapter 5. The Medical Battery in the United States (1870-1920): Electrotherapy at Home and in the Clinic. This chapter focuses on the history of a portable shock-producing electrotherapeutic device known as the medical battery (1870-1920), which provided both direct and alternating current and was thought to cure a wide variety of ailments. The product occupied a unique space at the nexus of medicine, consumerism and quackery: it was simultaneously considered a legitimate device by medical professionals who practiced electrotherapeutics, yet identical versions were sold directly to consumers, often via newspaper advertisements and with cure-all marketing language. Indeed, as I show in this chapter, the line between what was considered a medical device and a consumer product was often blurred. Even though medical textbooks and journals never mentioned (much less promoted) the home use of electricity, every reputable electrotherapy instrument manufacturer sold a "family battery" for patients to use on themselves at home. While a handful of physicians spoke out against the use of electricity by the laity—as they felt it undermined the notion of electrotherapy as a skilled medical procedure—existing evidence suggests that many physicians were likely recommending the home use of medical electricity to their patients. Thus, this chapter shows how the professional ideals of electrotherapeutics were not always aligned with physicians' actual practices.

Chapter 6. Recurrent Themes in the Home Use of Electrical Stimulation: tDCS & the Medical Battery. Although scientific literature on tDCS often notes the link between tDCS and early medical applications, such as the use of electric fish to treat gout and headaches in the Roman

Empire, mentions of the home use of electrical stimulation for treatment in the late nineteenth and early twentieth century are completely absent. Yet according to historians, between 1870 and 1915 there was a "heyday of public interest in electricity and electrotherapy"[78] in the United States and home-use galvanic shock machines were sold by both physicians and "quacks."[79] Similar to the present-day contestations over tDCS, the late nineteenth and early twentieth centuries saw controversies over the home use of electrical medicine. Who owned such technology, and who had the "expertise" necessary to utilize it? Strikingly, the rhetoric regarding the hopes for the future use of electrical stimulation—as a therapy that could be provided easily and cheaply in one's home to cure a wide variety of ailments—is almost identical to the rhetoric surrounding the modern-day use of tDCS.

This chapter situates the current controversy over tDCS within the larger context of the historical use of electrical medicine, with a particular focus on the late nineteenth and early twentieth century usages of home electrical brain stimulation devices. It reviews a number of features thought to be unique to the present day home use of brain stimulation, with a particular focus on analogies between tDCS and the medical battery. I show how many of the features characterizing the contemporary home use tDCS—a do- it-yourself movement, anti-medical establishment themes, conflicts between lay and professional usage—are a repetition of themes that occurred a century ago with regard to the medical battery. A number of features, however, seem to be unique to the present, such as the dominant discourse about risk and safety, the division between cranial and non-cranial stimulation, and utilization for cognitive enhancement

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[78] Timothy W. Kneeland and Carol A. B. Warren, *Pushbutton Psychiatry: A Cultural History of Electric Shock Therapy in America (Updated Edition)* (Walnut Creek, CA: Left Coast Press, 2008), 37.

[79] Carolyn Thomas de la Peña, *The Body Electric: How Strange Machines Built the Modern American* (New York: New York University Press, 2003), http://nyupress.org/books/9780814719831/.

purposes. Viewed in the long durée, I show how the contemporary use of electrical stimulation at home is not a novel phenomenon, but rather the latest wave in a series of ongoing attempts by lay individuals to utilize electricity for therapeutic purposes.

Chapter 7. Conclusion. In the final chapter, I summarize my main arguments, and highlight how the story I have told in this dissertation diverges from previous scholarship on electricity and medicine in that it is not about electrical medicine practitioners struggling for broader professional acceptance or fending off encroachments from irregular practitioners. Rather, what this dissertation has focused on is the "incursion" by lay individuals, as described in the practices of DIY tDCS, the regulatory issues surrounding consumer brain stimulation devices, the home use of the medical battery in the U.S. in the late nineteenth and early twentieth century, and a comparison of the medical battery to present-day uses of tDCS. While previous work, therefore, has focused on the struggles of electrical medicine practitioners, this dissertation has centered on the challenges presented to electrical medicine by lay users: a dispersed, informal set of individuals that have no formal relationship with one another.

CHAPTER 2

The Practices of DIY tDCS

The first time Anthony Lee stimulated his own brain with electricity, he recorded himself and posted the video on YouTube.[1] In it, he has what looks like ace bandages wrapped around his head, which hold up two wire-ends that dangle loosely in front of his eyes (**Fig 2.1.**). He connects the two wires to a homemade circuit board and looks directly into the camera. "I'm turning it on. Moment of truth!" There's a flick of a switch. Anthony's eyes appear to blink, or maybe twitch. He's frozen for a second or two, then gazes down and to the left, as if trying to gather the words to describe what just happened.

He begins to rapidly narrate his experience, giving a detailed play-by-play: "white flash, really brief, really quick… my pulse is kind of elevated, but that might be because of the placebo effect, I've been kind of excited about this day for a while…" At some point one of the wires detaches, so he reconnects it and turns the machine on again. "No white flash that time," he reports. "There's definitely current going through my skull, though. Aright, well, I'll keep you guys posted," he says, and the video ends.

Anthony, a thirty-three year old content writer based in Alabama, is a part of a loose-knit group of individuals who stimulate their own brains with electricity using a technology called transcranial direct current stimulation (tDCS), which provides a constant low current to the brain. Such individuals typically have one of two goals: enhancing their cognitive abilities or self-

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[1] Anthony Lee, *I Zapped My Brian With tDCS and LIVED!*, 2012. http://www.youtube.com/watch?v=I7nehK63Uk4 (accessed April 27, 2014).

treating a medical condition. They either build stimulation devices from scratch (sometimes with the assistance of video tutorials) or purchase commercially available models.

Unlike other electrical stimulation technologies used at home—many of which have been dismissed by the mainstream science and medical profession[2]—tDCS is firmly rooted in the scientific literature. As noted in the introductory chapter, nearly one thousand peer-reviewed studies have been published in scientific journals in the last decade. There are two main lines of tDCS research: studies that explore the effects of tDCS on treating a variety of diseases and disorders, and studies that examine its effects on cognition. The first line includes research that has claimed to show the beneficial effects of tDCS for treating schizophrenia, depression, chronic pain, stroke, Parkinson's disease and even eating disorders.[3] The second line is comprised of studies showing that tDCS can enhance learning and cognition in healthy individuals, on tasks requiring working memory, motor skills, mathematical ability, motor dexterity, perception, and creative problem solving.[4] To experiment with tDCS, accredited academic or medical researchers, whom I refer to here as "professional researchers," must comply with formal, institutional regulations. Professional researchers have not taken kindly to the home use of tDCS and have warned of its risks both in the popular media and in scientific articles. They have attempted to police the boundaries of tDCS by calling its use by lay individuals "fringe" or "unorthodox."

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[2] Pehr Granqvist et al., "Sensed Presence and Mystical Experiences Are Predicted by Suggestibility, Not by the Application of Transcranial Weak Complex Magnetic Fields," *Neuroscience Letters* 379, no. 1 (April 29, 2005): 1–6.

[3] Andre Russowsky Brunoni et al., "Clinical Research with Transcranial Direct Current Stimulation (tDCS): Challenges and Future Directions," *Brain Stimulation* 5, no. 3 (July 2012): 175–95.

[4] Brian A. Coffman, Vincent P. Clark, and Raja Parasuraman, "Battery Powered Thought: Enhancement of Attention, Learning, and Memory in Healthy Adults Using Transcranial Direct Current Stimulation," *NeuroImage*, Neuro-enhancement, 85, Part 3 (January 15, 2014): 895–908.

The home use of tDCS is certainly not the first instance where "lay" individuals have closely engaged with knowledge produced by professional researchers. For example, in the 1980s gay activists groups became "experts" in the technical, scientific literature on anti-AIDS drugs—and in doing so, gained sufficient credibility in the eyes of scientists to influence the direction of medical research.[5] In another example of the interaction between lay individuals and professional researchers, scholars have documented how members of the French association of muscular dystrophy effectively became "researchers in the wild" by collecting knowledge from their own members (via surveys, photographs, and other documentation) about their condition.[6] Members of the association shared this data with laboratory scientists, and in some cases the two groups—scientists, who were the "technical experts," and patients, who were the "experts of experience"—worked together collaboratively on research endeavors.[7] Other examples of lay individuals influencing the direction of medical research include Vietnam veterans who fought for recognition of post-traumatic stress disorder[8] and the transformation of sudden infant death syndrome (SIDS) into a pressing medical research question.[9]

Yet patient or lay initiatives do not always succeed in influencing a research direction or political outcome. For example, one sociologist documented the failed attempts by patients in the

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[5] Steven Epstein, "The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials," *Science, Technology & Human Values* 20, no. 4 (October 1, 1995): 408–37; and Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (Berkeley, Calif.: University of California Press, 1996).

[6] M. Callon and V. Rabeharisoa, "Research 'in the Wild' and the Shaping of New Social Identities," *Technology in Society*, Studies in Science, Technology, and Society (STS) North and South, 25, no. 2 (April 2003): 193–204.

[7] Ibid.

[8] Wilbur J. Scott, "PTSD in DSM-III: A Case in the Politics of Diagnosis and Disease," *Social Problems* 37, no. 3 (August 1, 1990): 294–310, doi:10.2307/800744.

[9] Michael P. Johnson and Karl Hufbauer, "Sudden Infant Death Syndrome as a Medical Research Problem Since 1945," *Social Problems* 30, no. 1 (October 1, 1982): 65–81, doi:10.2307/800185.

UK to achieve recognition for the condition known as Repetitive Strain Injury (RSI).[10] In attempting to understand why their efforts were ultimately fruitless, she suggested that medical and scientific knowledge could only be challenged from within: either when lay individuals become experts in technical knowledge, or when they form alliances with professional researchers.[11] Indeed, more recently, in an examination of four different patient groups in four countries, several scholars put forth the term "evidence-based activism" to capture how rather than contesting institutions from the outside, it is becoming more and more common for patient organizations to "work 'from within' to imagine new epistemic and political appraisal of their causes and conditions."[12]

A related approach has been to study how lay individuals and professional researchers differ in their "ways of knowing." As one scholar put it: "the emphasis on ways of knowing makes sense because knowledge is often what is debated in struggles to win ownership of a social problem."[13] For example, an examination of the differences between lay and professional ways of knowing about environment-related health hazards[14] in Woburn, Massachusetts, revealed that community groups and scientists fundamentally differed on what they considered to

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[10] Hilary Arksey, "Expert and Lay Participation in the Construction of Medical Knowledge," *Sociology of Health & Illness* 16, no. 4 (September 1, 1994): 448–68.

[11] Ibid., 463.

[12] Vololona Rabeharisoa, Tiago Moreira, and Madeleine Akrich, "Evidence-Based Activism: Patients', Users' and Activists' Groups in Knowledge Society," *BioSocieties* 9, no. 2 (June 2014): 111–28, doi:10.1057/biosoc.2014.2.

[13] Phil Brown, "Popular Epidemiology and Toxic Waste Contamination: Lay and Professional Ways of Knowing," *Journal of Health and Social Behavior* 33, no. 3 (September 1992): 268, interpreting the work of Joseph Gusfield. Joseph R. Gusfield, *The Culture of Public Problems: Drinking-Driving and the Symbolic Order* (Chicago: University of Chicago Press, 1984).

[14] Phil Brown, "Popular Epidemiology and Toxic Waste Contamination: Lay and Professional Ways of Knowing," *Journal of Health and Social Behavior* 33, no. 3 (September 1992): 267.

be legitimate methods of analysis, what they thought constituted "quality data," and what they believed to be accepted statistical significance levels, among other factors.

Taken together, the previous literature has highlighted the importance of two central themes for understanding the interaction between lay individuals and scientific professionals: (a) whether and how lay individuals interact with professional researchers (and scientific or "expert" knowledge); and (b) differences in "ways of knowing" among lay individuals and professional researchers. Thus, the present chapter explores the practices of the home use of tDCS and addresses a series of questions related to these themes: How do home users of tDCS produce knowledge? How do they view, and interact with, existing scientific literature? What are their methods of analysis and "ways of knowing," and how do they cope with the methodological limitations inherent in self-experimentation?

The present chapter extends the literature in a number of ways. First, while previous work has, for the most part, examined lay knowledge at it relates to *patient* populations (or those whose health may have been adversely affected by environmental pollutants), home users of tDCS are partially comprised of *healthy* individuals interested in enhancing their cognition. Second, while social scientists have studied how lay individuals work to gain credibility and thereby influence a larger political outcome or research direction, the case at hand concerns lay individuals who utilize scientific knowledge with the primary aim of self-improvement. Third, while previous work has focused mainly on engagement with scientific literature or data-gathering initiated and conducted by a specific population, the home use of tDCS centers on a specific experimental *intervention*—transcranial brain stimulation—being performed on oneself. Finally, because home users and professional researchers utilize an identical technology—sometimes even the same brand and model of tDCS stimulation device—the present study allows

for the examination of "lay" and "expert" groups who use a single technology in parallel but in widely divergent ways.

This chapter is based on semi-structured interviews with home users of tDCS, extensive observations of the main online forum where members communicate, and analyses of videos, websites, and blogs related to the home use of tDCS. It presents the first exploration of the practices of home users of tDCS, with a focus on knowledge that is formed, shared and appropriated within it. I begin by providing a brief description of home users of tDCS. The main part of my analysis centers on three stages of the home use of tDCS: making/acquiring a device, using the device (i.e., applying stimulation), and measuring its effects. It should be emphasized that these are my own categories, not distinctions made by the users themselves, and correspond to a rough chronology of stages that a user encounters after deciding to use tDCS. First, a user must source a stimulation device, either by constructing it from scratch or by purchasing a ready-made product. Second, a user must figure out how to apply stimulation for an intended purpose. Third, a user must assess whether the device has had any kind of meaningful effect. Though these categories are not neat and there is certainly some overlap across them, they are conceptually useful for understanding the home use phenomenon.

Home users of tDCS

Who are the people known as home users of tDCS? The question is not a simple one to answer, as there is no formal organization or group dedicated to tDCS. To complicate the matter, the most active nexus of interaction among home users of tDCS is an online forum dedicated to tDCS on Reddit.com. On the forum, individuals are identified by self-created usernames (known

as "flairs"), which most often do not contain an individual's actual name. Clicking on an individual's flair yields a detailed history of their postings to all Reddit forums, but there is no profile page displaying a self-description or demographic information. To the best of my knowledge, home users of tDCS have yet to convene in a non-virtual arena (though there have been at least several instances of local members of "hackerspaces" meeting to experiment with tDCS). Indeed, the home users I interviewed—all relatively high-profile members of the community—said that they had not met another home user in person. Thus, the home use of tDCS is simultaneously private, as stimulation is most often done in the seclusion of one's home, and public, as an individual's forum posts are visible to any casual Internet user.

The vast majority of tDCS websites, blogs and videos are created by males, and I have watched videos from, or spoken to, those ranging in age from late teens to early 60s. The phenomenon seems to be global: on the DIY tDCS Facebook group and other websites where users list their location, I have counted users from over three-dozen countries around the world.[15] There are at least a handful of members of the Reddit tDCS forum whose posts have made it clear that they are involved in neuroscience research at a graduate or post-doc level. There are other users who have a good deal of electrical engineering expertise; some have indicated that they have professional experience in the field. However, a large number of posts seem to come

[15] I viewed websites and/or profiles from users who had listed their current location as one of the following: Australia, Belgium, Bosnia, Brazil, Canada, Chile, China, Croatia, Czech Republic, Denmark, Finland, France, Germany, India, Iran, Israel, Italy, Japan, Malaysia, Mexico, Namibia, Netherlands, New Zealand, Norway, Pakistan, Palestine, Peru, Philippines, Poland, Russia, Serbia, Singapore, Slovenia, Sweden, Spain, Turkey, Uganda, United Kingdom, and United States. In addition, several other members appeared to be from Croatia, Japan, Romania, and Slovenia (judging by the language used and the groups they were members of) but I excluded them from the list as they did not have a publicly listed location. Note that I have not verified locations with each individual user. However, for the most part, Facebook use is not anonymous. Even if a handful or members have lied about their location (or have since moved), the enumeration here provides preliminary evidence that the home use of tDCS is a relatively global phenomenon.

from those without engineering or neuroscience backgrounds. A recent survey published in *Brain Stimulation* provides initial validation that neuroscientists are, for the most part, not involved in using tDCS on themselves.[16] (Further information about the demographics of home users of tDCS is presented in Chapter 3, which discusses the results of an online survey of consumers of tDCS devices.)

Making/Acquiring a tDCS Device

When Anthony Lee learned that tDCS could be used for cognitive enhancement, he emailed several neuroscientists, asking for more information about the technology. The response was overwhelmingly negative. Most scientists did not reply, and those who did told him there was "no magic pill" for the brain. "They shunned me entirely," he said. "That's partly what motivated me, just 'cuz I thought, well, I could figure this stuff out on my own. All I need is help with the electronics stuff."[17]

For members of the academic and research community, obtaining a tDCS device is not a major obstacle: they can purchase devices from several companies, such as Soterix (USA), StarStim (Spain), and neuroConn (Germany). In the US, tDCS devices manufactured by those companies are considered investigational devices under the Food and Drug Administration (FDA), and therefore can be sold to researchers but not to the general public. Some researchers, unable or unwilling to pay $4,500-11,000 for the tDCS device from the above-mentioned companies, purchase an iontophoresis device, a handheld machine prescribed for individuals

[16] Yuichiro Shirota, Manuel Hewitt, and Walter Paulus, "Neuroscientists Do Not Use Non-Invasive Brain Stimulation on Themselves for Neural Enhancement," *Brain Stimulation*, March 4, 2014.

[17] Interview with Anthony Lee, conducted March 26, 2014.

with hyperhydrosis (excessive sweating) that can deliver a constant current. Iontophoresis devices, which are available to the public (no prescription necessary), retail for approximately $300-400 and can be modified for tDCS use.

Home users of tDCS, on the other hand, lack the research credentials to obtain a medical device from the above-mentioned companies. Thus, one of the primary topics of conversation on the Reddit tDCS forum is the construction, modification, or acquisition of a tDCS device. Here, I outline the device options available to a home user (see **Table 2.1** for summary).

The cheapest but most difficult option is to construct the device on one's own with the help of various online tutorials, which vary in level of detail, ease, and quality of function of the resulting device (e.g., more sophisticated devices include components that can regulate or measure current). On YouTube, the two top video tutorials (one from Anthony Lee) have tens of thousands of views and hundreds of comments. On forums, blogs, and websites, users post descriptions and diagrams of their self-built devices. They document and share their experiences, and often post images of the final product. Occasionally a user less versed in electrical knowledge will post a device schematic and asked the community to review it. There are frequent message board discussions about fuses, voltages, electrodes, resistors, diodes, transistors, and regulators.

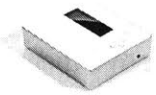
Type of device	**SELF-BUILT**	**TDCS DEVICE "KIT"**	**IONTO-PHORESIS DEVICE**	**DEVICE DESIGNED FOR TDCS**	**DIRECT-TO-CONSUMER HEADSET**
					
Description	Diagrams and how-to videos are available online; schematics vary. Construction requires some amount of electrical knowledge.	Often made by individuals involved in DIY tDCS community; some kits require more assembly than others.	Can be purchased without prescription but requires slight modification for tDCS use.	One of earliest and most expensive models. Marketed directly for tDCS; requires no modification	Headsets have fixed electrode design, but some allow for placement variation
Marketed for	N/A	Varies; website often explicitly says kit is "not a medical device."	Hyperhydrosis (excessive sweating)	Website notes that research has found benefits of tDCS for treating disease and enhancing cognition	Cognitive, mood, or athletic enhancement
Cost	$30-50	Varies, $40-185	$300-400	$379	$249 + $49 for extras pack
Manufac-turer	Oneself	Over a dozen different manufacturers as of April 2016	ActivaTek (Activa Dose II), Chattanooga Medical Supply, Inc. (Chattanooga Iontophoresis System)	TCT Technologies; registered in Hong Kong but ships worldwide	Foc.us and Halo Neuroscience. Thync manufactures a variation of tDCS.

Table 2.1 Types of devices that home users can make or acquire.

A second way of acquiring a device is to buy a tDCS device kit. Although tDCS kits range in price and vary in level of sophistication, thy usually consist of some kind of 9V battery enclosure (or a snap connector that the battery attaches to), electrodes, headbands, and sometimes wires. The websites selling these devices often explicitly state that the products are not medical devices. Indeed, there is an emphasis on the "kit-like" nature of the device, which sometimes requires that users purchase the electrodes and other parts separately. In 2012 and 2013, Daniel Flynn*[18] sold a tDCS device kit, which was more kit-like than those of his competitor as it required users to assemble the actual battery enclosure, not just attach electrodes. By designing and marketing his product in a "disassembled" way, Daniel told me that he believed he was putting some degree of separation between his product and what could be construed as a "medical device" (and therefore regulated by the FDA). Though the federal government has yet to crack down on sales of DIY tDCS "kits," in June 2013 the California Department of Public Health shut down one California-based company that was selling kits on www.tdcsdevicekit.com (see Chapter 4 for detailed discussion).[19]

On the Reddit forum, users write reviews of the kits and share device specifications, which are not always provided by the manufacturers themselves. Sometimes the person selling the device is an active forum member: Daniel, for example, posts frequently to the forum, even though he is no longer selling his kit. Purely self-promotional posts by the makers of these devices are considered to be in bad taste and can be deleted by the forum's moderators.

A third way to acquire a tDCS device is to buy an iontophoresis machine, described above, which has the advantage of a digital display that indicates the current level. The two most

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[18] Name changed to protect identity.

[19] "CDPH Warns Consumers Not to Use TDCS Home Device Kit," June 28, 2013, California Department of Public Health, http://www.cdph.ca.gov/Pages/NR13-029.aspx

talked-about on the Reddit forum are the Activa Dose II and the Chattanooga Iontophoresis System; both retail for about $300-400 but need to be slightly modified and repurposed for tDCS use.[20] On the Reddit forum and on websites related to tDCS, users post suggestions for optimal modification components, which include sponge electrodes, banana plugs, saline solution, and headbands to suspend the electrodes against the head. Home users also suggest methods of getting cheaper iontophoresis devices—Anthony Lee ended up ditching his home-constructed stimulator for the Chattanooga system, which he bought for $65 on eBay.

A fourth option is to purchase a slightly higher-end device that is specifically marketed as a tDCS device, which comes with all the necessary parts for tDCS use and requires no repurposing or modification.[21] Once such device is sold by Hong Kong-based Transcranial Technologies ($379). The device is similar in appearance to the iontophoresis machine—a small square box that displays the current level—but comes with electrodes, cables, and a neoprene headband set specifically made for tDCS. The company has four well-written, detailed manuals on its website that are considered to be excellent guides, and frequently linked to, by home users of tDCS.[22] Unlike the manufacturers of the lower-end kits, who are often present and visible on the Reddit tDCS forum, manufacturers of these devices generally do not publicly post on the forum or interact with the community in an open way.

A fifth option for acquiring a tDCS device is to buy a direct-to-consumer headset that has a fixed electrode position. One example available is the foc.us v1 ($249), which is ostensibly

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[20] "Activa Dose II Controller Ionto Device," http://www.scriphessco.com/products/activa-activadose-ii-iontophoresis-device/; "Chattanooga Ionto Iontophoresis System," http://www.scriphessco.com/products/chattanooga-ionto-iontophoresis-system/ (accessed April 29, 2015).

[21] "Trans-Cranial Technologies," http://www.trans-cranial.com/ (accessed January 9, 2015).

[22] "Manuals," Trans-Cranial Technologies, http://www.trans-cranial.com/manuals accessed January 9, 2015).

marketed to gamers, with taglines such as "overclock your brain" and "make your synapses fire faster." With its neat, minimalist design, the foc.us looks more like Google Glass than a device soldered together using parts from a hardware store. The website states that the "foc.us gamer headset offers no medical benefits, is not a medical device, and is not regulated by the FDA." Many home users were disappointed when the headset first came out, because the fixed electrodes were located on the forehead, and not above common stimulation sites for learning or depression. However, users can purchase a foc.us "extras pack" that comes with an extra cable that allow for more flexible electrode positioning, and more recent devices from the same company have provided more flexibility in positioning.

When the Foc.us first came out in the middle of 2013, bloggers and home users excitedly reviewed the device and shared their experiences. However, excitement dampened soon afterward, largely due to reports of side effects by users. Some users posted pictures of superficial burns—quarter-size red circles on the forehead—and others have reported significant skin irritation. In response to the safety issue, the Reddit forum moderators pinned a thread to the top of the forum, calling on users to share their experiences: "Important: Potential safety issues with the foc.us device. Update here!"[23]

Some home users have had the same reaction to the Foc.us as professional researchers: that is, they are weary of making tDCS available to those without the requisite electrical knowledge. One user wrote on the forum that the Foc.us "appeals to end users due to its simplicity and apparent ease of use, which encourages people to just slap the thing on without

[23] "PSA: Potential safety issues with foc.us device. Update here!" *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/1y5otr/psa_potential_safety_issues_with_the_focus/ (accessed January 9, 2015).

paying attention to exactly where it should go and how to use it properly."[24] Later, s/he added: "casual users with a casually designed device is just asking for trouble..." Even before the release of the foc.us, new users were encouraged to "do their homework." After one user posted that s/he "hacked together a real quick device" that burned, another user responded: "A little reading would have saved you time and pain. Build on the information available."[25]

Thus, it seems that at least some users construe electrical knowledge as a kind of barrier to the home use of tDCS: immerse yourself in the resources, put in the effort to learn, and then you can join the club. Anthony told me that when new users contact him, he directs them to the resources listed on the Reddit tDCS sidebar and tells them "to pore through" all the links. Indeed, Anthony seemed to take pride in the fact that he taught himself electronics and built his first tDCS device on his own.

But the knowledge available to new users is "messy:" as of yet, there is no single guide or "how to" manual for the home use of tDCS. Instead the knowledge is dispersed in an incomplete way across forums, websites, videos and files. There is a FAQ on the Reddit forum but the greatest repository of knowledge seems to be the Reddit posts themselves, which are not organized topically but rather are displayed in rough chronological order. To find information about tDCS on the Reddit, one has to either read backwards chronologically or do a keyword search (which, in my experience, has not always yielded accurate results). This forum knowledge is constantly in flux, as users create, build, modify, document, share and interact with one another.

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[24] "First time using Foc.us: saw bright white flash, passed out momentarily. Help." https://www.reddit.com/r/tDCS/comments/1y1vlz/first_time_using_focus_saw_bright_white_flash/ (accessed April 18, 2014).

[25] "Simple tDCS experience," *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/23chxb/simple_tdcs_experience/ (accessed January 9, 2015).

In this sea of information, several individuals and websites stand out: Anthony Lee has over a dozen tDCS videos and websites on YouTube, and is an active, recognizable member of the forum. The website DIYtDCS.com is often the first thing that comes up when one Googles "tDCS" and the man behind it is also an active forum member. And a user named Brent Williams has a subsection of his website, speakwisdom.com, devoted to tDCS, and is also an active forum member. Because of their public visibility, these individuals have become recognizable figures in the "DIY tDCS" world, and are sometimes the first stop for potential tDCS users. Though they do not self-identify as "experts," by virtue of their experience and visibility, they are sought out for guidance.

Anthony told me that in addition to the hundreds of comments he receives on his videos, he gets "tons" of personal messages. And when he was first learning about tDCS, he benefitted from personal communications: he sent his questions to someone named Oleg, who had one of the earliest websites that contained diagrams and photos of tDCS devices. As Anthony put it: "I just kept emailing him, 'hey, if I do this, will it kill me? Hey if I do this, will it do what I want it to do?' and through his help eventually I converted an Electronics Learning Lab into a tDCS device."[26] Now Anthony himself has become a personal connection for others entering the DIY tDCS world. Indeed, especially when it comes to new users, personal messages seem to be a main method of sharing knowledge. Interestingly, the majority of this personal communication takes place exclusively online, mostly among users who have never met each other in person.

At this stage, the knowledge produced by home users of tDCS is completely separate from that produced by the scientific community, for whom the acquisition of a device does not

[26] Interview with Anthony Lee, conducted March 26, 2014.

present a major barrier. As I will show in the next section, an entirely different kind of knowledge production takes place at the next stage of the process.

Using tDCS

After sourcing a tDCS device, home users must make a number of decisions: what are their goals of stimulation (e.g., treating depression, improving learning)? Where should they place the electrodes, and how precise do they want to be in their placement? How much current should they apply? How many minutes should the stimulation session last for, and how often should they conduct sessions?

In using the device, home users of tDCS draw heavily upon scientific knowledge, especially when discovering whether a montage exists for their specific disorder or enhancement goal. On the Reddit tDCS forum, members frequently link to published scientific journal articles as well as popular news reports. When an academic article is behind a pay-wall, users sometimes post an unrestricted copy of the article.[27] Home users also make use of resources geared towards professionals, such as the video tutorial on electrode positioning and montage created by several prominent tDCS researchers and published in the *Journal of Visual Experimentation*.[28] Scientific review articles are particularly appealing to home users of tDCS as they often provide broad

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[27] "tRNS: Random Noise Stimulation Improves Neuroplasticity in Perceptual Learning," *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/qntv1/trns_random_noise_stimulation_improves/ (accessed February 17, 2015).

[28] DaSilva, A. F., Volz, M. S., Bikson, M., Fregni, F. Electrode Positioning and Montage in Transcranial Direct Current Stimulation. *J. Vis. Exp.* (51), e2744, doi:10.3791/2744 (2011). Retrieved from: http://www.jove.com/video/2744/electrode-positioning-montage-transcranial-direct-current (accessed January 9, 2015).

overviews of the medical conditions that have been successfully treated by tDCS or the cognitive functions that have been enhanced by it.

Because the scientific literature reports electrode placement locations in the 10-20 system (see **Figure 1.2** in the previous chapter), users have adopted this system as well, as it allows them to replicate the electrode placement used in scientific tDCS studies. Some users are more precise than others with their placement, using a tape measure (or rulers and string) to carefully measure the distances, in centimeters, between various landmarks on the head. Others are less concerned about the accuracy of their placement, and after obtaining a general idea of location from montage diagrams, experiment with the position that works best for them. Several users have built cap-like tDCS devices that can easily be put on the head, so that they do not have to measure and place the electrodes prior to each tDCS session.

Another area where home users of tDCS closely follow scientific precedent is in the current level. Scientific studies use between .5 and 2 milliamps of current, which is the maximum level currently deemed safe by the neuroscience community. Currents higher than 2 milliamps have been reported to be uncomfortable for subjects due to tingling. Home users generally adhere to these standards as well, and the hand-built "kits" provide up to 2 milliamps of current.

Sometimes home users co-opt and appropriate scientific knowledge, producing their own body of work based on scientific publications. For example, one home user of tDCS compiled a document of over 400 abstracts about tDCS.[29] Another user, frustrated that information about montage placements was scattered across the Reddit tDCS forum and the Internet, recently put

[29] Daily, Douglas. "Transcranial Direct Current Stimulation - Selected Abstracts." Revised July 3, 2011. http://dl.dropboxusercontent.com/u/27418725/tDCS%20Abstracts%20-%20July%202011.pdf (accessed January 9, 2015).

together a simple website called "tDCS placements" that features simple montage diagrams in a clean, easy-to-browse format (**Fig 2.1.**).[30] Thus, home users transform existing scientific knowledge and diagrams into user-friendly indexes and guides that are geared towards their needs.

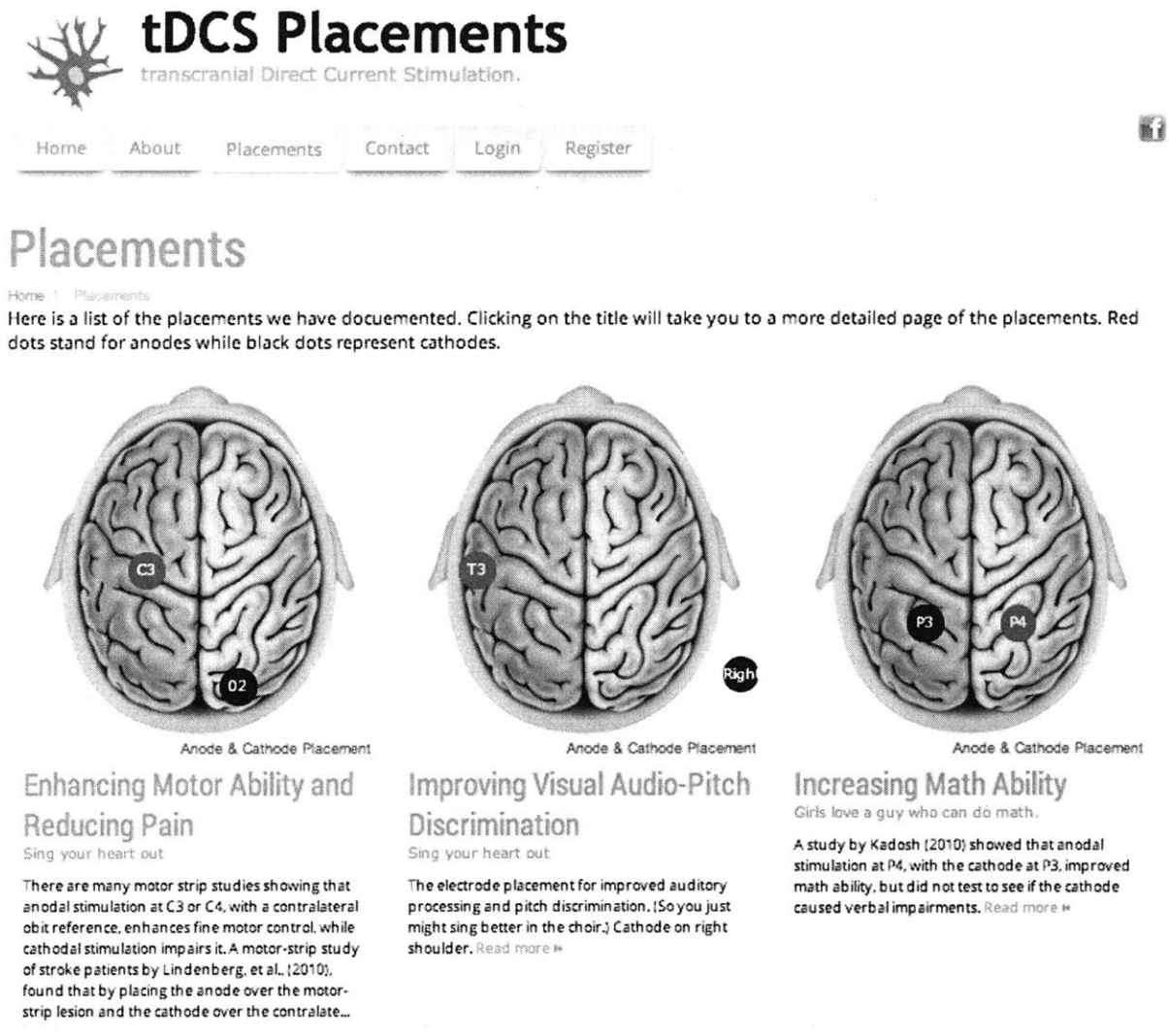


Figure 2.1. Screenshot from www.tDCSplacements.com, which features diagrams of tDCS montages.

[30] "tDCS Placements." http://tdcsplacements.com/ (accessed February 17, 2015).

But there are several points where the existing scientific literature does not extend far enough to cover the knowledge desired by home users of tDCS. Put another way, there are "gaps" between the edges of scientific knowledge and the kind of knowledge home users desire. One such "gap" is with regard to session length and frequency. Scientists and researchers, constrained by Institutional Review Boards (IRBs) and formal regulations, have mostly limited tDCS stimulation on subjects to one 20-minute session every 48 hours, though there are (rare) exceptions to this standard. In addition, studies have not yet been conducted on long-term use of tDCS. One frustrated user wrote on the Reddit forum that "most studies never measured 'the point at which it [tDCS] stops working.'"[31] His (or her) comment cuts to what lies at the heart of the issue for many home users: why limit tDCS, like the scientists do, to one 20-minute session once every other day? Wouldn't an hour (or more) of stimulation each day provide more effective cognitive enhancement or medical treatment?

To some extent, home users have a point: the scientific cut off point for length/frequency is somewhat arbitrary, as no studies have found *adverse* effects with longer or more frequent sessions. They have just found significant effects with their existing protocol. Why haven't scientists experimented with longer and more frequent sessions? There are likely a few reasons. First, although scientists have many goals when carrying out an experiment, one of their primary goals is knowledge-making (not self-improvement): therefore, a finding of significant effects is a reasonable end point. Second, because the effects of longer and more frequent sessions of tDCS are unknown, such studies are likely considered riskier and therefore less likely to obtain approval from IRBs, not to mention consent from the subjects themselves. Third, there are

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[31] "How long DO the effects of tDCS last?," *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/123kkz/how_long_do_the_effects_of_tdcs_last/ (accessed December 28, 2014).

funding considerations: longer studies are more expensive. Fourth, studies on learning, by their nature, are often short: researchers try to isolate and measure the acquisition of specific tasks or skills, which are usually gained in a matter of days or weeks, not months or years. Finally, the technology is relatively new, so while there are a few longitudinal tDCS studies for mental conditions in progress (e.g., depression, post-traumatic stress disorder), they have yet to be published.

Home users of tDCS are not limited by the same constraints as the scientists: they do not deal with IRBs or funding, nor is their primary goal to make knowledge. They want to push the limits—to learn the fastest, to self-treat in the most effective way possible—and so they experiment with longer and more frequent sessions. Anthony used tDCS for one hour each day as he tried to learn German, until his girlfriend had a baby and he no longer had the time to continue. Another user reported doing 90 minutes of stimulation, five days a week, for cognitive training purposes.[32] Much like they do when making/acquiring a device, home users create and share their own body of knowledge about optimal protocols. Thus, in contrast to other stimulation parameters utilized in professional tDCS research studies (such as maximum current level and electrode placement), when it comes to session length and frequency, users do not strictly adhere to scientific standards.

A second point where scientific knowledge breaks down for home users is the lack of scientific literature on a wide-enough variety of disorders. From a scientific standpoint, the rate of publication of tDCS studies is extraordinarily rapid. At a September 2013 tDCS conference, one well-known researcher commented that there "there's a paper coming out every day" [about

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[32] "Cognitive Training and tDCS," *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/23o1g2/cognitive_training_and_tdcs/ (accessed January 9, 2015).

tDCS].[33] But to those outside the academic community—and especially to individuals suffering from a debilitating disorder—the progress can seem downright glacial, especially for such a promising technology. In a comment about the value of experimentation, Anthony Lee wrote: "Sometimes waiting for academia to take interest and do testing takes too long."[34]

Indeed, where scientific literature is lacking,[35] home users sometimes take matters into their own hands: they experiment, try different montages, and document the results. For instance, one user posted on the subreddit that he "extrapolated" from a scientific finding about tDCS on depression to self-treat his bipolar disorder.[36] And another self-treated for seasonal affective disorder (SAD) and generalized anxiety disorder (GAD), for which tDCS has not been shown to be effective.[37]

But how do they know if tDCS stimulation is working? Do they adopt scientific methodology to test their results, or do they turn to other ways of knowing? In the next section I discuss how users measure and track the results of their self-experimentation.

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[33] *Cellular Mechanisms of Transcranial Direct Current Stimulation (tDCS)*, 2013. http://www.youtube.com/watch?v=WPE7mU3myfk&feature=youtube_gdata_player. (accessed January 9, 2015).

[34] Strickland, Eliza. "The Latest DIY Craze: Brain Hacking." IEEE Spectrum, Mar 14, 2014, http://spectrum.ieee.org/geek-life/reviews/the-latest-diy-craze-brain-hacking# (accessed January 9, 2015).

[35] Note that there is a publication bias here: while there may be studies conducted on the efficacy of tDCS for 30 different conditions, only the ones with significant results are likely to get published.

[36] "tDCS for depression?" Reddit /r/tDCS. http://www.reddit.com/r/tDCS/comments/227e2h/tdcs_for_depression/ (accessed January 9, 2015).

[37] "How would you describe your experience with tDCS?" *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/1red4v/how_would_you_describe_your_experience_with_tdcs/ (accessed February 17, 2015).

Measuring the effects of tDCS

The main experimental limitation for home users of tDCS is, of course, the fact that there is a sample size of one. Before delving further into the methodological constraints, it is worth taking a brief detour to understand how scientists construct validity in tDCS experiments, which are conducted on multiple subjects to ensure a constant result across varied populations. Study designs vary widely, but almost all make use of "sham" stimulation, which is the tDCS equivalent of a placebo, wherein a subject is set up for a regular tDCS session, but no current is passed through the device (except for up to a minute at the beginning of the session to mimic the sensation of a real session).[38]

Some tDCS studies are "double-blind sham-controlled," where both the subject and the experimenter administering tDCS are not aware of who received the stimulation and the sham. Others are single-blind, where only the subjects are unaware if they received the stimulation or the sham. Some clinical studies use a treatment group instead of a sham group, and compare the results of standard treatment to the results of tDCS. Others studies have within-subject designs, where, for example, a single individual is given both sham and tDCS at different sessions, and their performance is measured on a given task. In within-subject designs, the order of conditions is usually counterbalanced across subjects (e.g., half the subjects receive the sham first and the tDCS second, and vice versa). Although studies often incorporate more complex variations on

[38] Scientific tDCS studies have found that after approximately one minute of stimulation, users adapt to the sensation of current and do not experience tingling sensations. Thus, most of the sham settings on tDCS devices initially provide 30 second to one minute of current. Such a short amount of stimulation is unlikely to affect the outcome, as no significant effects of tDCS stimulation have been found with less than five minutes of current stimulation.

these designs, an experimental control is crucial to establishing the validity of all professional tDCS research.

How, then, do home users interested in cognitive enhancement attempt to validate their results? Those interested in tDCS for self-treating a mental disorder largely eschew scientific tests of validity; for them, a subjective feeling of improvement is often sufficient evidence of the effectiveness of tDCS. For example, the home users of tDCS quoted in the previous section who self-treated for bipolar disorder and anxiety did not quantify changes in their symptoms with well-validated neuropsychological measures, such as the Beck Inventory for Depression or the Hamilton Anxiety Scale. Nor did they see a clinician to assess variations in their conditions over time. Instead, they reflected upon their subjective feelings: "Yes I have found a montage that seems to alleviate some of the affects of bipolar disorder," wrote the user who self-treated for bipolar disorder, "I use the CATHODE on r4 and the anode over the motor cortex. This one basically stopped my mood swings."[39]

On the Reddit tDCS forum, the individual who self-treated for anxiety wrote:

> I can personally testify to it's effectiveness on seasonal affective disorder and generalized anxiety disorder. This is the first winter in memory that I haven't dropped into an annual months long depression as the days get shorter.[40]

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[39] "tDCS for depression?" *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/227e2h/tdcs_for_depression/ (accessed December 28, 2014).

[40] "How would you describe your experience with tDCS?" *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/1red4v/how_would_you_describe_your_experience_with_tdcs/ (accessed January 9, 2015).

These self-assessments are sometimes contested by other users. For example, in response to the post from the latter user, one home user responded:

> Glad that you're feeling better. Let's put things in perspective… Many treatments provide individual benefit, but when larger studies are done no improvement is demonstrated. tDCS is too frequently over-hyped. This is detrimental and can delay the clinical availability of tDCS. This occurred with TMS.

The first user defended himself:

> There is an intimate connection between anxiety and depression and I've been putting up with both for the better part of 35 years. I no longer am. This is a first. YMMV [Your Miles May Vary], duh. This is why it is referred to as 'anecdata'.

Thus, even users who subscribe to the validity of self-assessment are aware of the limitations of their reports; the user above readily acknowledges his experience as "anectdata." For those using tDCS for medical treatment, it is easy to see how such self-assessment makes sense: if you're feeling better, problem solved. But for home users of tDCS interested in cognitive enhancement, the issue of validity presents a much greater challenge. As one user told me:

> If I was clinically depressed and had tried a bunch of medications, I would be all over tDCS, from what I'm hearing. That would be an easy one. And then I would subjectively

have a sense—even if it was a placebo effect, if I could feel better, I think I would know it… But for cognitive enhancement, I think that's another kettle of fish, altogether, really.

Indeed, those who use tDCS for cognitive enhancement often strive for some kind of validation of tDCS, and attempt to quantify their performance on cognitive tests. Some track their scores on open-source versions of dual n-back tests, which are performance measures often used in scientific studies that assess working memory. Others use cognitive tests that are freely available online, such as the ones from Quantified Mind and Cambridge Brain Sciences.[41] On the forums and blogs, home users of tDCS share the testing protocols that they create for themselves.

But as the following exchange (edited for brevity, not spelling) on the Reddit tDCS forum illustrates, validation is not *always* an issue for those interested in cognitive enhancement. Pay particular attention to User 3:[42]

User 1: … what do you track? i'm just getting starting with tdcs device i bought. And here is a draft of my spreadsheet and what i will try to track…

User 2: Hi! For me this is still the fundamental question. If I can't measure the difference, what's the point? …

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[41] "/r/tDCS FAQ: How do I know if my montage is working?" *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/wiki/faq#wiki_how_do_i_know_if_my_tdcs_montage_is_working.3F (accessed January 9, 2015).

[42] "How do you keep track of your sessions?" *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/18g2xr/how_do_you_keep_track_of_you_sessions/ (accessed December 28, 2014).

User 1: completely agree. If we don't have some quantified way to measure than it's all based on "feeling"…

User 3 [in response to User 1's initial post]: … what is your purpose? Is it to improve your math skills? Then why would you care if the increase is due to placebo or due to tDCS, as long as your math skills improve?

User 1: … placebo effect is a lie, why would i want zap my brain if it makes no effect?

Thus, in contrast to Users 1 and 2, who desire some sort of validation, User 3 is of the opinion that when the goal is purely self-improvement, validation is irrelevant. There are many on the Reddit tDCS forum who share the view of User 3. For example, when a similar discussion took place on a different thread, one user wrote: "… if I use this stuff to help learn how to juggle and I'm juggling like a pro in a week, I don't care if it's actually doing anything or not."[43] Anthony Lee has summed up the views of such users succinctly: "someone looking to tDCS for enhancement may not be concerned with whether their positive findings are a result of placebo."[44] But for others, such as User 2 ("If I can't measure the difference, what's the point?") the goal is not *purely* self-improvement. Such users want proof of causality: evidence that tDCS is causing any perceived improvements.

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[43] *"Placebo effect?" Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/tm8su/placebo_effect/ (accessed February 17, 2015).

[44] Strickland, Eliza. "The Latest DIY Craze: Brain Hacking." IEEE Spectrum, Mar 14, 2014, http://spectrum.ieee.org/geek-life/reviews/the-latest-diy-craze-brain-hacking# (accessed February 17, 2015).

For some users, achieving a higher score after taking a test while stimulated is sufficient proof of the effectiveness of tDCS. But at some home users have pointed out, there is the problem of the practice effect: that is, one's experience taking a test will influence one's outcome on the same (or similar) future tests. Anthony Lee told me that other users pointed out this problem to him when he posted his initial test results on the Reddit tDCS forum. He subsequently set out to control for the practice effect, which he referred to as "test-wiseness." In the video he posted on YouTube about his second round of tests, he describes his strategy of avoiding test-wiseness. Essentially, he *first* takes a set of tests with stimulation, then takes a second set of the same tests without stimulation:[45]

> I think there's 16 total assessments on Lumosity, various little games or whatever that require a level of thinking and memory. All of them I took while stimulating the dorsolateral prefrontal cortex. I then took them all after a weeks of not using any nootropics, or being stimulated at all. I was completely and totally normal-headed at this point... One of the assessments, I scored an equal score. Three of the assessments I actually did better on. The remaining 12, I did worse. So that means that I decreased my score 75 percent of the time, and increased only 19 percent. So collectively I actually performed somewhere around 57% worse in these cognitive games when not stimulated. And that was the second time around, unstimulated, which means that test-wiseness did not play, didn't have a factor in that at all. So my conclusion is that dorsolateral prefrontal cortex, while stimulated, is very effective.

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[45] Lee, Anthony. The Uber-Brain; Brain Zapping, Smart Drugs, and Brainwave Therapy All At Once!" *YouTube*, May 23, 2012, https://www.youtube.com/watch?v=oPj43cQqcsg (accessed January 9, 2015).

Anthony concluded that tDCS was effective, since if test-wiseness played a role, he should have performed better (or at least the same) on the second set of tests. However, there is another problem here, one that is often discussed on the forum: the placebo effect. Perhaps Anthony performed better on the first set of tests because he was aware that he was being stimulated. Maybe he subconsciously thought was supposed to perform better, and therefore did. To control for the placebo effect, a user would have to receive several sessions of real and placebo (sham) tDCS, but be unaware of what kind of stimulation s/he was receiving.

Some tDCS devices available to home users do come with sham settings: both the Transcranial Technologies device and the foc.us have such a sham setting, and the iontophoresis devices can be modified to deliver a sham. But using the sham setting isn't exactly straightforward: first, it is possible that unlike inexperienced subjects, frequent tDCS users can tell the difference between sham and real settings. Second, there is currently no built-in way to randomize the sham and real settings on these devices, so barring a more creative solution, a second individual would have to be present to covertly select the stimulation setting. While such a scenario is possible—and seems to have taken place on at least one occasion—I have not come across an instance of any solo user employing such a technique.[46] This is probably due to both practical issues (most home users utilize tDCS privately, in the comfort of their own homes) and motivational ones (their primary goal is self-improvement, not knowledge-making).

Instead, users seem to construct their own "tests" of validity, which are personal and vary across subjects. One home user told me how he planned to test for validity:

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[46] "Shutting down the destructive internal monologue through transcranial direct current stimulation," *Less Wrong Discussion,* http://lesswrong.com/r/discussion/lw/aa1/link_shutting_down_the_destructive_internal/5x3v?context=2#comments (accessed February 17, 2015).

> I found a downloadable dual-n-back app last night. It's available on Mac and Linux and Windows. And it's a state-of-the-art test and what I'm thinking of doing is trying to maximize my scores on the n-back, even if it's a month of doing it regularly, just trying to get to where I hit a wall, and the wall is consistent, [he mimics talking to himself] "This is kind of where you're at, John, this is where you hit the wall and can't get any farther." And then try to apply the tDCS and see if there's a difference.

Another user reported taking two IQ tests and scoring 112 on them both. He then began regular 15-minute tDCS sessions during which he would take dual n-back tests (he did not specify the frequency of sessions). Two years later, he took an IQ test and scored 126, 14 points higher than his initial scores. He specifically rationalized the two-year gap as being advantageous for the validity of his results, as it got around the practice effect (that is, if he wasn't taking the IQ test, then he wasn't "practicing" it, and therefore his improvement could not be due to a practice effect).[47] On the forum, other home users challenged this user's design and conclusion.

Thus, home users are aware of the experimental imitations, and as shown here, often actively adopt strategies to circumnavigate them. There is no single strategy or test of validity that is widely accepted. Rather, tests are personal and often contested by other users. A small number of users seem to be concerned about the experimental limitations and have urged their peers to start gathering or aggregating data as a way of overcoming the sample-of-one constraints. However, as of yet, there has been no formal data aggregation initiative.

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[47] "My anectodal findings: With assistance of homemade tDCS device, my IQ increased 14 points!" *Reddit /r/tDCS.* http://www.reddit.com/r/tDCS/comments/1sovk3/my_anecdotal_findings_with_assistance_of_homemade/ (accessed December 28, 2014).

Conclusion

The home use of tDCS differs in a number ways from previous examples of lay interaction with scientific knowledge. While home users, by virtue of using an experimental scientific technique, are making an inherent political statement about scientific knowledge—and who should be allowed to use it—their ultimate goal is self-improvement, not influencing the direction of medical research or achieving a political outcome. Thus they are different from the "patient activists" that have been previously been described. Furthermore, home users have not formed alliances with professional researchers; rather, researchers view home users as a threat to the reputation of the field, and are wary of having any kind of direct communication with them. In addition, although home users may indeed be "experts of experience," at this point professional researchers have not recognized or placed value on this kind of expertise.

But as has been previously shown regarding lay epidemiology studies, lay individuals can challenge "normal science" by highlighting inconsistencies and weaknesses within the research literature and accompanying methodologies. This is indeed what has occurred with regard to the home use of tDCS: lay individuals experiment and extrapolate where there are gaps or unknowns in scientific literature, or where they feel that the stimulation parameters that researchers adhere to is arbitrary. Thus, rather than sticking to one twenty-minute session every few days, home users stimulate their brains with longer and more frequent sessions.

In sum, this chapter has provided an initial description of the practices of tDCS, with a focus on how home users interact with scientific knowledge. When making or acquiring a device, home users of tDCS produce, document, and share their own body knowledge, through online forums, blogs, videos and personal communications. The resulting knowledge is messy

and constantly in flux. When it comes to using the device, home users of tDCS draw heavily on existing scientific knowledge, posting links to academic journal articles and scientific resources, and adopting the standardized electrode placement system used by scientists. They sometimes co-opt scientific knowledge and modify it by creating their own manuals and guides based on published papers. Interestingly, where there are "gaps" in scientific literature, home users of tDCS experiment and extrapolate; they create, document, and share a new body of self-produced knowledge, much like they do in the making/acquiring stage. Finally, when it comes to measuring the effects of tDCS, home users struggle to create validity in the face of experimental limitations. Home users interested solely in self-improvement seem to accept subject self-assessment (i.e., their "feelings") as validation, but there are others—mostly those who use tDCS for cognitive enhancement—who strive for some additional measure: they want evidence of causality. These users often create their own "tests" of validity, which are personal, contested, and vary widely across users.

CHAPTER 3

Surveying Consumers of tDCS Devices

The home use of noninvasive brain stimulation has been a subject of much discussion in the bioethics literature.[1] Scholars have expressed concerns regarding safety (e.g., whether the technique may cause harm, either in the short-term or long-term), distributive justice (that enhancement technologies such as tDCS will be available to the privileged few, and thereby increase current gaps in inequality), autonomy (i.e., fears that if brain stimulation becomes widespread individuals may be coerced into using it), and authenticity (concerns that tDCS could fundamentally alter a person's identity or personality).

Yet as Voarino et al. (2017) point out in their comprehensive review of this literature, each of these concerns rests on underlying assumptions for which there is little empirical evidence. For example, concerns about safety are valid only if there are detrimental effects to using the technology, or if home users are "misusing" the technology (i.e., using it in ways that

[1] For comprehensive review, see Nathalie Voarino, Veljko Dubljević, and Eric Racine, "tDCS for Memory Enhancement: Analysis of the Speculative Aspects of Ethical Issues," *Frontiers in Human Neuroscience* 10 (2017), doi:10.3389/fnhum.2016.00678. See also Roy Hamilton, Samuel Messing, and Anjan Chatterjee, "Rethinking the Thinking Cap Ethics of Neural Enhancement Using Noninvasive Brain Stimulation," *Neurology* 76, no. 2 (2011): 187–93; Martha J. Farah, "The Unknowns of Cognitive Enhancement," *Science* 350, no. 6259 (2015): 379–80; Olivia M. Lapenta et al., "An Ethical Discussion of the Use of Transcranial Direct Current Stimulation for Cognitive Enhancement in Healthy Individuals: A Fictional Case Study," *Psychology & Neuroscience* 7, no. 2 (2014): 175–80; Laura Y Cabrera, Emily L Evans, and Roy H Hamilton, "Ethics of the Electrified Mind: Defining Issues and Perspectives on the Principled Use of Brain Stimulation in Medical Research and Clinical Care," *Brain Topography* 27, no. 1 (2013): 33–45; Nicholas S. Fitz and Peter B. Reiner, "Buttressing Regulation of Cognitive Enhancement Devices with Principles of Harm Reduction," *Journal of Law and the Biosciences* 1, no. 3 (2014): 322–27.

have not been previously tested by scientists). Considerations of coercion are relevant only if there is widespread social uptake of brain stimulation, while those regarding distributive justice are persuasive only if the technology is both efficacious (i.e., actually works to enhance cognition) and available only to certain socioeconomic groups. Concerns about authenticity would only be significant if tDCS does indeed cause changes to one's personality, and if one is not comfortable with such alterations.[2]

By systematically teasing out the ethical concerns from the factual assumptions they rest on, Voarino et al. (2017) demonstrate the importance of considering empirical evidence when formulating bioethical concerns. For example, although the issue of "coercion" is a theoretical possibility, it is one that is highly speculative; as I will show in this chapter, there is no evidence that noninvasive brain stimulation will achieve widespread social acceptance (and in fact, as I will show here, there may in fact be evidence to the contrary). The entanglement of facts and ethics has been well articulated by Ragan et al. (2013), who note that "facts alone cannot resolve ethical dilemmas; however, ethical dilemmas cannot be fruitfully discussed in the absence of facts either."[3]

To date, there has been relatively little empirical data on the home use of tDCS. In the previous chapter, I presented an account of the practices of home users of tDCS, based on

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[2] Voarino et al. (2017) frame this in terms of one's ideological stance, "bioconservative" vs. "biolibertarian." As discussed in literature on the ethics of cognitive enhancement, bioliberals tend to be more embracing of technological innovations that affect one's biology, whereas bioconservatives tend to be against the use of such technology. See discussion in Rebecca Roache and Julian Savulescu, "Enhancing Conservatism," in *The Ethics of Human Enhancement: Understanding the Debate*, ed. Steve Clarke et al. (Oxford: Oxford University Press, 2016), 145–59.

[3] C. Ian Ragan, Imre Bard, and Ilina Singh, "What Should We Do about Student Use of Cognitive Enhancers? An Analysis of Current Evidence," *Neuropharmacology*, 64 (2013), 593.

interviews and data of tDCS-related forums, websites, and blogs (Wexler 2016).[4] In late 2013 and early 2014, a preliminary survey was conducted by a researcher at Stanford University (Jwa 2015), which provided the first quantitative data on home users of brain stimulation.[5] Taken together, these two studies yielded initial descriptions of the practices of DIY tDCS and the general demographic makeup of users.

These studies also had a number of limitations. First, they both relied on Internet sources, deriving content (forums, websites, videos) and recruiting subjects by posting online, mostly to the tDCS subreddit (www.reddit.com/r/tdcs). Although the tDCS subreddit forum is the most active nexus of communication for home users of tDCS,[6] this method of recruitment may have had the effect of skewing towards younger, technology-savvy users of tDCS. Furthermore, as those who quit using tDCS presumably no longer visit tDCS-related websites, these studies may have been biased toward active users of tDCS, and likely did not capture those who stopped using the technology. Second, both of these studies were conducted in late 2013 and early 2014, soon after the first direct-to-consumer wearable tDCS device was marketed to the general public. The consumer neurotechnology market has changed significantly in just three years; as of June 2016 there were approximately ten additional companies selling brain stimulation devices to the general public, and the phenomenon of the home use of tDCS was covered in major media

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[4] Anna Wexler, "The Practices of Do-It-Yourself Brain Stimulation: Implications for Ethical Considerations and Regulatory Proposals," *Journal of Medical Ethics* 42, no. 4 (2016): 211–15.

[5] Anita Jwa, "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, no. 2 (2015): 292–335.

[6] As I described in Chapter 1, home users of brain stimulation do not hold in-person meetings or other gatherings.

outlets in 2014 and 2015.[7] Thus, even in just a short period of time, the demographic makeup of home users, as well as the devices they use, may have shifted significantly.

Given that many bioethical concerns rest on assumptions for which there is currently little evidence, the study described in this chapter aimed to provide an updated, comprehensive examination of those who purchase consumer tDCS devices. Rather than recruiting via online avenues, my collaborator on this project, Nicholas Fitz,[8] and I partnered with seven different consumer tDCS companies to directly email their user base, thereby obtaining a sample of all those who had ever purchased a consumer tDCS device—not just those who visited online forums. Furthermore, we designed a survey that included both open-ended and forced-choice responses, allowing us to capture easily comparable data for some questions but also hear directly from participants for other questions.

We interrogated some of the main empirical assumptions outlined by Voarino et al. (2017)—prevalence, efficacy, and safety[9]—to better understand if the concerns outlined in

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[7] See, e.g., Greg Miller, "Inside the Strange New World of DIY Brain Stimulation," *Wired*, May 5, 2014, http://www.wired.com/2014/05/diy-brain-stimulation/; Radiolab, "9-Volt Nirvana," June 26, 2014, http://www.radiolab.org/story/9-volt-nirvana/; Elif Batuman, "Adventures in Transcranial Direct-Current Stimulation," The New Yorker, April 6, 2015, http://www.newyorker.com/magazine/2015/04/06/electrified.

[8] As the study itself was a joint effort, I use the word "we" throughout this chapter. However, I conducted all analyses and wrote this chapter.

[9] Although Voarino et. al (2017) outline seven factual assumptions—prevalence, social acceptance, efficacy, ideological stance, potential for misuse, long term side effects and the delivery of complete and clear information—we did not agree with these exact divisions. For example, in this study we considered social acceptance within prevalence, because if a device is not prevalent, it follows that it does not have social acceptance. We also included a broad category of safety to encompass what Voarino et al. (2017) refer to as "long term side effects" and the "potential for misuse." This was done for two reasons: we felt that "long term effects" and "side effects," which generally refer to acute short-term effects during or immediately after use, were two different fundamentally things. Second, we feel that "misuse" is not sufficiently clear as it incorrectly implies that there is a single *correct* use. We did, however, assess a corollary of this by examining how users' practices departed from those of scientists. With regard to ideological stance, we assessed participants' political views (but did not ask specifically how

bioethics literature are supported by empirical evidence. We also addressed additional questions. First, although most bioethical literature on noninvasive brain stimulation has covered concerns regarding its use for *enhancement*, Wexler (2016) and Jwa (2015) have shown that individuals utilize tDCS both for enhancement *and* treatment. Thus, it is important to gain a better understanding of the reasons why individuals utilize tDCS, and if there are any characteristics that may differentiate treaters and enhancers. In other words, do "treaters" and "enhancers" differ from each other in meaningful ways, for example, on demographics, attitudes towards regulation, usage practices, and whether they find tDCS to be successful? If so, are there separate ethical considerations that might differ for each group? Relatedly, although much existing bioethics literature on cognitive enhancement has *a priori* assumed a treatment/enhancement distinction, we wanted to assess whether users themselves make that distinction, and if there are other reasons why users might purchase consumer tDCS devices.

Second, this study aimed to better understand those who quit using tDCS, a population that has not yet been examined. What proportion of those who try tDCS stop using the technology, and what are their reasons for doing so? What differentiates them, if at all, from current users of tDCS? These questions are relevant to bioethical concerns, as they may provide indirect measures both of the efficacy of tDCS as well as the prevalence (i.e., if a large proportion of those who try tDCS quit using the technology, this would indicate that tDCS is not likely to achieve widespread social uptake, and therefore concerns about coercion would not be relevant).

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they felt about the issue of authenticity); and with regard to the delivery of complete and clear information, this issue relates more to companies' claim—which are discussed in depth in Chapter 4—than users themselves.

Third, both in the bioethical literature and in media reports of the home use of tDCS, the tDCS subreddit forum (http://www.reddit.com/r/tDCS), which is the most active online forum for home users, has often been assumed to be representative of the population who utilize tDCS at home. Thus, one of the aims of the present study was to assess if the tDCS subreddit was representative of the population of home users, both by probing online engagement with the forum amongst our sample, and comparing responses between those who had visited the subreddit to those who had not.

Fourth, we tried to get a better sense of how home users of tDCS differed from the general population. Thus, we collected extensive data on socio-demographics and participant characteristics, and where possible, compared it to existing data from the U.S. population.[10] Such a comparison is useful both for bioethical considerations (i.e., comparing the household income of home users to the general population can yield insights into whether distributive justice is a well-founded concern) and for the existing literature on attitudes toward cognitive enhancement. For example, while several studies have examined the attitudes of the general public towards a variety of cognitive enhancement techniques,[11] the present study yields data from a population that is actively utilizing cognitive enhancement (or treatment) technologies.

Fifth, most bioethical literature has assumed that individuals utilize tDCS on themselves. However, our ongoing research has indicated that a small group of individuals may be using tDCS on others—which might raise an entirely different set of ethical issues. In the present

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[10] We chose to compare our data with that of the U.S. population, as it was the most-represented country in our sample (by a large margin); see **Fig 3.4**.

[11] See, e.g., Nicholas S. Fitz et al., "Public Attitudes Toward Cognitive Enhancement," *Neuroethics* 7, no. 2 (2014): 173–88; Pew Research Center, "U.S. Public Wary of Biomedical Technologies to 'Enhance' Human Abilities," July 2016, http://www.pewinternet.org/2016/07/26/u-s-public-wary-of-biomedical-technologies-to-enhance-human-abilities/; see also Laura Y. Cabrera and Peter B. Reiner, "Understanding Public (Mis)understanding of tDCS for Enhancement," *Frontiers in Integrative Neuroscience* 9 (2015).

study, we did not *a priori* assume that individuals use tDCS primarily on themselves; instead, those who answered affirmatively to using "primarily on others" took a different branch through the survey. Thus, we aimed to provide the first descriptive account of those who utilize tDCS primarily on others.

Finally, although there has been much discussion about the regulatory issues regarding the home use of noninvasive brain stimulation (see Chapter 4 for in-depth review), comparatively little data exists on users, demographics, and the actual consumer tDCS marketplace. Thus, in addition to assessing whether bioethical concerns in the literature are supported by factual evidence, we aimed to provide a comprehensive, in-depth, empirical description of the home use of phenomenon that could serve as a cornerstone for future policy frameworks.

I. Methods

Of the ten companies actively selling tDCS directly to consumers as of spring 2016, seven agreed to participate in the study on the condition of anonymity. Between June 14-17, 2016, an email was sent to companies' customer lists with a unique link to the online survey (five companies emailed their customers directly; we emailed the customers of two companies via Qualtrics online survey software). A follow-up reminder email was sent to the email lists of five of the seven companies after approximately three weeks (two companies did not comply with our requests to send out a reminder email). The text of both the initial email and the reminder email (**Appendix A**) were kept consistent across companies. The survey was open for approximately 30 days, and closed on July 15, 2016. Following completion of the survey, all participant data

was anonymized and divided into subsets based on the unique links assigned to each company. We shared each company's subset of data with that specific company; in other words, each company saw data only from respondents who clicked through their unique link.

The survey instrument was designed in response to our previous work studying home users of brain stimulation. We solicited comments on the initial draft of the survey from members of the DIY brain stimulation community, consumer tDCS manufacturers, sociologists, ethicists, and neuroscientists. The survey instrument underwent pilot testing prior to launch to ensure that all questions were clear and that navigation through the survey functioned as expected.

The survey contained questions about participants' tDCS device(s), usage practices, beliefs, attitudes, and sociodemographics; the number of questions displayed for any one respondent was contingent upon participants' particular involvement with tDCS. For example, participants who reported using tDCS both on themselves and others saw the greatest number of questions (80), whereas participants who reported purchasing a device for use on oneself, but never using it, saw the fewest number of questions (40). The survey, which is reproduced in full in **Appendix B**, contained a mix of closed and open-ended responses for conventional content analysis.

Closed-ended questions were analyzed using SPSS v24 (SPSS Inc., Chicago, IL). Descriptive statistics were used to characterize the composition and properties of the sample, and simple inferential statistics (Pearson Chi-Square) and effect sizes (Cramer's V), as well as independent samples t-tests, were used to explore if any observed differences between groups were meaningful. For each open-ended question, we began by separately analyzing a subset of responses (generally ~100), developing categorical themes or codes iteratively as we worked

through the data.[12] Next, following discussion of our central concepts and research questions, we agreed upon a final set of thematic categories, with sets of indicator codes. With final coding themes in place, we each proceeded to code the entire data set separately. Each theme was treated as a binary variable, and each open-ended response received a "1" if the theme was present or "0" if it was absent. Once all comments were coded, the frequency with which any theme emerged in the comments was compared across contrastive conditions. We calculated the initial inter-coder reliability[13] across the ten open-ended questions coded (Cohen's Kappa was 0.97); after review, agreement was 100%.

II. Results

Response rate

The recruitment email message (**Appendix A**) was sent to a total of 10,393 email addresses across seven companies. Because 232 emails bounced, the message was successfully delivered to 10,161 email addresses. Note that this number does not necessarily reflect the total number of unique individuals who received the recruitment email; it is possible that (a) participants purchased devices from two companies in our survey, and therefore received an email from each company; and/or (b) a single participant used multiple email addresses to purchase a device even within the same company.

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[12] Virginia Braun and Victoria Clarke, "Using Thematic Analysis in Psychology," *Qualitative Research in Psychology* 3, no. 2 (2006): 77–101; Michelene T. H. Chi, "Quantifying Qualitative Analyses of Verbal Data: A Practical Guide," *Journal of the Learning Sciences* 6, no. 3 (1997): 271–315.

[13] Matthew Lombard, Jennifer Snyder-Duch, and Cheryl Campanella Bracken, "Content Analysis in Mass Communication: Assessment and Reporting of Intercoder Reliability," *Human Communication Research* 28, no. 4 (2002): 587–604.

Although we requested that companies send emails only to those who had purchased a tDCS device, one company's mailing list did not differentiate between those who purchased accessories versus devices, and another company sent emails to everyone who had opted in to their mailing list. Together, these two companies made up approximately 7 percent of all those emailed. However, to validate that our sample was comprised of only those who had actually purchased a consumer tDCS device, we later excluded individuals who had not reported purchasing a consumer tDCS device, and performed additional checks on our data (see discussion of inclusion criteria below).

To ensure as well-controlled a sample as possible, we did not recruit via social media, nor did we post the survey link to the tDCS subreddit or other tDCS-related websites. During the month that the survey was open, we closely monitored the tDCS subreddit, Twitter, and tDCS-related blogs and websites for mentions of the survey. To our knowledge, aside from a home user who posted to Twitter with a link to the survey (which was re-tweeted six times) the survey remained limited to the seven companies' customer lists.

In total, 349 respondents completed the survey in its entirety, for an aggregate response rate of 3.9%. Response rates for individual companies ranged from 1.1% to 5.7%, with a median of 5%.[14] Although this response rate is relatively low, it is in line with response rates for web-based customer surveys, which are not typically reported in peer-reviewed literature. Furthermore, we did not offer participants any incentive for participation, other than emphasizing that their data would contribute to research (**Appendix A**).

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[14] See, e.g., Kim M. Nazi, "Veterans' Voices: Use of the American Customer Satisfaction Index (ACSI) Survey to Identify My HealtheVet Personal Health Record Users' Characteristics, Needs, and Preferences," *Journal of the American Medical Informatics Association* 17, no. 2 (March 1, 2010): 203–11, noting that "Response rates for web-based ACSI [American Customer Satisfaction Index] surveys are typically low, with an average rate of 4–8%."

Eight participants were excluded because they did not report owning a consumer tDCS device. Another two participants were excluded because they had typed random letters for all the open-ended responses. Thus, in total, we analyzed data from 339 participants.

As an additional check on our data, we reviewed all responses to ensure that those coming from each company's unique link reported purchasing a device from that company. We found that 96.5% (n=327) of respondents "matched" in terms of unique company link and reported device, while 3.5% (n=12) were "mismatches." The "mismatches" may have occurred for a number of reasons: (a) participants who purchased devices and accessories from more than one company may have received multiple survey links, and may have clicked through the link from the company from which they purchased an accessory, not a device; (b) participants may have clicked on the survey link through the Twitter postings mentioned above, or were forwarded the survey link by a friend; and (c) participants may have simply made mistakes. However, after ensuring that each of the twelve participants who were "mismatches" owned at least one consumer tDCS device, we opted to include these participants in our study.

Prevalence and popularity

One of the most important unanswered questions regarding the home use of noninvasive brain stimulation is the prevalence of the phenomenon.[15] Previously, the closest measure of the popularity of tDCS was the number of subscribers to the tDCS subreddit forum, which increased from roughly 1,000 subscribers in the fall of 2012 to nearly 10,000 as of April 2017 (**Fig. 3.1**). However, as Peter Reiner and I have argued previously, subscribing to the tDCS subreddit is

[15] Prevalence data is more readily available in the literature for those who use cognitive enhancement pharmaceuticals.

relatively meaningless,[16] as one can visit (and post to) the tDCS subreddit without subscribing. Thus, we argue that the growth in number of subscribers to the tDCS subreddit is better taken as a proxy for increasing *interest* in the home use of tDCS, rather than increasing *use* of tDCS.

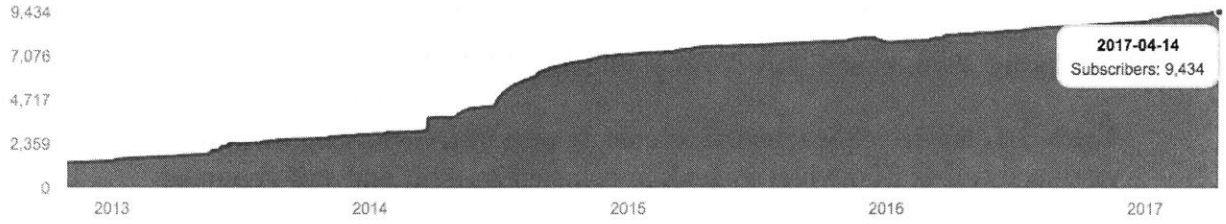


Figure 3.1. Number of subscribers to the tDCS subreddit (www.reddit.com/r/tdCS) between October 2012 and April 2017. Data obtained from http://redditmetrics.com/r/tDCS.

We suggest that a more accurate—though still highly imperfect—measure of the popularity of the home use of tDCS can be gleaned from the total number of consumer tDCS devices sold. Indeed, purchasing a device is a financial commitment—it requires not just clicking "subscribe" on the subreddit, but actually spending a significant sum of money on a stimulation device (on average, participants in our survey paid $177 for a device; **Table 3.1**). In the present study, which included seven of the ten companies selling tDCS devices directly to consumers as of spring 2016, companies' customer lists totaled approximately 10,000 individuals.[17]

How representative is this figure of the total number of devices sold? One way of analyzing this number is to obtain a better sense of the market share distribution amongst

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[16] Subscribing merely means that the subreddit shows up on a user's Reddit homepage when they are logged in, and that they can "upvote" or "downvote" other users' posts to the forum. See Anna Wexler and Peter B Reiner, "Home Use of tDCS: From 'Do-It-Yourself' to 'Direct-To-Consumer,'" in *The Routledge Handbook of Neuroethics*, ed. L. Syd M Johnson and Karen S. Rommelfanger (Routledge, 2017).

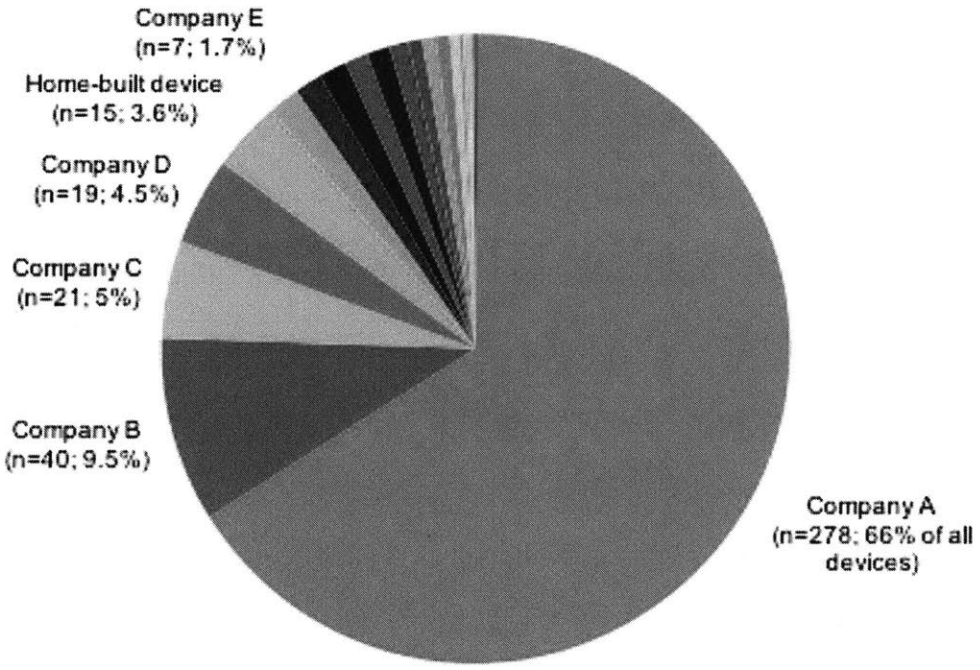
[17] As noted earlier, customer lists for roughly 7% of this emailed included those who may have purchased accessories, not devices, and some individuals may have been emailed more than once.

consumer tDCS companies. As shown in **Fig 3.2**, participants reported owning a total of 421 stimulation devices from 18 different companies. This figure includes manufacturers selling devices that are not expressly marketed for tDCS (e.g., iontophoresis devices, research-grade devices, and Thync edition one), as well as several companies no longer actively selling tDCS devices as of spring 2016. In addition, 3.6% of all reported devices were home-built.

Table 3.1. Device characteristics: cost, length of time having owned a device, number of devices owned, purchase location, and self-reported likes/dislikes of the device.

	n	%	Mean	Median
Number of participants owning:		*n=339*		
one device	271	79.9%		
two devices	57	16.8%		
three devices	8	2.3%		
four devices	3	0.9%		
Price of tDCS device			$177	$139
Length of time having owned device (in months)			16.9	14
Device was purchased from...		*n=421 (devices)*		
Company/manufacturer	382	90.7%		
eBay	6	1.4%		
Amazon	4	1.0%		
Other	29	6.9%		
Most common likes		*n=339*		
Ease of use	115	33.9%		
Design of the device	108	31.9%		
Portability	65	19.2%		
Cost	50	14.7%		
Most common dislikes		*n=339*		
Poor design/quality	108	31.9%		
Electrodes	93	27.4%		
Side effects	46	13.6%		
Lack of directions	46	13.6%		
Lack of efficacy	39	11.5%		

Notably, 66.0% of all devices came from a single manufacturer (Company A in **Fig. 3.2**). Given that response rates were relatively constant (i.e., within a few percentage points) across customers from each of the seven companies we surveyed, it is likely that **Fig 3.2** represents a rough approximation of the market distribution (e.g., one dominant company, several medium-sized companies, and a handful of much smaller ones). Given our previous work studying the consumer tDCS landscape and knowledge of the three companies who declined to participate—i.e., length of time in business, extent of publicity received—we speculate that they had only medium or small shares of the market. Provided that is the case, it is likely that the total number of consumer tDCS devices sold is a low, five-digit figure.



Note: Companies F through R (less than six devices each) are not labelled on this chart.

Figure 3.2. Distribution of purchased tDCS devices (n=421) across 18 different companies.

Of course, an approximation of the total number of consumer tDCS devices sold is not an estimate of the prevalence of tDCS—we do not have control data from the general population. In

addition, it is not clear how many of those who purchased tDCS devices actually use them. As will be discussed below (and as shown in **Fig. 3.9**), approximately 40% of our sample had never used tDCS or had quit using it. Thus, the number of active users is likely significantly lower than the total number of devices sold.

Despite the lack of data on prevalence, media reports and scholarly articles have reported that the home use of brain stimulation is increasing and may become mainstream.[18] This characterization is not unique to tDCS—Partidge et al. (2011) found that 94% of media articles related to the use of cognitive enhancement drugs characterized the phenomenon as either "common" or increasing, despite there being little evidence to justify such claims.[19] Similar to both Partridge et al. (2011) and Jwa (2015)—who speculated that there "may be some hype" around the estimates of the size of DIY tDCS—[20]we argue that there is little evidence to support the notion that the home use of tDCS is increasing. While there was certainly more attention paid to the movement in 2014 and 2015 (by the media, academia, regulatory authorities, non-governmental organizations, etc.)—and subscribers to the Reddit forum roughly tripled in 2014—we argue that this should not be taken to reflect an increase in *the use* of noninvasive brain stimulation devices, rather an increase *in attention* toward those who use tDCS. In addition, the results of this study suggest that media reports may in fact be driving individuals to utilize

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[18] See, e.g., Anna Denejkina, "The Promise and Peril of DIY Electrical Brain Stimulation," *The Kernel*, April 10, 2016, http://kernelmag.dailydot.com/issue-sections/headline-story/16371/diy-electrical-brain-stimulation-tdcs-promise-and-peril/; Nicholas S Fitz and Peter B. Reiner, "The Perils of Using Electrical Stimulation to Change Human Brains," in *The Stimulated Brain: Cognitive Enhancement Using Non-Invasive Brain Stimulation* (Elsevier, 2014).

[19] Bradley J. Partridge et al., "Smart Drugs 'As Common As Coffee': Media Hype about Neuroenhancement," *PLOS ONE* 6, no. 11 (2011): e28416.

[20] Jwa, "Early Adopters," 25.

tDCS.[21] Very few participants heard about tDCS from within their own social networks (i.e., from another person); rather, most heard about it from the Internet (which presumably includes media websites, although these were not specific by participants), podcast/radio, or news outlets (**Fig. 3.3**). The fact that approximately 1 in 8 participants in our sample came to tDCS after hearing about it from a specific source (a Radiolab podcast episode) was striking. Furthermore, the effect of media attention on interest in tDCS is also evident from sharp increases in subscribers to the tDCS subreddit that appear immediately after high-profile media articles.[22]

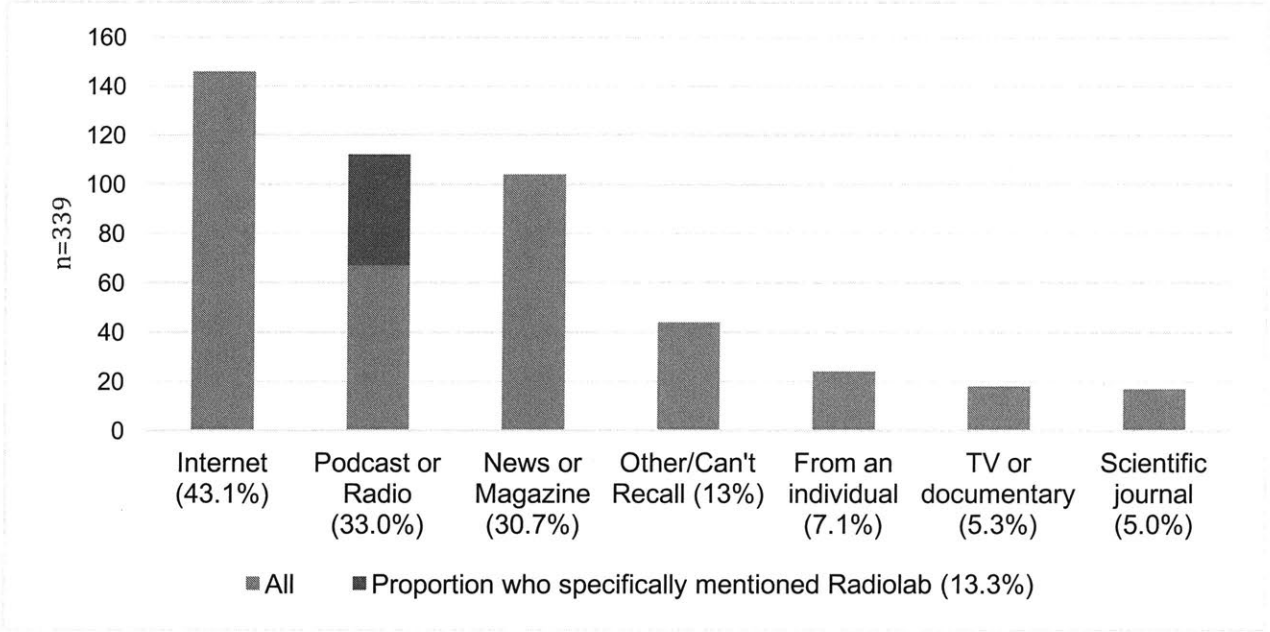


Figure 3.3. How participants first heard about tDCS.

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[21] Indeed, several studies on the lay use of cognitive enhancement drugs have suggested a similar phenomenon: see, e.g., Simon M Outram, "The Use of Methylphenidate among Students: The Future of Enhancement?," *Journal of Medical Ethics* 36, no. 4 (2010): 198–202, and Cynthia Forlini and Eric Racine, "Disagreements with Implications: Diverging Discourses on the Ethics of Non-Medical Use of Methylphenidate for Performance Enhancement," *BMC Medical Ethics* 10, no. 9 (2009).

[22] For example, when looking at the graph of subscriber growth (http://redditmetrics.com/r/tDCS) increases are apparent following the release of the *Wired* article (May 5, 2014) and the Radiolab podcast (June 26, 2014). See Greg Miller, "Inside the Strange New World of DIY Brain Stimulation," *Wired*, May 5, 2014, http://www.wired.com/2014/05/diy-brain-stimulation/; Radiolab, "9-Volt Nirvana," June 26, 2014, http://www.radiolab.org/story/9-volt-nirvana

The results of this study suggest that there may be a cyclical effect when it comes to media attention and uptake of tDCS that may amplify the perceived prevalence of the phenomenon. Media attention—and portrayals of neuroenhancement as "common" or "increasing"— may drive more participants to use tDCS (and may drive more media attention), which in turn may drive attention from other outlets (i.e., academic scholarship, conferences, and meetings), which in turn may drive additional media attention as press outlets report that "experts" are discussing the phenomenon, which may in turn drive more individuals to utilize tDCS. This may lead to an "echo chamber" effect, where the increased attention makes it seem like the home use of tDCS is a booming phenomenon, but in reality the prevalence is quite low. Future research is needed to better elucidate this cycle.

Demographics

While previous studies have portrayed the typical home user as a twenty- or thirty-something male,[23] one of the most surprising demographic findings (**Table 3.2**) from the present study was a mean age of 42.5, and a higher proportion of females (15.3%) than the 4% previously reported by Jwa (2015). It is unclear if these differences reflect real shifts in the demographics of users of consumer tDCS devices, or whether they merely reflect differences in sampling methodology, as we recruited by emailing all those who had purchased consumer tDCS devices. We did, however, find approximately the same percentage of participants based in North America (**Fig. 3.4;** 73%) as Jwa (2015). The consistency of this result across studies could reflect a lower prevalence of use outside North America; indeed, in a review of the literature on the use

[23] Jwa, "Early Adopters," and Wexler, "Practices of DIY Brain Stimulation."

of cognitive enhancement drugs, Ragan et al. (2013) suggest that there may be a lower prevalence outside the United States.[24]

Table 3.2. Gender, age, race and marital status (n=339)

	n (%)	Range
Gender		
Male	238 (83.5%)	
Female	52 (15.3%)	
Prefer not to answer	4 (1.2%)	
Age, mean (SD)	45.32 (13.93)	20-87
Age, by generation*		
Millenial (ages 18-35)	99 (29.2%)	
Generation X (ages 36 to 51)	113 (33.3%)	
Baby Boomer (52 to 70)	106 (31.3%)	
Silent Generation (71+)	10 (2.9%)	
Race		
White	286 (84.4%)	
Asian	32 (9.4%)	
Hispanic	19 (5.6%)	
Other	22 (6.5%)	
Marital Status		
Never Married	96 (28.3%)	
Married	151 (44.5%)	
Living with a partner	35 (10.3%)	
Separated	13 (3.8%)	
Divorced	40 (11.88%)	
Widowed	4 (1.2%)	
Parental status		
No children	194 (57.2%)	
Has at least one child	145 (42.8%)	

*Generation categories were defined according to Pew generational statistics as of 2016. See Pew Research Center, "The generations defined" (August 26, 2016), http://www.pewresearch.org/fact-tank/2016/08/29/this-may-be-the-last-presidential-election-dominated-by-boomers-and-prior-generations/ft_16-08-26_generationsdefined_2016_silentgreatest/.

[24] Ragan et al., "What Should We Do about Student Use of Cognitive Enhancers," 590.

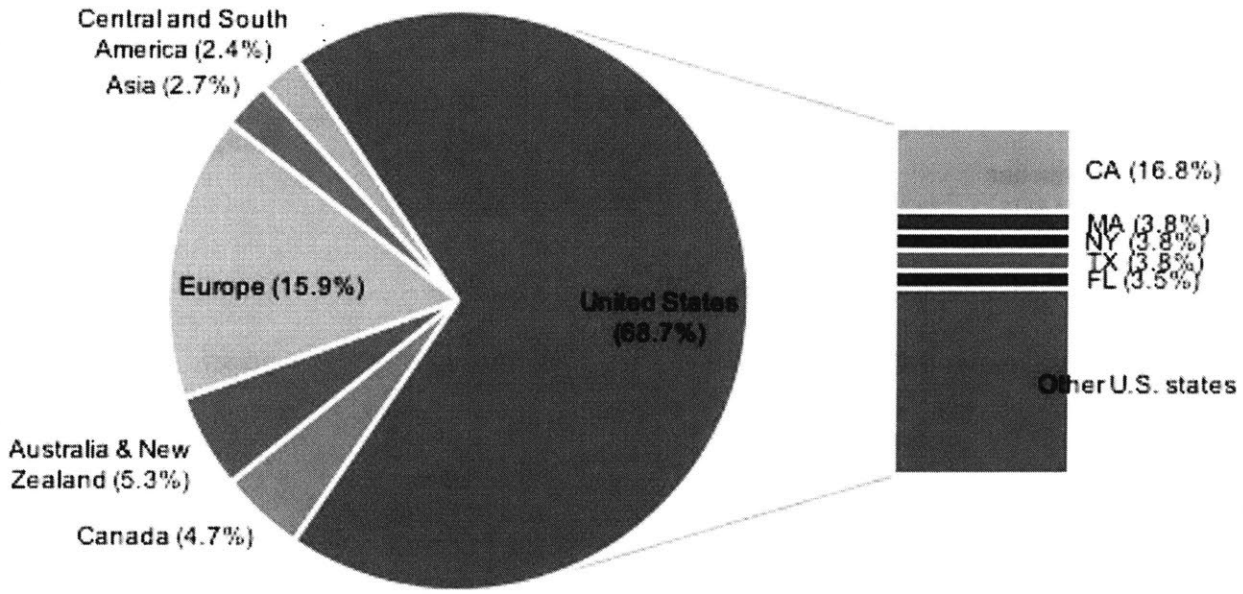


Figure 3.4. Participants' (n=339) geographical locations.

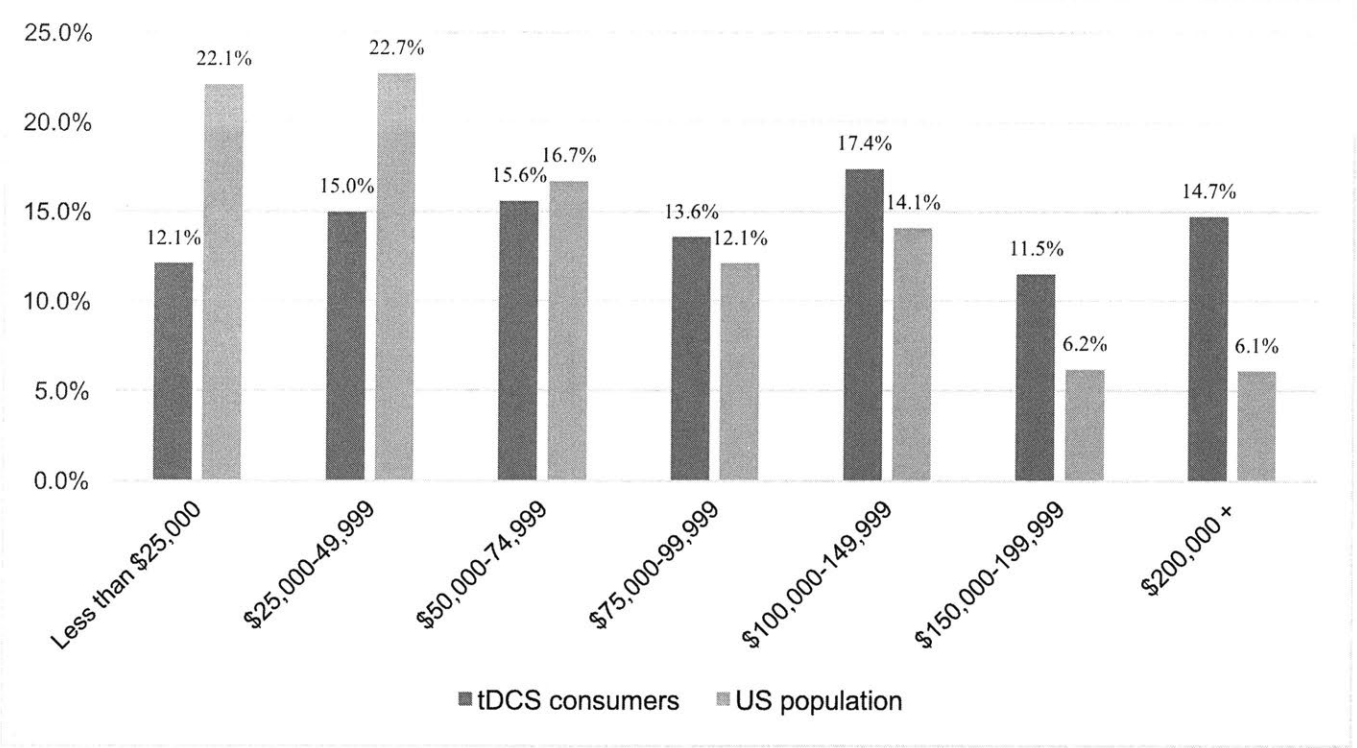


Figure 3.5. Household income distribution, tDCS consumers compared to U.S. population. (US population data: U.S. Census Bureau, Current Population Survey, 2016 Annual Social and Economic Supplement).

Table 3.3. Education, employment and political views (n=339)

	n (%)
Education	
High school or less	19 (5.6%)
Some college or university	56 (16.5%)
College or university degree	141 (41.6%)
Master's degree	68 (20.1%)
Doctorate/professional degree	55 (16.2%)
Employment	
Employed full-time	231 (68.1%)
Employed part-time	27 (8.0%)
Unemployed	17 (5.0%)
Retired	36 (10.6%)
Student	19 (5.6%)
Disabled	6 (1.8%)
Politics	
Liberal	239 (70.5%)
Moderate	59 (17.4%)
Conservative	41 (12.1%)
Political Affiliation (US-based participants only, n=233)	
Democrat	165 (70.8%)
Republican	45 (19.3%)
Other	23 (9.9%)

Compared to the U.S. population,[25] our sample had a higher educational attainment (**Table 3.3**): most participants (77.9%) reported having a college degree or higher (compared to 44.5% of Americans) and 36.3% reporting having a master's or doctoral-level degree (compared

[25] Although participants were from 32 different countries, we chose to compare our data to that of the U.S. population, as it was the most-represented country in our sample.

to just 12.0% percent of Americans).[26] Given that educational attainment has been shown to be positively correlated with income level,[27] it was not surprising that our sample also reported much higher levels of income as compared to the US population[28] (**Fig. 3.5**). In one sense, this finding can be expected, as those in lower income brackets likely do not have spare funds to spend on an experimental technique of questionable efficacy, and a similar income distribution would be expected for those who opt for other enhancement techniques (e.g., elective and cosmetic surgery). Still, **Fig. 3.5** provides empirical support for concerns expressed by bioethicists regarding distributive justice (i.e., that enhancement technologies may be used by those who are wealthier, thereby increasing current inequality gaps). An alternative interpretation of the figure, however, is that tDCS users are relatively well-distributed across income brackets, and that it is the U.S. income distribution that is skewed.

Most participants in our survey (70.5%) reported being politically liberal (**Table 3.3**); this proportion is nearly three-times the number of the general U.S. population who self-identify as liberal (24%).[29] Similar, most US-based participants (70.5%) reported having an affiliation with,

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[26] U.S. Census Bureau, "Educational Attainment in the United States: 2015," March 2016, https://www.census.gov/content/dam/Census/library/publications/2016/demo/p20-578.pdf. See p. 2, Table 1.

[27] See, e.g., Ray Boshara, William R. Emmons, and Bryan J. Noeth, "The Demographics of Wealth: How Age, Education and Race Separate Thrivers from Strugglers in Today's Economy. Essay No. 2: The Role of Education" (Center for Household Financial Stability, Federal Reserve Bank of St. Louis, May 2015).

[28] U.S. Census Bureau, "Household Income in 2015, All Races (Current Population Survey, 2016 Annual Social and Economic Supplement)," accessed March 25, 2017, https://www.census.gov/data/tables/time-series/demo/income-poverty/cps-hinc/hinc-01.html. Though not depicted in Fig. 3.5, this data shows that the median US household income in 2015, was $56,515; in our sample the median was in the $75,000 to $99,000 category (participants did not report exact figures but rather selected from income brackets).

[29] A 2014 Gallup poll found that just 24% of Americans self-identify as liberal, whereas 38% self-identify as conservative and 34% as moderate. Lydia Saad, "U.S. Liberals at Record 24%, but Still Trail Conservatives" (Gallup, January 9, 2015), http://www.gallup.com/poll/180452/liberals-record-trail-conservatives.aspx.

or leaning toward, the Democratic party (**Table 3.3**).[30] In addition, as shown in **Fig. 3.6**, consumers of tDCS devices are far less engaged with religion than the U.S. population (as measured by frequency of attending religious services); the majority of our respondents (77.9%) never or rarely attend religious services, compared to 36% of the U.S. population.[31]

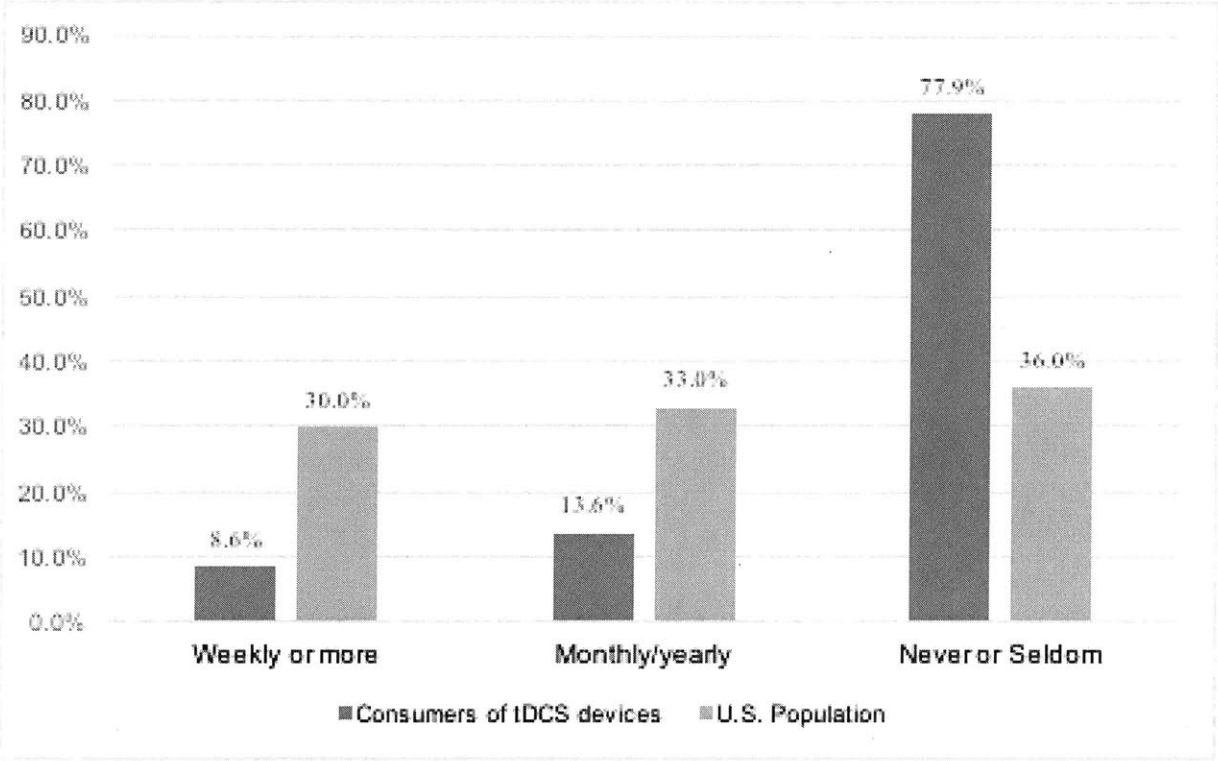


Figure 3.6. Frequency of attending religious services, tDCS consumers (n=339) compared to U.S. population (data from Pew Research Center, 2014 Religious Landscape Study).

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[30] It is unclear how political views map onto views regarding biotechnological enhancement (e.g., "bioliberals" and "bioconservatives" discussed in footnote 2). Some have argued that "bioconservatives are often political conservatives" [see Rebecca Roache and Julian Savulescu, "Enhancing Conservatism," in The Ethics of Human Enhancement: Understanding the Debate, ed. Steve Clarke et al. (Oxford: Oxford University Press, 2016), 145], whereas others, such as Erik Parens, have argued that liberal/conservative views towards technological enhancement do not map neatly onto political lines. See Erik Parens, "Authenticity and Ambivalence: Toward Understanding the Enhancement Debate," *Hastings Center Report* 35, no. 3 (May 6, 2005): 34–41.

[31] Pew Research Center, "U.S. Public Becoming Less Religious," November 3, 2015, http://www.pewforum.org/2015/11/03/u-s-public-becoming-less-religious/. See p. 152, "Attendance at Religious Services by Religious Tradition."

The data on religion is particularly salient, given that a recent Pew report on Americans' views towards enhancement found a very strong effect of religion; that is, those who were more religious were less likely to report being comfortable with the use of hypothetical future enhancement technologies.[32] Although the hypothetical enhancement technologies presented in the Pew study (synthetic blood transfusions, brain chip implants, gene editing) were far more invasive than tDCS, the results of our study suggest that this same effect may hold for less invasive enhancement technologies as well.

Participants in our sample were also earlier adopters of technology than the US population; most (63.7%; n=217) report being "the first" or "among the first" to try a new technology product relatively to their peers, compared to just 15% of Americans.[33] In addition, most participants (82.3%; n=279) reported reading articles about science frequently or very frequently. Compared to the U.S. population, consumers of tDCS devices seem far more interested in science: a 2014 Pew survey found that 37% of Americans enjoy keeping up with science news "a lot."[34] This finding, which shows that participants have a strong affinity towards science, provides indirect support for the qualitative results reported in the previous chapter, that participants rely heavily upon science in general and look to scientific articles for guidance. Thus, it seems that while home users of tDCS may not appreciate the way science is

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[32] Pew Research Center, "U.S. Public Wary of Biomedical Technologies to 'Enhance' Human Abilities," July 2016, http://www.pewinternet.org/2016/07/26/u-s-public-wary-of-biomedical-technologies-to-enhance-human-abilities/

[33] A 2016 Pew report found that just 15% of Americans report trying a new technology before others. See Pew Research Center, "Early Technology Adopters: Methodology," July 12, 2016, http://www.pewresearch.org/fact-tank/2016/07/12/28-of-americans-are-strong-early-adopters-of-technology/.

[34] Pew Research Center, "Public and Scientists' Views on Science and Society," January 29, 2015, http://assets.pewresearch.org/wp-content/uploads/sites/14/2015/01/PI_ScienceandSociety_Report_012915.pdf. See p.82, Q3.

disseminated (as discussed in Chapter 2), they also do not reject the scientific enterprise as a whole.

tDCS is not the only technique that participants utilize to improve their brain function: strikingly, nearly half of all participants reported using dietary supplements or non-prescription drugs to improve cognition; and more than a third each reported using brain-training games, binaural beats, or self-tracking tools to optimize productivity (**Table 3.4A**). Interestingly, just 7.7% of our sample have used direct-to-consumer electroencephalography (EEG) devices, which purportedly record and display a user's electrical brainwave activity and are currently marketed for "wellness" purposes.[35] Thus, although these two types of products—EEG and tDCS—are the only direct-to-consumer, wearable neurotechnology products marketed for self-improvement, there seems to be little overlap amongst their users.

Interestingly, more individuals in our sample reported using non-prescription drugs (48.4%) as compared to prescription drugs (26.5%) to enhance cognition. To-date, however, the literature on the use of cognitive enhancement drugs has almost exclusively focused on the use of prescription drugs, mainly amphetamine, methylphenidate, and modafinil (more commonly known by their brand names, Adderall, Ritalin, and Provigil, respectively).[36] While our sample may not be representative of general usage patterns, these results suggest that scholars should look to explore the phenomenon of non-prescription drugs for enhancement in tandem with their on prescription drugs.

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[35] See, e.g., Emotiv Insight (https://www.emotiv.com/insight/) and Muse (http://www.choosemuse.com/).

[36] For reviews see M. Elizabeth Smith and Martha J. Farah, "Are Prescription Stimulants 'Smart Pills'?," *Psychological Bulletin* 137, no. 5 (2011): 717–41, and C. Ian Ragan, Imre Bard, and Ilina Singh, "What Should We Do about Student Use of Cognitive Enhancers? An Analysis of Current Evidence," *Neuropharmacology*, 64 (2013): 588–95.

Table 3.4 Use of other brain enhancement/modification techniques. Panel A, left: responses for all respondents. Panel B, right: responses for those who visited the tDCS subreddit compared to those who had never visited and X^2 significance.

A. All respondents (n=339)			*B. Visited tDCS subreddit (VR; n=179) vs. never visited (NV; n=160)*		
	n	**%**	**VR**	**NV**	X^2
Dietary supplements or non-prescription drugs to improve cognition	164	48.4%	99	65	**
Brain-training games (e.g., Lumosity or CogniFit)	132	38.9%	79	53	*
Binaural beats	125	36.9%	75	50	*
Self-tracking tools to help optimize some aspect of my life (e.g., sleep or productivity)	116	34.2%	72	44	*
Prescription drugs to improve cognition	90	26.5%	57	33	*
Other	40	11.8%	20	20	
Transcutaneous electrical nerve stimulation (TENS)	39	11.5%	24	15	
Self-tracking tools to help cope with a disease/condition	37	10.9%	26	11	*
Transcranial alternating current (tACS)	32	9.4%	22	10	†
Consumer electroencephalography device (EEG)	26	7.7%	20	6	**
tRNS (transcranial random noise stimulation)	20	5.9%	14	6	†
Audio visual entrainment (AVE) therapy	19	5.6%	13	6	
Cranial electrotherapy stimulation (CES)	12	3.5%	9	3	
Transcutaneous vagus nerve stimulation (tVNS)	6	1.8%	6	0	‡

†p <=.10; *p <= .05; **p < =.01; ***p <= .001 (two-tailed test). ‡ = Fisher's exact test, p<.05.

Use of tDCS on others

While studies to-date have assumed that individuals purchase tDCS for use primarily on themselves, we found that a small number of respondents (3.5%; n=12) purchased a tDCS device to use primarily on others. In all but one case, the intended subject(s) of stimulation included a

family member, most commonly a child (n=6) or spouse (n=4). Most individuals (n=11) were using tDCS on others to treat disease or mitigate disease-related symptoms: depression (n=4), traumatic brain injury (n=2), chronic pain (n=1), migraine headaches (n=1), epilepsy (n=1), incontinence due to multiple sclerosis (n=1), and memory loss due to primary progressive aphasia (n=1). Five individuals reported using tDCS to affect cognition—memory, focus, attention—in some way, although the line between treatment and enhancement was not always clear (e.g., two participants used tDCS in an attempt to improve a family member's concentration levels: one reported that a diagnosis of ADD had been given, whereas the other only noted that the child had low grades).[37]

Half of those who use tDCS on others (n=6) found tDCS to be successful; some (n=3) were not sure and a few (n=2) felt it was unsuccessful. When asked if tDCS caused any unwanted effects in those to whom it was administered, most (n=7) said it did not, though some (n=3) reported skin sensations (tingling/itching) and one reported a visual phosphene (flash of light in the visual field). Six participants currently administer tDCS to others once a month or more, some (n=2) use it in fits and spurts, and some (n=3) no longer use tDCS, mostly (n=2) due to lack of efficacy.

Though the number of individuals using tDCS on others was relatively small, the practice raises complicated ethical questions. In particular, in half of all cases in our sample, participants were utilizing tDCS on their children (though it was unclear how old the children were). As there is currently little evidence regarding how electrical stimulation may affect a developing brain,

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[37] Amongst those who used tDCS on others, the number of sessions administered ranged from 5 to 100 with a mean of 28; current levels ranged from .5 to 2 milliamps (mA) with a mean of 1.59 mA; and the typical length of stimulation session in minutes ranged from 10 to 40 with a mean of 23.64. Most (n=7) have used tDCS at least once on themselves, but only some (n=3) reported still actively self-administering stimulation.

the potential risks may be even greater in these cases. Furthermore, it is not clear whether subjects have the ability to decline stimulation, or whether they understand that the technique is still experimental. Thus, the use on others represents cases not of individuals assuming risks for themselves, but rather applying an experimental therapeutic technique to others.

Purpose of tDCS use

Amongst the 96.5% (n=327) of participants who reported using tDCS primarily on themselves, we assessed the reasons why participants purchased consumer tDCS devices in two ways: first via an open-ended response question and later with forced-response questions that were shown to all those who reported using tDCS at least once on themselves. For the open-ended response question ("Why did you purchase a tDCS device?"), approximately two-thirds of participants mentioned cognitive enhancement reasons and one-third mentioned therapeutic reasons.[38] Notably, one-quarter mentioned curiosity, novelty, and/or self-experimentation, suggesting that enhancement and treatment are not the only reasons why individuals purchase consumer tDCS devices. Indeed, a recent study on the use of cognitive enhancement drugs found that some participants were motivated by curiosity.[39] Thus, it seems that some individuals are not completely driven by a specific purpose (i.e., treatment or enhancement) but rather are interested in trying out enhancement or perhaps even curious about the latest technology, which is line with our finding that most participants reported being early adopters of technology. All participants who reported using tDCS at least once on themselves (n=308) were asked to indicate (yes/no)

[38] Although responses to this question were coded in detail, for clarity we have opted to report detailed statistics only for the forced-response questions, which asked participants specifically about each usage indication (see figure **Figs. 3.7-8** and **Table 3.5**).

[39] Elisabeth J. Vargo and Andrea Petróczi, "'It Was Me on a Good Day': Exploring the Smart Drug Use Phenomenon in England," *Frontiers in Psychology* 7 (2016), 779.

whether they had ever self-administered tDCS "to treat a medical/psychological disease or condition" (i.e., treatment), "to restore diminished cognitive abilities (for example, to counteract the effects of aging" (i.e., restoration), or "to improve your own cognitive abilities" (i.e., enhancement). Responses are depicted in **Fig. 3.7**, and show that three-quarters (76.9%) of all those who used tDCS at least once reported using tDCS for enhancement, a little under a half (42.5%) for treatment, and roughly one-quarter (26.3%) for restoration.[40] Both across open-ended responses and forced-response question we found approximately the same proportion (2:1) of those who use the technology to enhance a cognitive ability vs. those who use it to treat a condition or disease; this is roughly the same proportion as reported by Jwa (2015).

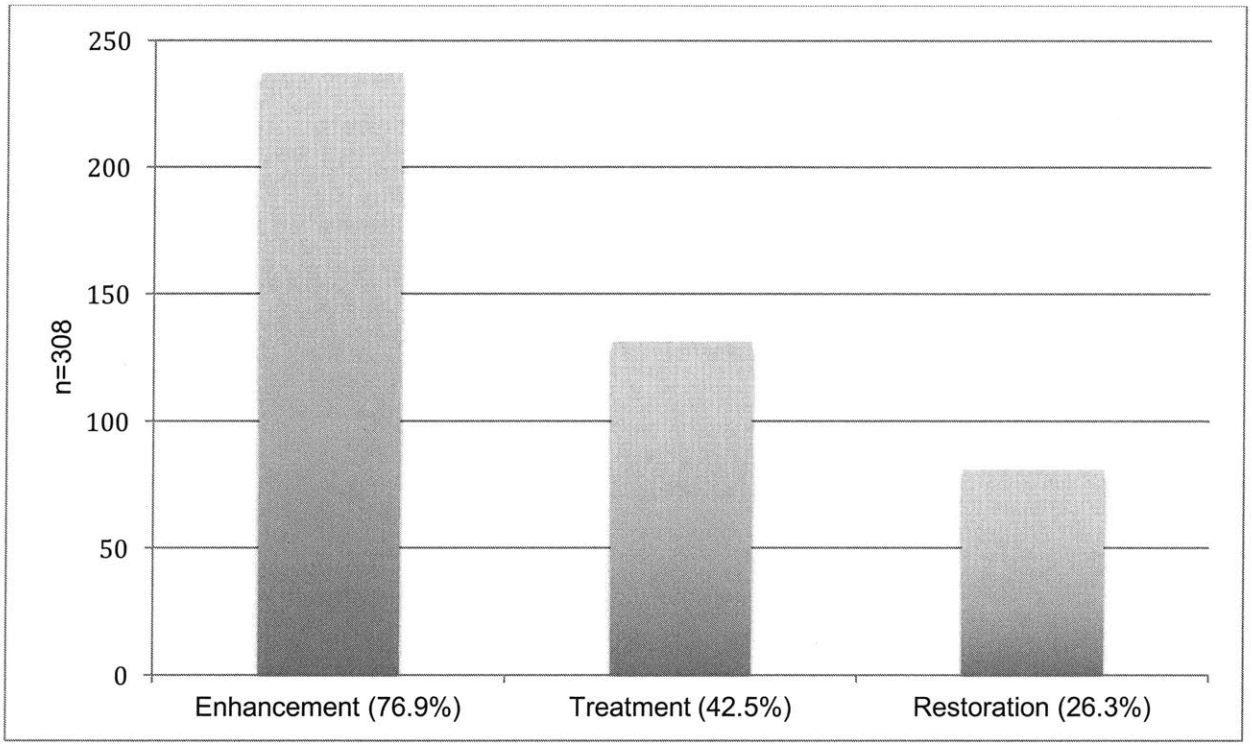


Figure 3.7. Primary purpose of tDCS, as indicated by yes/no forced responses.

[40] The percentages reported here are slightly higher than those reported in the previous question for two reasons: first, here we specifically asked participants if they had used tDCS for each of these particular indications, as opposed to a general question about why they purchased a tDCS device; second, our denominator is smaller, as this question was shown to those who had actually used tDCS at least once (n=308).

Similar to Jwa (2015), we found overlap in terms of usage indications; only 56.8% of our sample selected a single indication (i.e., only treatment, only enhancement, or only restoration). **Fig. 3.8** depicts the percentage of participants falling within each combination of indications, and suggests that the treatment/enhancement distinction is not clear cut. Indeed, even coding participants' responses to the open-ended response questions was challenging, particularly with regard to attention disorders (i.e., is using tDCS to improve focus/concentration meaningfully different for those who mentioned a diagnosis of ADD vs. those who did not) and mood disorders (where some participants reported using tDCS to improve the cognitive sluggishness that often accompanies depression). Thus the border between treatment, enhancement and restoration is a slippery one, and users themselves do not always clearly distinguish among them.

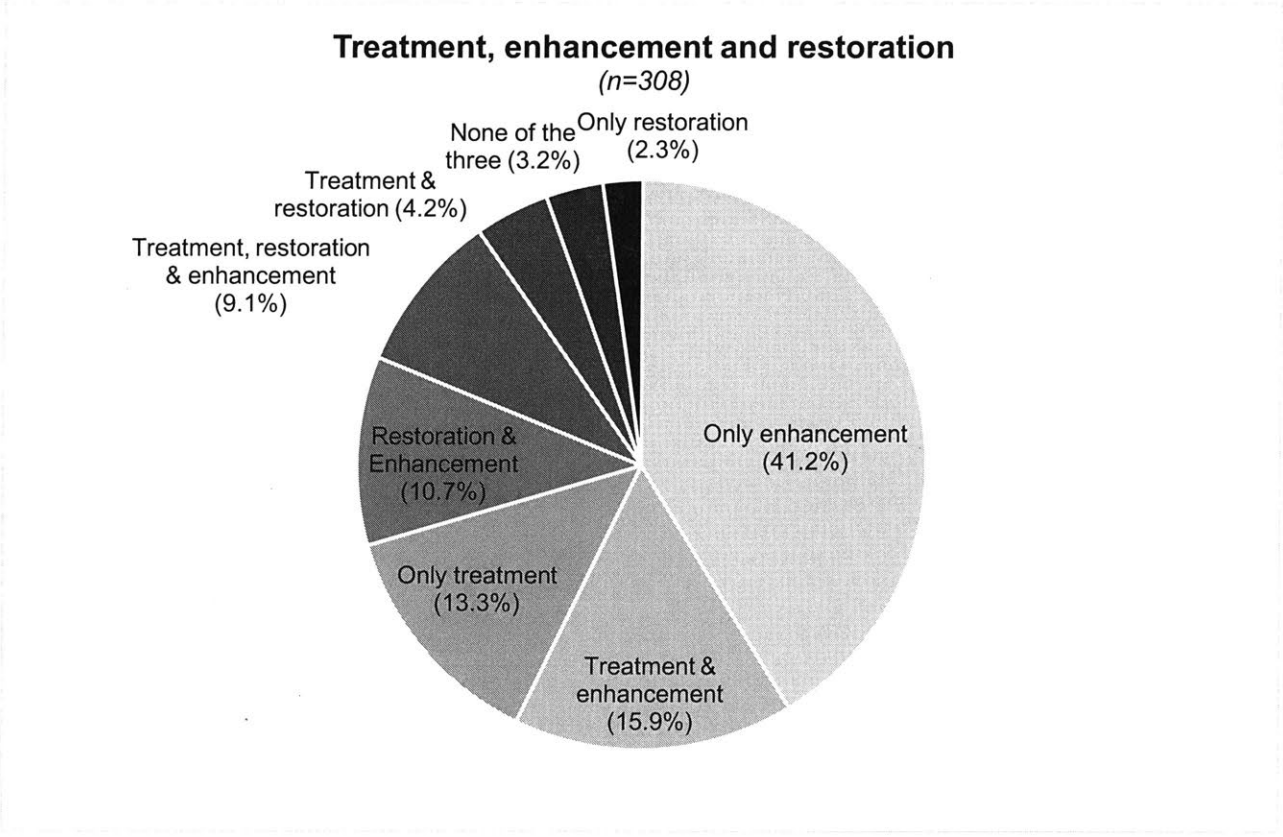


Figure 3.8. Percentages of participants falling within each combination of usage indications (treatment, restoration, enhancement).

Table 3.5. Detailed usage indications for treaters, enhancers, and restorers*

Treatment	**n**	*% within category (n=131)*
Depression	97	74.0%
Anxiety	55	42.0%
ADD/ADHD	35	26.7%
Other	21	16.0%
Chronic pain	12	9.2%
Bipolar disorder	7	5.3%
Migraine	7	5.3%
Tinnitus	6	4.6%
Addiction	5	3.8%
Enhancement	**n**	*% within category (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**	*% within category (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%

*Participants who answered affirmatively to having used tDCS for either treatment, enhancement, or restoration were asked to provide follow-up information, by selecting from a list of diseases/conditions (for treatment) or elaborating via free-form text (for restoration/enhancement).

One of the most notable findings of the present study was the large number of participants who utilize tDCS to self-treat depression. Indeed, as shown in **Table 3.5**, nearly three-quarters of all those who use tDCS for treatment do so in an attempt to treat depression, with anxiety and ADD representing the second- and third-most common categories. The number of participants who used tDCS for depression was particularly striking: put in perspective, of all individuals who purchased and used a tDCS device on themselves (n=308), approximately one-third (31.5%; n=97) have used it specifically to treat depression—despite the fact that almost all consumer tDCS devices are marketed for enhancement, not treatment. Among both enhancers and restorers, the two most common indications were improving focus/concentration and memory (**Table 3.5**). Interestingly, however, the order of these two indications was flipped for each group: memory was the most common target of restorers (which is not surprising, as it is the most salient cognitive ability to decline with age), whereas focus/concentration was the most common target of enhancers.

How might treaters, enhancers, and restorers differ from each other? As depicted in **Fig. 3.8**, there was significant overlap amongst treaters, enhancers, and restorers, with many participants selecting more than one usage indication. However, as restorers were similar to enhancers in that they were aiming to affect a cognitive function (as opposed to treating a disease) we grouped together all those who had selected using tDCS for treatment (n=131) and compared them to a separate set of individuals who had selected only enhancement, only restoration, or enhancement and restoration (n=167). While not a perfect comparison—as those who selected treatment and enhancement, treatment and restoration, or all three indications were included in the "treatment" category—we felt this represented the strongest conceptual distinction in terms of purpose of use amongst our sample. We then compared the effect of

"purpose of use" (i.e., treaters vs. enhancers/restorers) across categorical variables (using Pearson's Chi-squared tests, occasionally collapsing Likert-scale responses into two categories) and continuous variables (using independent samples t-tests, with "purpose of tDCS" as our independent variable).

Most notably, there was a significant relationship between gender and usage purpose, with females significantly more likely to be treaters and males more likely to be enhancers/restorers, as shown in **Fig. 3.9**. It is unclear why this is the case, although depression, which was the most common treatment indication in our study, has been shown to be nearly twice as prevalent as women than in men.[41] There was also significant relationship between gender and perceived success of tDCS, with treaters more likely than enhancers/restorers to rate tDCS as successful (and vice versa; see **Fig 3.10**). This effect was robust and apparent across other indirect measures of success: enhancers/restorers were more likely to agree that they expected to get more out of tDCS than they did, and more likely to agree that tDCS is merely a novelty item (**Table 3.6B**). Furthermore, those who cited "lack of efficacy" as a reason for quitting tDCS were significantly more likely to be enhancers than treaters [$X^2(1, N=298)=4.45$, $p=.035$; Cramer's V = .117]. Not surprisingly, treaters—who found tDCS to be more successful—were more likely to be current users of tDCS [$X^2(1, N=298)=4.24$, $p=.04$; Cramer's V = .122].

[41] See studies cited in Paul R. Albert, "Why Is Depression More Prevalent in Women?," *Journal of Psychiatry & Neuroscience* 40, no. 4 (2015): 219–21.

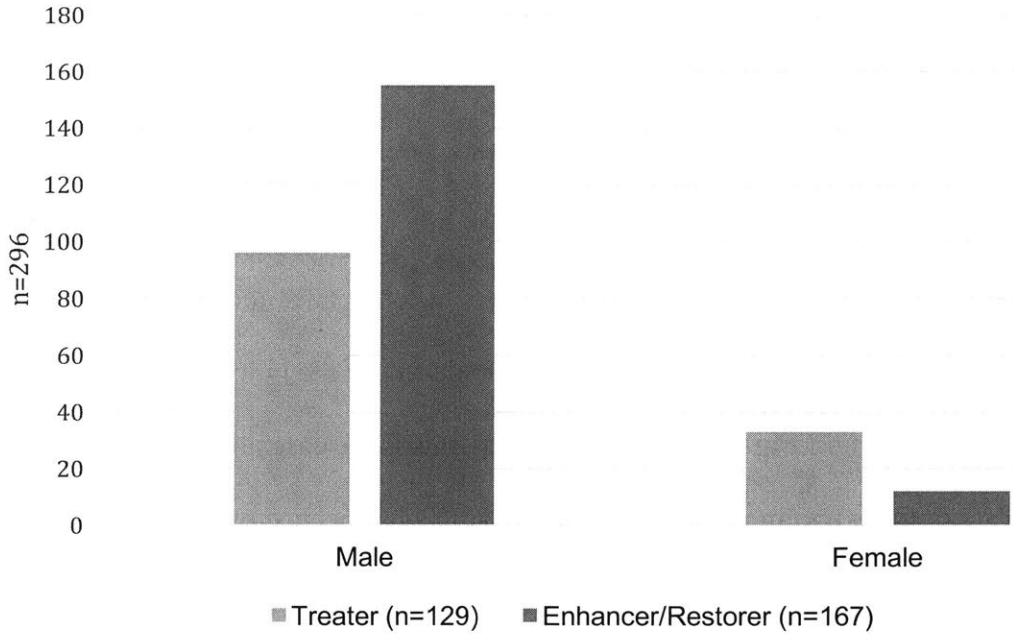


Figure 3.9. Treaters vs. enhancers/restorers, by gender [$X^2(1, N=296)=19.11, p<.001$; Cramer's V = .254].

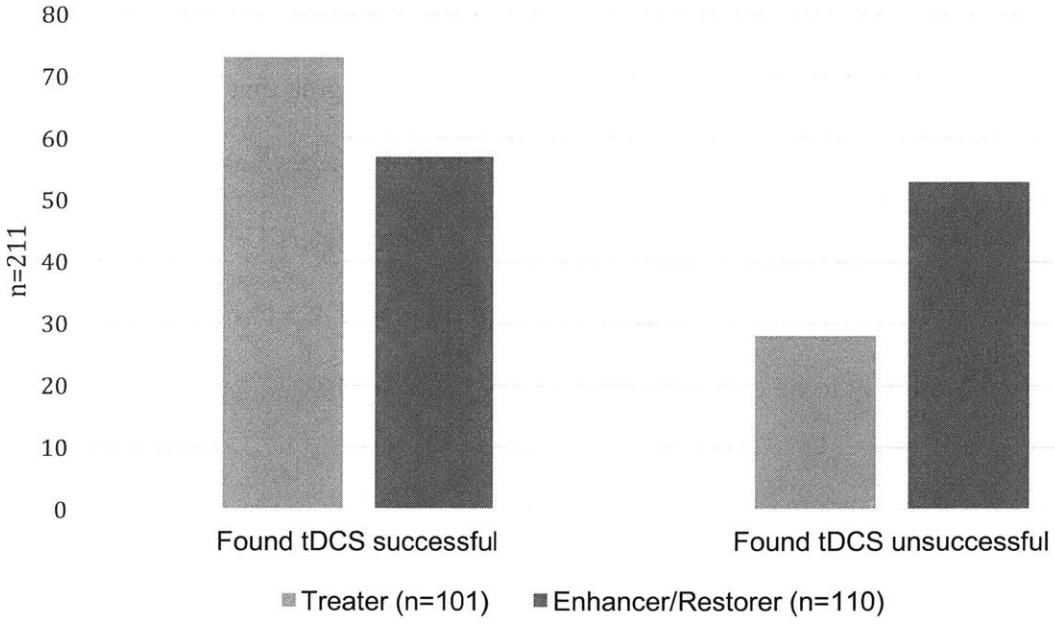


Figure 3.10. Treaters vs. enhancers/restorers, by ratings of success of tDCS [$X^2(1, N=211)=9.32, p=.002$; Cramer's V = .210].

Table 3.6. Responses to attitude questions. Panel A, left: for all participants (n=339). Panel B, right: mean responses for treaters (n=131) vs. enhancers/restorers (n=167) and t-test significance.

	A. All respondents (n=339)					*B. Treaters (n=131)*	*Enhancers /Restorers (n=167)*	
	Strongly agree (1)	Somewhat agree (2)	Neither agree nor disagree (3)	Somewhat disagree (4)	Strongly disagree (5)	mean (SD)	mean (SD)	*t*-test
Expectations about tDCS & consumer tDCS as novelty items								
Direct-to-consumer tDCS devices are merely novelty items.	2.7%	20.6%	28.3%	**29.5%**	18.9%	3.7 (1.1)	3.2 (1.1)	***
I expected to get more from tDCS than I actually did.	24.8%	28.9%	**30.1%**	11.2%	5.0%	2.6 (1.2)	2.3 (1.1)	**
Opinions about safety								
The risks of using tDCS at home outweigh the benefits.	6.2%	11.8%	**27.7%**	**27.7%**	26.5%			
tDCS should not be used on children.	31.6%	22.4%	**39.5%**	3.5%	2.9%	2.4 (1.1)	2.1 (1.0)	*
tDCS is a relatively safe technique.	34.2%	**38.6%**	21.5%	4.7%	0.9%	1.8 (.9)	2.1 (.9)	**
Regulation and availability of tDCS to the general public								
tDCS should remain available to the public.	**65.5%**	25.1%	8.0%	1.2%	0.3%	1.3 (.7)	1.5 (.7)	*
Government regulations should control the technical features (e.g., current output) of direct-to-consumer devices.	10.0%	25.7%	25.1%	20.4%	18.9%			
tDCS should not be used without supervision/guidance from a trained professional.	4.4%	13.0%	**32.4%**	**32.4%**	17.7%			
Identification with DIY tDCS and thoughts on media coverage								

I identify with the DIY tDCS movement.	18.9%	29.5%	**32.4%**	10.9%	8.3%	2.4 (1.1)	2.7(1.2)	*
The media blows the issue of do-it-yourself tDCS out of proportion.	15.3%	27.4%	**50.7%**	6.2%	0.3%			
Beliefs about brain optimization								
People don't use their brains to their fullest potential.	**39.2%**	36.3%	14.7%	5.9%	3.8%			
The brain is an organ that can be "hacked" to improve performance.	**38.9%**	37.8%	18.6%	4.4%	0.3%	2.0 (0.9)	1.76 (0.8)	*
Attitudes towards mainstream and alternative medicine								
Mainstream medicine is often out of touch with the needs of patients.	28.6%	**32.4%**	23.3%	8.6%	7.1%	2.1 (1.1)	2.5 (1.2)	***
I value alternative medicine practices.	26.3%	**32.7%**	20.6%	11.2%	9.1%			
I learned most of what I know about tDCS from my colleagues.	2.4%	5.0%	15.3%	20.6%	**56.6%**			
Neuroscience literacy								
Left-brained people are more rational and scientific, whereas right-brained people are more creative and artistic.	6.5%	19.5%	**47.2%**	11.5%	15.3%	3.0 (1.1)	3.3 (1.1)	*
Drugs and alcohol kill brain cells.	**37.5%**	32.2%	18.9%	6.5%	5.0%			
We use our brain 24 hours a day.	**71.7%**	17.7%	6.2%	3.5%	0.9%			
Brain activity can be studied through the oxygen consumption of specific brain areas.	19.8%	28.3%	**48.4%**	2.4%	1.2%			
People only use a small percentage of their brains.	22.1%	17.4%	17.7%	14.2%	**28.6%**	3.0 (1.5)	3.3 (1.5)	†

†p <=.10; *p <= .05; **p < =.01; ***p <= .001 (two-tailed test).

Treaters were also significantly more likely to agree that mainstream medicine is out of touch with the needs of patients (**Table 3.6B**). Interestingly, there were no significant differences between treaters and enhancers/restorers when it came to how they value alternative medicine (**Table 3.6B**). Thus, while treaters may be frustrated with modern medicine, they are not necessarily more likely than enhancers to turn to alternative medicine; this makes sense given that our sample is comprised of individuals who have a strong affinity towards science. Additionally, as shown in **Table 3.6B**, enhancers/restorers were more likely to agree that the brain can be "hacked" to improve performance. In other words, while treaters may be turning to tDCS because of how they feel, enhancers are more likely to conceptualize the brain as an organ that can be optimized for productivity.

Attrition rate and usage patterns

Is tDCS a technique that individuals take up (and keep using), or is it something that individuals utilize for a short period of time, then quit? Although Jwa (2015) found that half of respondents were "regular and continuous users" (though the meaning here was not clearly defined), to-date there has been no further detailed measures of usage patterns, nor the attrition rate amongst consumers of tDCS devices. The distribution of current users, former users, and those who never used tDCS amongst our sample is shown in **Fig. 3.11**; only 59.3% of our sample reported being current users, who were further subdivided based on their frequency of use, with the largest group of current users reporting using tDCS only in "fits and spurts." Approximately half of all current users of tDCS (n=92) report that their frequency of use has remained constant since they began using tDCS. Those who reported that their frequency of use has changed were asked to describe their previous patterns of usage; while these responses were not coded thematically, the

overall trend was towards decreasing usage (e.g., participants report using tDCS less now than they did in the past). Thus, even among current users, tDCS is a technique that participants use less over time, not more.

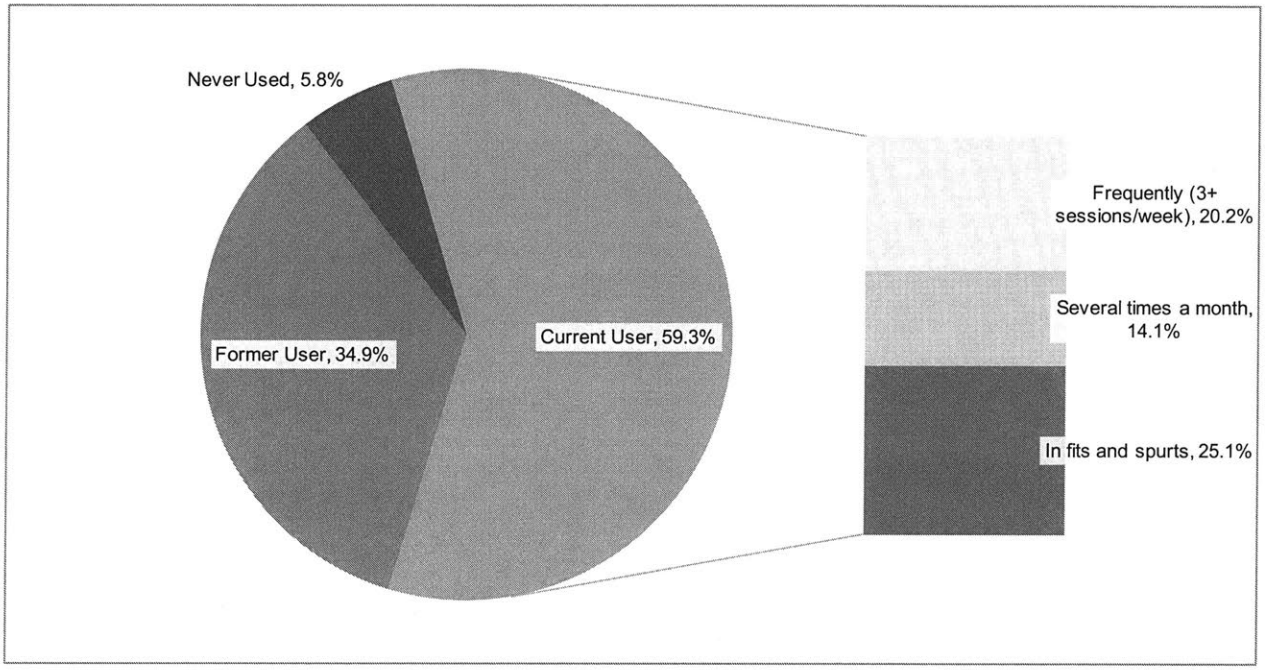


Figure 3.11. Participants tDCS usage distribution (n=327): current users, former users, and those who never used tDCS.

The 5.8% of our sample who purchased a consumer tDCS device but never used it were asked to describe, in their own words, why they had not tried stimulation. The most common reasons provided were concerns regarding the safety of the procedure and lack of information provided by the manufacturer, particularly with regard to electrode placement. All participants reported that they were open to using tDCS, provided there was additional evidence to validate the efficacy and safety of technique, and/or if more information was provided by the manufacturer regarding electrode placement.

Notably, one-third of users (34.9%) reported being former users of tDCS, with the most common reason for quitting being lack of efficacy, although participants also cited side effects,

lack of information about stimulation protocols, and concerns about potential long-term effects, among other reasons (**Table 3.7**). When asked if they would use tDCS again (and if so, to describe why), only 7% of respondents said that they would not use tDCS again; the remaining 93% reported being open to using tDCS again, if there was additional evidence regarding efficacy, additional guidance from the manufacturer, or other reasons (**Table 3.7**).

Table 3.7 Reasons former users (n=114) quit using tDCS and why they would begin using tDCS again

Why did you stop using tDCS?	**n**	**%**
Lack of efficacy	54	47.4%
Experienced unwanted effects	19	16.7%
Other	18	15.8%
Lack of information about stimulation protocol	14	12.3%
Concerns about long-term effects	13	11.4%
Boredom/lack of time	12	10.5%
Broken or defective tDCS unit	6	5.3%
Would you use tDCS again, and if so, why?		
Yes, if there was more evidence regarding efficacy	45	39.5%
Yes, if the manufacturer provided more guidance about stimulation protocols	22	19.3%
Yes, if the device and/or electrodes were improved	19	16.7%
Yes (no reason provided)	14	12.3%
Yes, if tDCS was safer and had fewer side effects	14	12.3%
Yes, if there was guidance from professionals	7	6.1%
No, would not use again	**7**	**6.1%**
Yes, other reasons	6	5.2%
Yes, if I needed to	5	4.4%
Yes, if the price was lower	5	4.4%

This finding—that most users quit due to lack of efficacy—is notable, as indicates that participants are not quitting because of side effects, but rather because they are not experiencing

any benefits of the technique. This general finding was supported when we conducted further statistical analysis on the differences between current and former users. Current users were much more likely than former users to rate tDCS as successful (**Fig 3.12**), and agree on related measures shown in **Table 3.6**, such that they expected to get more out of tDCS then they actually did [$X^2(1, N=226)=21.32, p<.001$; Cramer's V = .307], and that tDCS devices are merely novelty items [$X^2(1, N=220)=33.53, p<.001$; Cramer's V = .390]. In general, former users seemed to a hold a more negative and skeptical view of tDCS, being more likely to agree that tDCS should not be used without professional guidance [$X^2(1, N=207)=10.73, p=.001$; Cramer's V = .228], and more likely to disagree that tDCS is a relatively safe technique [$X^2(1, N=239)=15.56, p<.001$; Cramer's V = .255]. As noted earlier in the discussion of treaters vs. enhancers/restorers, current users are more likely than former users to use tDCS for treatment than enhancement/restoration.

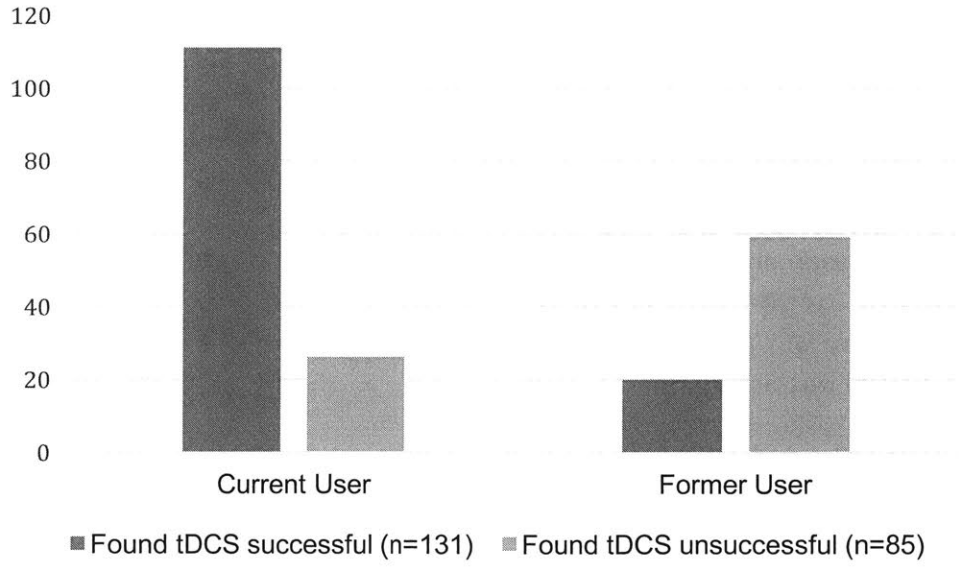


Figure 3.12. Relationship between current use and success of tDCS. [$X^2(1, N=216)=65.5, p<.001$; Cramer's V = .549].

Perceived efficacy of tDCS

As efficacy was shown by Voarino et al. (2017) to be one of the main factual assumptions underlying bioethical concerns about tDCS, we assessed whether or not respondents felt that their use of tDCS had been effective. While one can turn to the scientific literature on tDCS studies to attempt to answer the question of efficacy, we argue that *perceived* efficacy, as reported by users themselves, is actually a more relevant measure, as (a) laboratory studies may not translate to home users; and (b) effects found in laboratory studies, while statistically significant, may be too small to be apparent to home users; and (c) if subjects *perceive* the technology to be effective—even if this due to a placebo effect—then bioethical concerns regarding the home use of tDCS still hold.

Participants were asked to rate the extent that they felt tDCS was successful on a 1 to 5 scale (1= totally unsuccessful; 5= totally successful). As shown in **Fig. 3.13**, more individuals found tDCS to be successful (42.5%) than unsuccessful (27.6%).

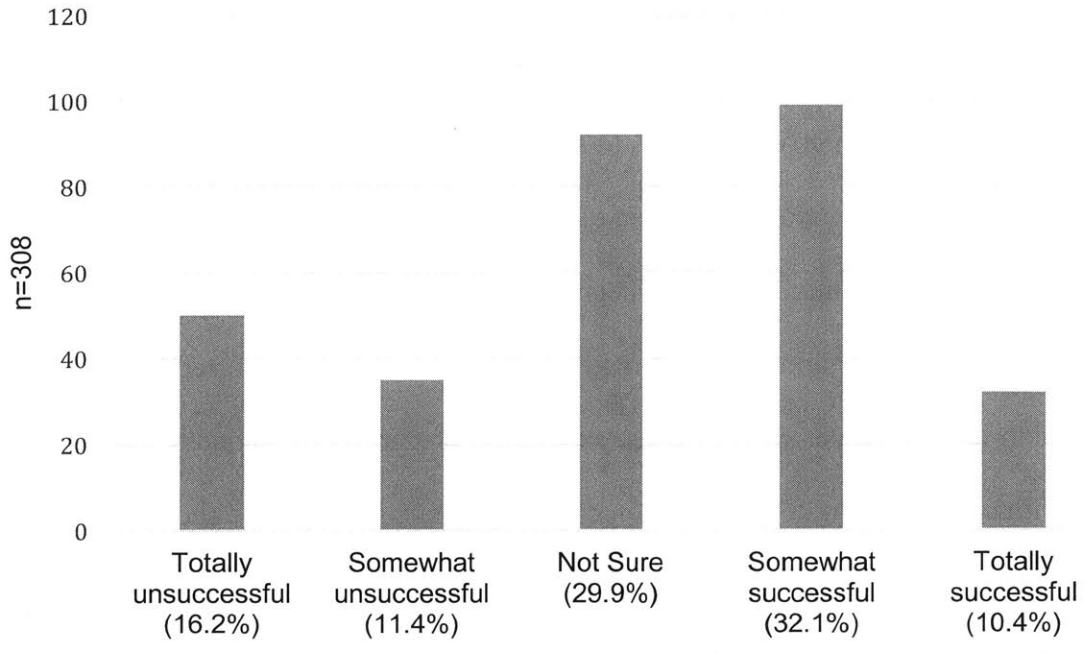


Figure 3.13 Participants' ratings of their success with tDCS.

However, even amongst participants who rated tDCS as successful there was lingering uncertainty, as the most common response (32.1%) was that tDCS was "somewhat successful." Furthermore, amongst those who felt more strongly about the effects of tDCS, a greater number found it totally unsuccessful than totally successful. Thus, it seems that many participants—even those felt tDCS was successful—were somewhat disappointed in the effects of tDCS. Indeed, as shown in **Table 3.6,** slightly more than half of participants (53.7%) agreed that they expected to get more out of tDCS than they actually did; only 16.2% disagreed with this statement, though disagreement could mean that (a) their expectations of tDCS were met; or (b) tDCS exceeded their expectations. Not surprisingly, there was a relationship between perceived success and current use, with current users being far more likely to rate tDCS as successful (and vice versa), as shown in **Fig. 3.12**.

Safety of tDCS: reported side effects and beliefs about risk and regulation

One of the concerns underlining the ethical and regulatory issues regarding tDCS is the safety of the technique. In the literature to-date, the term "safety" has been used to describe at least two distinct phenomena: the acute effects of stimulation (sometimes referred to as "side effects") and the potential deleterious long-term effects on cognition. With regard to acute effects, in published tDCS studies, there have been no "serious" adverse events (i.e., those requiring hospitalization or resulting in life-threatening injuries or death) reported in the 10,000 subjects studied to-date; however subjects often experience skin irritation, redness and headaches.[42] With regard to long-term effects on cognition, some studies have shown that

[42] Felipe Fregni et al., "Regulatory Considerations for the Clinical and Research Use of Transcranial Direct Current Stimulation (tDCS): Review and Recommendations from an Expert Panel," *Clinical Research and Regulatory Affairs* 32, no. 1 (2015): 22–35.

enhancing one brain region may have negative effects on another.[43]

As assessing long-term cognitive effects is a complex and challenging endeavor—which would require more intimate knowledge of participants' lifestyles and the ability to control for a myriad of other factors, including sleep, nutrition, life stressors, etc.—in the present study we focused only on short-term effects. We asked participants if they experienced any unwanted side effects from tDCS, and if so, to describe them. We specifically used an open-ended format for this question, as a pre-populated list might have biased participants to report more effects; and we wanted to see if any themes arose that are not currently described in the neuroscience literature on tDCS. The largest group of participants reported not experiencing unwanted effects from tDCS (**Fig 3.14**), although approximately one-third of all participants reported experiencing skin irritation (i.e., redness, tingling, itching). Less common side effects were headaches, flashes of light in the visual field, known as "phosphenes," dizziness, and experiencing a metallic taste.[44]

Notably, 16.9% of participants used the word "burn" (e.g., "skin burn" or "burning sensation") to describe an unwanted side effect. Mentions of burns were difficult to interpret further, as individuals appear to use the term interchangeably to describe everything from heat sensations to varying degrees of skin redness. However, a small number of participants (n=10) reported more serious burns, as determined by mentions of scarring (n=5) or language that indicated severity (n=5; e.g., "severe scalp burn," "third-degree burn," "red mark that took days

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[43] Teresa Iuculano and Roi Cohen Kadosh, "The Mental Cost of Cognitive Enhancement," *Journal of Neuroscience* 33, no. 10 (2013): 4482–86.

[44] Another 16.6% (n=51) of participants reported side effects that we coded as "other" (not shown in **Fig. 3.14**). These included, among other things, sleepiness/fatigue (n=4), difficulty finding words (n=4), insomnia (n=3), mania (n=3), muscle twitching (3), overstimulation (n=2), and blurred vision (n=3). Reports of mania and overstimulation are especially intriguing as another paper also found a small number of reports of mania following tDCS stimulation in depressed individuals; see Hideyuki Matsumoto and Yoshikazu Ugawa, "Adverse Events of tDCS and tACS: A Review," *Clinical Neurophysiology Practice* 2 (2017), 21, Table 2.

to clear").[45] That a small number of subjects report persistent "burns" is in line with several reports of "skin lesions" in the tDCS literature;[46] these have occurred while tDCS is being administered by trained professionals in laboratory settings. Thus, it should not necessarily be concluded that users had skin burns/lesions because they did not know how to use tDCS, as such burns/lesions have occurred in controlled laboratory settings as well.[47]

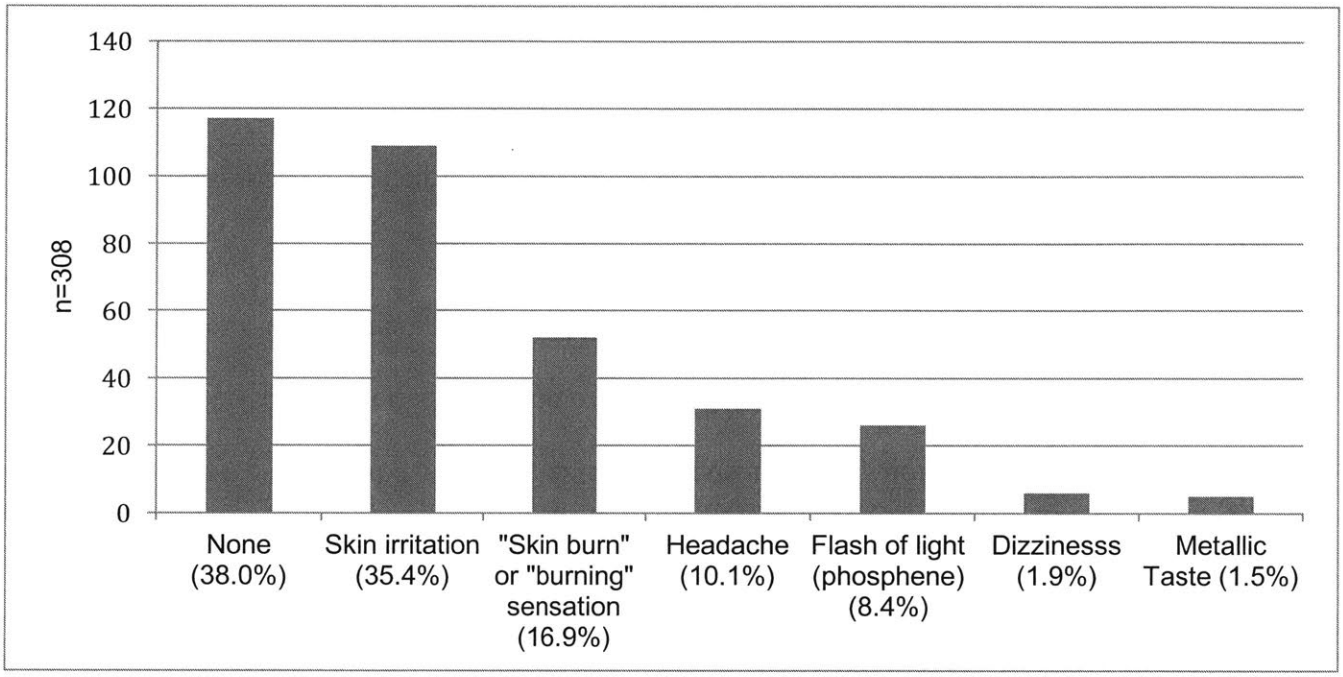


Figure 3.14 Participant-reported side effects from using tDCS.

[45] Note that participants who reported "third-degree burns" (n=2) were most likely referring to first-degree burns. Third-degree burns are considered the most serious kind of burn, generally necessitating immediate medical attention (and often skin grafting). However, not a single participant in our sample mentioned seeking out medical attention.

[46] Neus Rodríguez et al., "Skin Lesions Induced by Transcranial Direct Current Stimulation (tDCS)," *Brain Stimulation: Basic, Translational, and Clinical Research in Neuromodulation* 7, no. 5 (2014): 765–67; Jing Wang et al., "Skin Burn After Single Session of Transcranial Direct Current Stimulation (tDCS)," *Brain Stimulation: Basic, Translational, and Clinical Research in Neuromodulation* 8, no. 1 (2015); Hideyuki Matsumoto and Yoshikazu Ugawa, "Adverse Events of tDCS and tACS: A Review," *Clinical Neurophysiology Practice* 2 (2017): 19–25.

[47] In the two-day tDCS training course I attended, burns were ascribed to untrained individuals who were administering the "wrong way." However, as noted in the previous footnote, more recent mentions of burns and skin lesions have been reported by trained individuals using tDCS in the "correct" manner.

In addition to asking participants about effects they themselves had experienced, we probed their attitudes toward the safety, risk, and regulation of tDCS. As shown on **Table 3.6**, nearly three-quarters of our sample (72.9%) agreed that tDCS was a relatively safe technique, and only a small number (5.6%) disagreed (i.e., felt that tDCS was not safe). More than half (54.3%) felt that the risks of using tDCS at home *did not* outweigh the benefits; in other words, they felt that the benefits of tDCS justified the risks. Interestingly, however, slightly more than half (54.0%) agreed that tDCS should not be used on children, and only a very small proportion (6.5%) disagreed. Thus, while most participants consider tDCS to be a relatively safe, many also have significant reservations about the use of the technology (as measured by their responses to the acceptability of using tDCS on children).

More than 90% agreed that tDCS should remain available to the public; this was the strongest consensus achieved on any of the questions in this section. Participants results on this response diverge widely from scientists; a recent survey of tDCS researchers found that 71% believed that tDCS should not remain available to the public.[48] Interestingly, however, participants were mixed when it came to views on regulation: while 39.2% disagreed that government regulation should control the technical features of tDCS devices, almost as many (35.5%) were in favor of such regulation. In addition, a little more than half (50.1%) disagreed that tDCS was a technique that should be only used with guidance from professionals, whereas approximately one-third (32.4%) were not sure, and 17.4% agreed. Responses to the latter question imply that a small but significant percentage (17.4%) feel that tDCS is fundamentally a

[48] Kate Riggall et al., "Researchers' Perspectives on Scientific and Ethical Issues with Transcranial Direct Current Stimulation: An International Survey," *Scientific Reports* 5 (2015): 10618, doi:10.1038/srep10618.

research/professional technique that should not be available for unsupervised or unguided home use.

Safety of tDCS: stimulation parameters and protocol

In the previous chapter, I discussed how mostly adhered to the scientific parameters set out in stimulation studies, especially with regard to current level; however, those I interviewed would sometimes stimulate longer, and more frequently, than tDCS researchers. This is important as "potential for misuse" of tDCS was a factual assumption identified by Voarino et al. (2017) as underlying bioethical concerns. However, "misuse" implies that there is single, defined correct usage, which there is not. Thus we refrain from utilizing that terminology, and instead focus on how the stimulation parameters and protocols used by participants compare to those used by scientists, with regard to current level, length of stimulation session, and frequency of stimulation.

Similar to what I found in the previous chapter, most participants adhered to 2.0 milliamps (mA) of current or less; all those who inputted numbers higher than 2.0 mA reported not understanding the question and/or owning only devices that do not provide higher than 2.0 mA of current. This is similar to the levels of current utilized in scientific studies, which rarely exceed 2.0 mA. Participants also roughly adhered to typical length of stimulation sessions used in scientific studies (~20-30 minutes), with the most common reported length being 20 minutes **(Fig. 3.15)**.

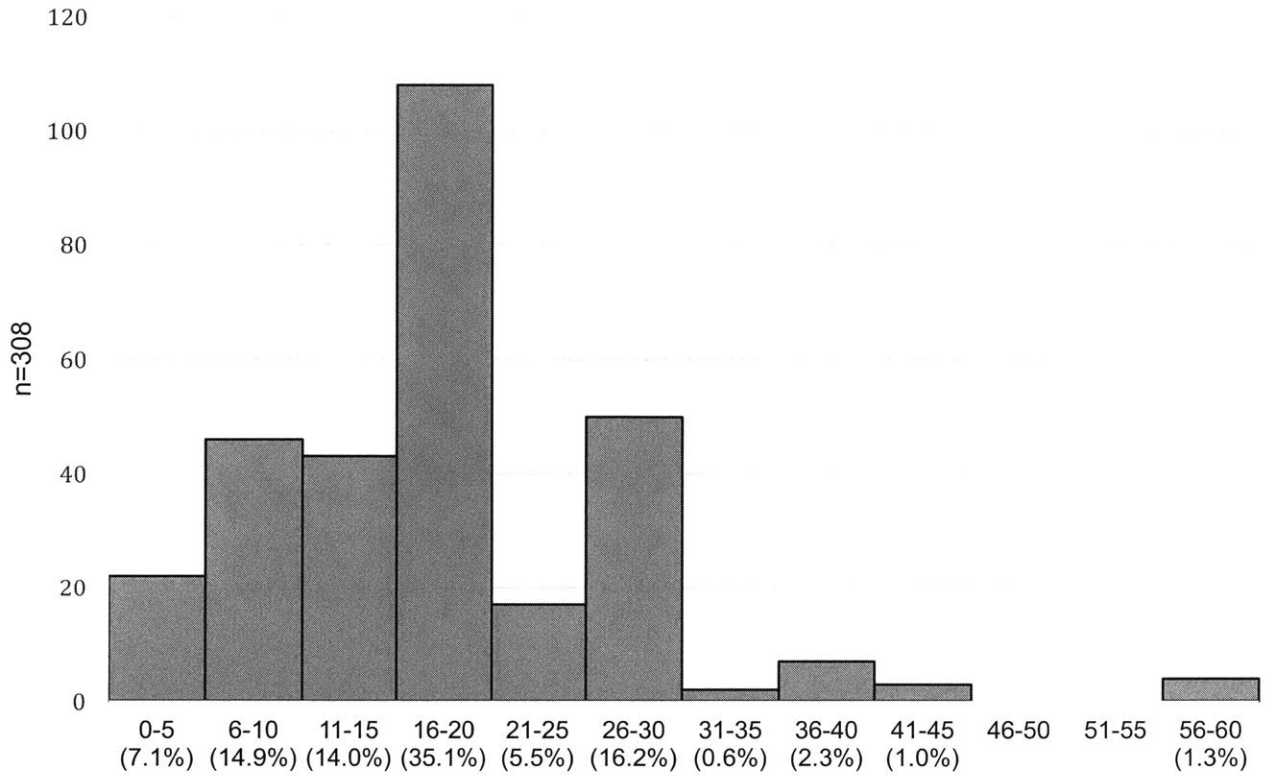


Figure 3.15. Typical length of participants' stimulation sessions, in minutes.

Notably, participants departed from established scientific tDCS protocols when it came to frequency of stimulation (i.e., total number of sessions administered). Laboratory studies of tDCS that examine the effects of tDCS on cognition often administer a single session of stimulation (and occasionally multiple sessions); those that examine the effects of tDCS in clinical populations (i.e., to treat depression) often administer on the order of 10-15 sessions (or less).[49] As shown in **Fig 3.16**, more than 40% of participants had self-administered more than 21 sessions of tDCS, and 8.4% were "super-users" that had self-administered 100 or more sessions of tDCS. Thus, the present study shows that users home users depart most dramatically from scientific precedent when it comes to frequency of use. As there is currently little data on the

[49] Jean-Pascal Lefaucheur et al., "Evidence-Based Guidelines on the Therapeutic Use of Transcranial Direct Current Stimulation (tDCS)," *Clinical Neurophysiology* 128, no. 1 (2017): 56–92.

effects of "chronic" or long-term use of tDCS, the concerns expressed by bioethicists regarding potential risks may be most relevant for "super-users" of tDCS.

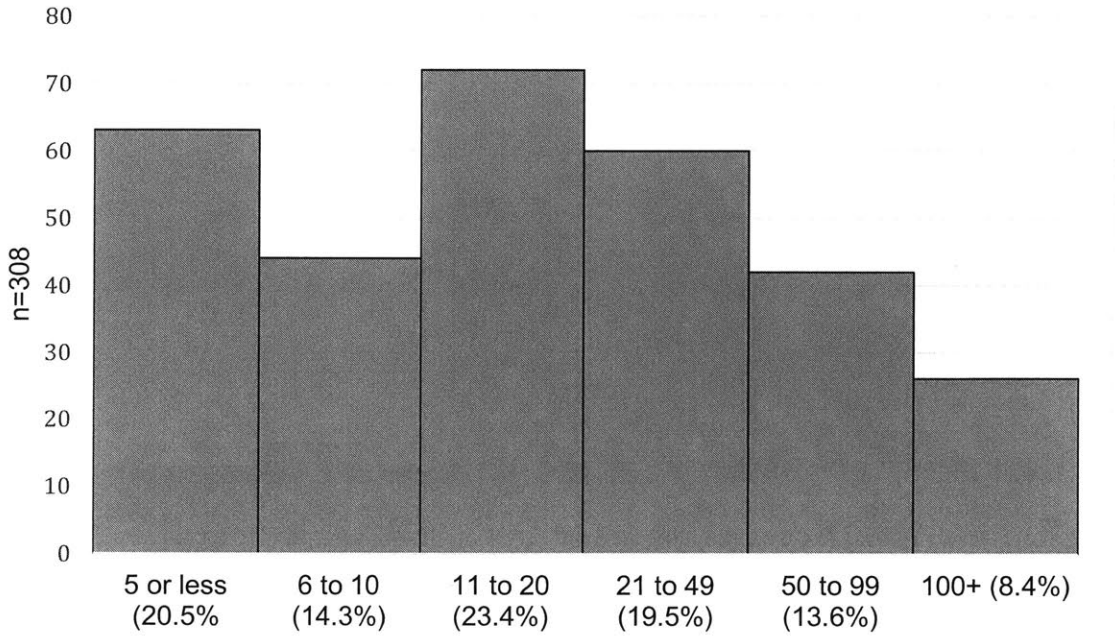


Figure 3.16. Number of times participants' administered tDCS to themselves.

Engagement with online tDCS community

As noted in the introduction, one of the questions of this study was if the tDCS subreddit (www.reddit.com/r/tDCS) could be taken to be representative of home users of noninvasive brain stimulation. Surprisingly, as shown in **Fig. 3.17,** more than a third of participants had never even heard of the tDCS subreddit and in total, almost half of all respondents had never visited it. Among the 52.8% who had visited the tDCS subreddit, the vast majority (95%) were "lurkers" who reported never or rarely posting to the forum. Thus, the tDCS subreddit does not provide an ideal representation of home users, and it appears that posts to the forum represent only a tiny fraction of communication amongst users.

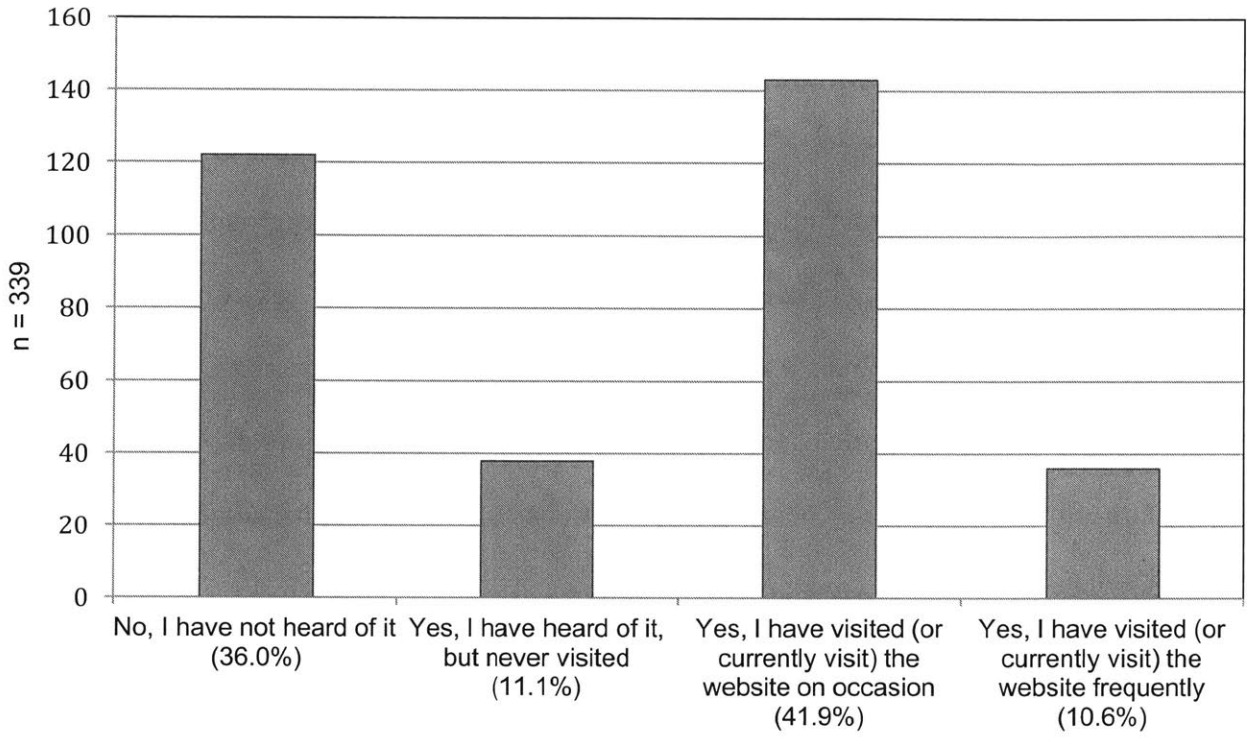


Figure 3.17. Participants' familiarity with the tDCS subreddit

To further understand how those who had visited the tDCS subreddit differed from those who had never visited, we used Pearson's chi-squared tests and independent samples t-tests to compare differences in responses across these two groups. Most notably, those who had visited the tDCS subreddit were significantly more likely (than those who had not visited) to have used a wide variety of other brain enhancement techniques (see **Table 3.4B.**). It is not apparent why this is the case: although there is a separate forum dedicated to "nootropics" (i.e., dietary supplements and drugs used to enhance cognition) on Reddit.com (which could explain why the use of non-prescription drugs and supplements was significantly different across the two groups, as there may be overlap amongst those visit both forums) it is unclear why the differences were significant for many other techniques as well.

III. Discussion

To our knowledge, this study provides the largest and most comprehensive survey to-date of users of consumer tDCS devices. Although there have been many studies of users of cognitive enhancement drugs—ranging from large-scale surveys to in-depth focus groups—there are relatively few studies on cognitive enhancement devices. The methodology employed here was unique as we were able to obtain a sample of all participants who had purchased a consumer tDCS device, thereby allowing us to tap into both former and current users. It would be hard to imagine a similar methodology being viable for studies of cognitive enhancement drugs, where their distribution and procurement is more diffuse.

As Voarino et al. (2017) neatly elucidated, many of the ethical concerns that have been raised regarding the home use of noninvasive brain stimulation have rested on factual assumptions regarding prevalence, efficacy, and safety. With regard to prevalence, this study estimated that the total number of consumer tDCS devices sold in the last several years has been in the low five figures. While this is far from a perfect measure, it does provide at least some sense of scale. Of course, the total number of active users is likely significantly lower than that figure, given that 40% of individuals in our sample alone were former users or had never used tDCS, and it is likely that many former users did not respond to the survey. We also found no evidence that the home use of tDCS is increasing; rather, we argued that the increased attention to the phenomenon, both in the media and in scholarly articles, might make it seem like the home use of tDCS is a larger phenomenon than it actually is—and may in fact be driving individuals to utilize tDCS. Thus, concerns expressed in the bioethical literature about potential threats to

autonomy based on the possibility of coercion—which are premised on the fact that tDCS may achieve widespread social uptake—are likely not relevant, as Voarino et al. (2017) speculated.

With regard to efficacy, one of the most notable findings from our study is that those who use tDCS for treatment rate the technology as more effective than those who use it for enhancement, and this effect was robust across other measures of success. This could be the case for a number of reasons. One possibility is that tDCS may actually be more successful when used for treatment as opposed to enhancement; this possibility is line with current reports in the neuroscience literature, which have shown stronger effects for depression than for other indications.[50] Another possibility is that the effects of stimulation may be more pronounced for treaters than enhancers/restorers; in other words, a small percentage increase on a cognitive domain—if one does exist—may be so small as to not be apparent to the average user; whereas symptom relief from depression may be more salient. A third possibility is that tDCS is not effective for any indication, but that there is a greater placebo for those who use it for depression than for those who use it for enhancement or restoration.

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[50] A recent meta-analysis examining the use of tDCS in clinical contexts found that the highest levels of "probable" efficacy for tDCS were related to its use in fibromyalgia, depression, and addiction/craving. See Jean-Pascal Lefaucheur et al., "Evidence-Based Guidelines on the Therapeutic Use of Transcranial Direct Current Stimulation (tDCS)," *Clinical Neurophysiology* 128, no. 1 (2017): 56–92. While this review did not examine studies of tDCS in healthy populations, there is currently a debate in the literature about whether tDCS does indeed have "cognitive enhancement" effects; see, e.g., Jared Cooney Horvath, Jason D. Forte, and Olivia Carter, "Evidence That Transcranial Direct Current Stimulation (tDCS) Generates Little-to-No Reliable Neurophysiologic Effect beyond MEP Amplitude Modulation in Healthy Human Subjects: A Systematic Review," *Neuropsychologia* 66 (2015): 213–36, and Jared Cooney Horvath, Jason D. Forte, and Olivia Carter, "Quantitative Review Finds No Evidence of Cognitive Effects in Healthy Populations From Single-Session Transcranial Direct Current Stimulation (tDCS)," *Brain Stimulation* 8, no. 3 (2015): 535–50; Amy R. Price and Roy H. Hamilton, "A Re-Evaluation of the Cognitive Effects From Single-Session Transcranial Direct Current Stimulation," *Brain Stimulation* 8, no. 3 (2015): 663–65.

As Voraino et al. (2017) found that assumptions regarding efficacy were underlying three of four main ethical bioethical concerns (autonomy, justice, authenticity), the findings here suggest that bioethical concerns with regard to tDCS for enhancement may not be pressing; indeed, only a third of users found tDCS to be effective for enhancement or restoration. Thus, more pertinent ethical issues may arise with regard to the home use of tDCS for treatment, particularly for depression. Here, the risk-benefit tradeoff is altered, as individuals presumably have more to gain than lose, and the main ethical concerns would likely center on issues of safety.

Safety, or the potential harm to users, is the most widely discussed topic in the bioethics literature related to tDCS. With regard to acute short-term effects (i.e., "side effects") we found that similar to Jwa (2015) and reports in the tDCS literature, skin irritation was the most commonly reported side effect. However, ten individuals noted more serious burns, as determined by language indicating severity. Given that similar skin "lesions" have been recently reported in the tDCS literature as well—even when stimulation is administered by trained professionals under controlled conditions—it is far from clear that the burns reported by participants were due to "misuse" of the technology. Furthermore, we found that participants departed from scientific tDCS protocols most notably with regard to frequency of stimulation, with many users stimulating far more frequently than reported in scientific studies of tDCS. Thus, when considering issues of safety, we suggest that ethicists and regulators focus on two primary concerns that this empirical study has identified—skin burns and the unknown effects of the chronic use of tDCS.

In addition, participants in our sample reported much higher levels of income compared to the U.S. population (as shown in **Fig 3.5)**; this finding may provide empirical support for

issues of distributive justice, which is the concern that tDCS may be available only to those who are wealthier—although as discussed above, it is not clear that tDCS is overwhelming effective for cognitive enhancement. (We cautioned that an alternate interpretation of **Fig. 3.5** is that consumers of tDCS devices are relatively well distributed across income brackets, and that it is the U.S. income distribution that is skewed.) We found that compared to the U.S. population, those who owned tDCS devices were more educated, more liberal, less religious, more engaged with science, and more likely to be early adopters of technology. Our population had a greater proportion of females than previously reported by Jwa (2015), most of whom were using tDCS for treatment purposes.

With regard to purpose of use, one of the most striking findings from the present study was that approximately one-third of all those who had purchased and used a tDCS device on themselves did so to treat depression. Furthermore, although we analyzed differences between treaters and enhancers/restorers, the reality was much more complicated, as shown in **Fig 3.8**; that is, many people purchase tDCS and use it both for treatment and enhancement and the border between these indications is not always clear. For example, as depression is often accompanied by cognitive impairment, individuals may be using tDCS both to improve their mood and their focus/concentration; those with a diagnosis of ADD may consider their use of tDCS to be "treatment" whereas those without a formal diagnosis, but with the same symptoms, may consider their use of tDCS to be "enhancement."

The difficulty of establishing clear boundaries between the usage indications may have both policy and ethical implications; as will be discussed in Chapter 4, tDCS devices marketed for treatment are subject to completely different regulatory pathways than those marketed for cognitive enhancement. Furthermore, ethicists rely heavily on risk-benefit tradeoffs when

considering potential harms of a given technique or therapy; experimental therapies are generally viewed as more ethically permissible when an individual is "sick" (and utilizing the therapy to return to "baseline") than when an individual is "healthy" and attempting to enhance cognition. Yet at this study and Jwa (2015) have demonstrated, the border between treatment/enhancement is murky, and users themselves may not distinguish between them.

The methodology utilized in the present study allowed us to examine the population of users who have stopped using tDCS; we found that the most common reason for quitting was related to questions about efficacy. Thus, it is not side effects or concern about long-term effects that are driving individuals away from tDCS, rather it is the fact that they are not experiencing benefits from the technique. Most individuals who stopped using tDCS reported being open to using the technology again, provided that there was greater evidence regarding efficacy of the technique.

In addition, we found that approximately one-third of respondents had never heard of the tDCS subreddit, and it total, more than half had never visited; even among those who had visited, the vast majority were lurkers who never or rarely posted to the forum. Thus, the tDCS subreddit should not be taken to be representative of home users of tDCS. Furthermore, we found that a small percentage of individuals use tDCS on others, and provided an initial description of their usage practices: namely, that most use tDCS on family members, most commonly children or spouses, for treatment purposes.

The study had a number of limitations. First, it was based on self-report measures; we did not examine companies' customers list nor did we independently verify that participants had purchased and used tDCS devices. Still, we performed additional checks on our data to ensure that those coming from each company's unique link reported purchasing a device from that

company. Second, although we encouraged former users (and those who had never used tDCS) to complete the survey in our recruitment email (**Appendix A**), it is likely that respondents skewed towards being active users of tDCS or former users who had negative experiences with the device. Third, our response rate was relatively low, which raises issues regarding the representativeness of our sample. However, we did find relatively similar response rates (within a few percentage points) across all seven companies. Fourth, we focused only on those individuals who had purchased direct-to-consumer tDCS devices, not those who made their own devices or those who repurpose iontophoresis devices (although some of our participants reported owning these devices). However, it is our impression, from ongoing studies of home users, that as direct-to-consumer devices have become more affordable and have improved in quality, fewer users today build their devices from scratch or repurpose iontophoresis devices, compared to the "early days" of do-it-yourself tDCS from 2011 to 2013.

Conclusion

Though the home use of noninvasive brain stimulation has been a subject of much discussion in the bioethics literature, many of the ethical concerns raised rely on underlying factual assumptions (Voarino et al. 2017), particularly regarding prevalence, efficacy, and safety. In this empirical study, we provided the first estimate of number of tDCS devices sold, and found no evidence that the home use of tDCS was increasing or may achieve widespread social uptake. We found that home users who utilize tDCS for treatment rate it as significantly more effective than those who use it for enhancement/restoration, even though enhancement uses have comprised the main focus of debates in the bioethics literature. With regard to safety, we

identified two primary concerns—skin burns and the unknown effects of the chronic use of tDCS—that should be the target of future research. Thus, it seems that while some issues identified in the bioethics literature—such as threats to autonomy due to potential coerced used of tDCS—are less relevant and highly speculative, while others, such as concerns about potential harm to home users, are empirically supported.

CHAPTER 4

A pragmatic analysis of the regulation of consumer tDCS devices in the United States

Currently, tDCS is not approved in the United States by the Food and Drug Administration (FDA) as a medical treatment for any indication. Researchers (but not the general public) may obtain tDCS devices for investigational use from either Soterix or Neuroconn, the two US companies whose devices have an "investigational device exemption" from the FDA.[1] However, as the Soterix and Neuroconn models cost thousands of dollars, some researchers have opted to repurpose cheaper iontophoresis devices (current-providing machines used to treat various conditions, such as excessive sweating) for tDCS use. By contrast, consumer tDCS devices—which are not regulated as medical or investigational devices—are available to the public; there are currently at least a half-dozen devices on the market ranging in price from $49-$299.

Several scientists and neuroethicists have argued that there is a need for additional regulation to cover consumer tDCS devices.[2] One paper proposed extending medical device

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[1] Felipe Fregni et al., "Regulatory Considerations for the Clinical and Research Use of Transcranial Direct Current Stimulation (tDCS): Review and Recommendations from an Expert Panel," *Clinical Research and Regulatory Affairs* 32, no. 1 (March 1, 2015): 22–35, doi:10.3109/10601333.2015.980944. See also Soterix Medical, http://soterixmedical.com/tdcs and Jali Medical (US distributor for Neuroconn) http://www.jalimedical.com/neuroconn_dc_stimulator_mc.html (accessed December 8, 2014).

[2] See, e.g., Veljko Dubljević, "Neurostimulation Devices for Cognitive Enhancement: Toward a Comprehensive Regulatory Framework," *Neuroethics*, November 12, 2014, 1–12, doi:10.1007/s12152-014-9225-0; and Hannah Maslen et al., "Do-It-Yourself Brain Stimulation:

regulation in Europe to include not just tDCS devices but also consumer electroencephalography (EEG) devices, which passively record electrical brainwaves and display them to users.[3] (I focus here only on non-invasive electrical brain stimulation devices, because as has been previously pointed out, EEG devices in themselves are measuring tools, akin to heart-rate monitors.)[4] Some scholars have written extensively about the moral and ethical considerations related to non-invasive brain stimulation.[5] Others have argued that there is a need for greater engagement with the DIY brain stimulation community.[6] Collectively, existing scholarship has contributed important normative and ethical perspectives on the regulation of such devices.

Missing from this literature, however, are accounts that consider the practicalities of the law and how it applies to existing and foreseeable consumer brain stimulation devices. For example, an examination of the current tDCS consumer device market has shown that while some individuals from the DIY tDCS movement build their own devices, others acquire a wide range of devices, from device "kits" (which require assembly) and iontophoresis devices (which

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A Regulatory Model," *Journal of Medical Ethics*, July 30, 2013, medethics – 2013–101692, doi:10.1136/medethics-2013-101692.

[3] Hannah Maslen et al., "The Regulation of Cognitive Enhancement Devices: Extending the Medical Model," *Journal of Law and the Biosciences* 1, no. 1 (March 1, 2014): 68–93, doi:10.1093/jlb/lst003.

[4] Andreas Kuersten and Roy H. Hamilton, "The Brain, Cognitive Enhancement Devices, and European Regulation," *Journal of Law and the Biosciences* 1, no. 3 (September 1, 2014): 340–47, doi:10.1093/jlb/lsu019.

[5] See, e.g., Roy Hamilton, Samuel Messing, and Anjan Chatterjee, "Rethinking the Thinking Cap Ethics of Neural Enhancement Using Noninvasive Brain Stimulation," *Neurology* 76, no. 2 (January 11, 2011): 187–93, doi:10.1212/WNL.0b013e318205d50d; Roi Cohen Kadosh et al., "The Neuroethics of Non-Invasive Brain Stimulation," *Current Biology* 22, no. 4 (February 21, 2012): R108–11, doi:10.1016/j.cub.2012.01.013.

[6] Nicholas S. Fitz and Peter B. Reiner, "The Challenge of Crafting Policy for Do-It-Yourself Brain Stimulation," *Journal of Medical Ethics* 41, no. 5 (May 1, 2015): 410–12, doi:10.1136/medethics-2013-101458.

require repurposing) to the Foc.us headset.[7] Given the variation in existing consumer tDCS devices, the consumer non-invasive brain stimulation market does not lend itself easily to regulation. Indeed, the proposed extension of medical device regulation in Europe would apply only to true direct-to-consumer headsets; it would not encompass self-built devices and iontophoresis devices, and it is unclear whether it would cover "kits."[8]

Furthermore, many proposals neglect to consider the practical differences between regulation and regulatory enforcement. Though an ideal model of the law envisions all regulations as being consistently and equally enforced, a more realistic view takes into account the resource-constrained nature of government bodies, who must formally, and sometimes informally, prioritize regulatory enforcement and often do so in unclear or unsystematic ways. Thus, before calling for additional regulation or concluding that there is a "regulatory gap," it must first be determined that the problem is the lack of regulation, not the lack of enforcement.[9]

It is also crucial to consider the precise statutory language of existing regulation. For example, in the United States, the Food and Drug Administration (FDA) makes its determination of whether a product is a medical device based on the *intended use* of the device as stated by the manufacturer—not based on the mechanism of action of the device itself. One recent paper co-authored by tDCS experts failed to take into account the intricacies of the statute, stating that it would be "logical to include tDCS devices" as medical devices according to the FDA, regardless

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[7] Anita Jwa, "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, no. 2 (July 13, 2015): 292–335, doi:10.1093/jlb/lsv017, and Anna Wexler, "The Practices of Do-It-Yourself Brain Stimulation: Implications for Ethical Considerations and Regulatory Proposals," *Journal of Medical Ethics* 42, no. 4 (April 1, 2016): 211–15, doi:10.1136/medethics-2015-102704.

[8] Wexler, "Practices of Do-It-Yourself Brain Stimulation."

[9] Veljko Dubljević, Victoria Saigle, and Eric Racine, "The Rising Tide of tDCS in the Media and Academic Literature," *Neuron* 82, no. 4 (May 21, 2014), 736, doi:10.1016/j.neuron.2014.05.003.

of "whether indicated for medical treatments, diagnostic purposes, wellness aids, entertainment devices, or any other purpose..."[10] However, legal authority carves up jurisdiction much more finely than this logic suggests. Within current statutory definitions, products marketed for entertainment or wellness purposes would *not* fall under the scope of the FDA (as long as they make no medical-related claims about modifying the structure or function of the body, as will be discussed in Part II below), whereas a device intended for medical treatment or diagnosis would indeed be regulated as a medical device.

This chapter contributes to the literature on the regulation of consumer brain stimulation devices in the US by providing a fact-based analysis of the consumer tDCS market and relevant laws and regulations. In the first section, I outline the basics of FDA medical device regulation and discuss how the definition of a medical device—which focuses on the *intended use* of the device rather than its mechanism of action—is of paramount importance for discussions of consumer tDCS device regulation. I then discuss how both the FDA and the courts have understood the FDA's jurisdiction over medical devices in cases where the meaning of "intended use" has been challenged. In the third section, I analyze the only instance of tDCS regulatory action to-date, in which the California Department of Public Health (CDPH) forced a firm to recall several hundred consumer tDCS devices. Although there exists a common perception that the FDA has not been involved with the regulation of consumer tDCS devices, the California case demonstrates that the CDPH's actions were instigated by an FDA engineer. Finally, I discuss the multiple US authorities, other than the FDA, that can regulate consumer brain stimulation devices.

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[10] Fregni et al., "Regulatory Considerations," 23.

In sum, this chapter dispels the notion of a "regulatory gap" with regard to consumer non-invasive brain stimulation (in the United States). Several papers—mostly those focusing on the appropriate "level" of regulation—seem to have assumed that additional regulation is the de facto appropriate response to the existence of consumer tDCS devices. I argue, however, that there already exists a comprehensive regulatory framework for both consumer and medical tDCS devices in the United States. Thus, rather than calling for additional regulation, I suggest the need for a pragmatic approach to consumer brain stimulation devices, one that outlines relevant issues of concern and considers multiple ways of addressing them.

I. The importance of "intended use" for FDA medical device regulation

Prior to 1976, medical devices were not required to secure FDA approval before being marketed.[11] But after a series of tragedies related to the implantation of pacemakers and intra-uterine devices,[12] Congress passed the Medical Device Amendments in 1976,[13] which set up a new regulatory scheme for devices, classifying them based on risk level.[14] Class I devices are low-risk devices, such as band-aids and examination gloves, which are subject to "general controls" (e.g., registration of facilities, device labeling, compliance with good manufacturing practices).[15] Class II devices are moderate risk devices, such as surgical drapes and breast pump kits, and are subject to additional "special controls" that vary by product (e.g., performance

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[11] Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, *Food and Drug Law: Cases and Materials*, 4th ed. (St. Paul, MN: West Academic, 2014), 1201.

[12] Ibid., 1202-1205.

[13] Medical Device Amendments of 1976, Pub.L. No. 94-295, 90 Stat. 539.

[14] 21 U.S.C. § 360c(a)(1)).

[15] Ibid. and U.S. Food & Drug Administration, "Regulatory Controls (Medical Devices)," http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm (accessed June 12, 2015).

standards, special labeling, and post-market surveillance).[16] To date, most devices that provide a low level of electrical stimulation to the body for medical purposes, such as transcutaneous electrical nerve stimulation (TENS) devices and powered muscle stimulation (PMS) devices, are considered Class II devices.[17] Class III devices are those that pose a high risk of illness or injury.[18] The only Class III non-invasive electrical stimulation devices are cranial electrotherapy stimulation (CES) devices and some iontophoresis devices, though in 2014 the FDA indicated that it planned to recategorize both as Class II.[19] Prior to being marketed, a new class III device must submit a premarket application (PMA) demonstrating safety and efficacy for a specific indication.[20] The PMA process, which is similar to the new drug approval process, is often a multi-year, multi-million dollar endeavor. Thus, most medical device manufacturers take a faster and cheaper path to market, by filing a 510(k) application to demonstrate "substantial equivalence" to a "predicate" device.[21] In 2011, nearly 99% of new medical devices were cleared

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[16] Ibid.

[17] See Fregni et al., "Regulatory Considerations," 2; and 21 C.F.R. §882.5890, §882.5891, §882.5810, and §882.5810.

[18] 21 U.S.C. § 360c(a)(1).

[19] For CES devices, see Food and Drug Administration 79 Fed. Reg. 33,712, (June 12, 2014) (codified at 21 C.F.R. 882), https://www.federalregister.gov/articles/2014/06/12/2014-13756/neurological-devices-withdrawal-of-proposed-effective-date-of-requirement-for-premarket-approval-for (accessed July 6, 2015). For iontophoresis devices, see Food and Drug Administration 79 Fed. Reg. 56,532 (proposed September 22, 2014) (to be codified at 21 C.F.R. pt. 890), available at https://www.federalregister.gov/articles/2014/09/22/2014-22453/reclassification-of-iontophoresis-devices-intended-for-any-other-purposes (accessed January 30, 2014).

[20] 21 U.S.C. § 360c(a)(1) and U.S. Food & Drug Administration, "Premarket Approval," http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm2007514.htm (accessed January 30, 2014).

[21] Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 360(k)) and 21 CFR § 807.92(a)(3).

by the FDA through the 510(k) process.[22] Note, however, that most new Class III devices (which require PMAs) cannot be cleared via the 510(k) process.[23]

While the level of risk determines the regulatory process for medical devices, a product must first meet the definition of a medical device to fall within the regulatory jurisdiction of the FDA. 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

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[22] Hutt et al., *Food and Drug Law,* 1219. ("In 2011, FDA cleared 3,072 premarket notifications while approving only 37 PMAs. In other words, approximately 98.8 percent of new devices cleared for marketing by FDA that year were cleared under section 510(k) rather than by PMA.")

[23] The only case wherein new Class III devices can be cleared via the 510(k) process is if the devices are substantially equivalent to certain "preamendment" (i.e., introduced to the market before May 28, 1976) Class III devices. When the new regulatory scheme for medical devices took effect in the late 1970s, the FDA temporarily classified over 100 devices as Class III devices. Such devices were never required to submit PMAs showing safety or efficacy. It has taken the FDA several decades to "reclassify" these devices—either into Class I or Class II, or sustain the Class III classification but require a PMA—and currently there are less than 20 such devices awaiting FDA action. Thus, if a new ("postamendment") device can demonstrate substantial equivalence to one of the few devices that were temporarily classified as Class III devices and have yet to be reclassified, the device can be cleared via the 510(k) process. See discussion of cranial electrotherapy stimulation (CES) devices later in this chapter, and U.S. Food and Drug Admin., "515 Program Initiative," http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm (accessed January 30, 2014).

dependent upon being metabolized for the achievement of any of its primary intended purposes.[24]

Importantly, the definition of a medical device is not based on the mechanism of action of the device, but rather on its intended use: a product is a medical device if it is *intended for* use in diagnosis or treatment, or *intended to* affect the structure or function of the body. Similar wording appears in the definition of a drug, and "intended use" language dates all the way back to the Federal Food and Drugs Act of 1906.[25]

How does the FDA establish intended use? According to the code of federal regulations Title 21, part 801, subpart A, Section 801.4 ("meaning of intended uses"), it focuses on "the objective intent of the persons legally responsible for the labeling of devices" as shown on both the product's labels and advertising.[26] That is, the product is classified according to the manufacturer's representation of it. Thus, to a large extent, manufacturers can maintain control

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[24] Section 201(h) of the FFDCA (21 U.S.C. § 321(h), and U.S. Food and Drug Admin., "Is this Product a Medical Device?" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm (accessed January 30, 2014).

[25] Section 6, 34 Stat. 768, 769 (1906).

[26] The text of 21 C.F.R. § 801.4 reads as follows: "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."

over how their products are regulated. Indeed, this was the legislative intent: a 1935 Senate report noted that the "manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product."[27]

A product's classification as a drug or device can have far-reaching consequences: as mentioned above, new drugs (and many new devices, if they cannot demonstrate substantial equivalence to a predicate device) must undergo costly clinical trials to demonstrate safety and efficacy, and it often takes several years to obtain FDA approval. In some industries, such as cosmetics, which have lenient regulatory requirements as compared to drugs, manufacturers take great pains to ensure that their advertising and product labels do not make disease or structure/function claims. It is no exaggeration to say that a manufacturer's fate may hinge on specific word choices. In the classic example, a cream that claims to "reduce wrinkles" will be classified as a drug (and subject to stringent regulatory requirements) because the wording makes a specific structure/function claim, but a cream that claims to "reduce the appearance of wrinkles" will be classified as a cosmetic because the language makes a beautification claim, not a structure/function one.[28]

Given the importance of intended use claims for the classification of drugs and devices, it is worthwhile to examine how manufacturers of consumer tDCS devices have represented their products. As can be seen in **Table 4.1**, the overall intended use implied by most manufacturers (based on their websites) is related enhancement or optimization of brain function. Two

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[27] This Senate report accompanied one of precursor bills to the FD&C. S.Rep. No. 493, 73d Cong., 2d Sess. 2-3 (1934), reprinted in 2 *Legislative History*, 721, 722-23.

[28] For comprehensive discussion, see Peter Barton Hutt, "The Legal Distinction In The United States Between A Cosmetic And A Drug," in *Cosmeceuticals and Active Cosmetics: Drugs vs. Cosmetics*, ed. Peter Elsner and Howard I. Maibach, 2nd ed. (Informa Healthcare, 2005), 223-240.

manufacturers (TCT Research Limited[29] and PriorMind, both based in Hong Kong) make explicit disease claims about their products. Several other manufacturers mention, or link to, studies on the therapeutic use of tDCS, while others refrain from referring to any such research. One manufacturer, Super Specific Devices, makes no claims at all.

Furthermore, it seems that at least some manufacturers have attempted to write around the provisions of the FDA. Seven of the nine manufacturers display some form of health or medical-related disclaimer on their websites, noting either that their product is not a medical device or that it is not intended to cure, treat, or diagnose diseases. To date, at least two manufacturers of tDCS devices have used the term "kit" in hopes that it would put distance between their product and the FDA's definition of a medical device.[30]

While products that make explicit or implied disease claims would be classified as medical devices, it is less clear whether those that mention, or link to, tDCS research could be considered medical devices. For example, while linking to a study describing the benefits of tDCS for depression may be considered an implied medical claim, noting that scientists are studying the use of tDCS for various indications may not be. Each manufacturer's claim and product would have to be reviewed in their own contexts. Although such individual reviews are outside the scope of this chapter, the issue of implied therapeutic claims is considered again in Part IV, in the discussion of the regulatory enforcement action taken by the California Department of Public Health against a small-scale consumer tDCS manufacturer.

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[29] TCT Research Limited previously conducted business as TCT Technologies, but its website (www.trans-cranial.com) remained the same.

[30] Richard O'Rourke of www.tDCSdevicekit.com (which does not appear in Table 1 because it shut down in 2013) stated this to a California Department of Health investigator, see discussion later in this chapter. A manufacturer of one the device kits in Table 1 stated: "I came up with the idea of a kit, skirting the line a little bit... it's a kit... it's not a TDCS device." Interview with manufacturer (March 27, 2014).

Table 4.1. Marketing language from the websites of consumer tDCS devices available for purchase as of June 2015.

CONSUMER TDCS DEVICE	MARKETING LANGUAGE
Brain Stimulator* https://thebrainstimulator.net/what-is-tdcs/	"tDCS allows you to unlock your brain's true potential"
Cognitive Kit* http://www.cognitivekit.com/	"Charge your mind"
tdcs-kit http://www.tdcs-kit.com/	"Power your mind"
ApeX Type A* http://www.apexdevice.net/	"Be happier. Be focused. Be smarter"
Foc.us* http://www.foc.us/	"make your synapses fire faster," "overclock your brain," "take charge"
Thync* www.thync.com	"quiet your mind," "boost your workout"
PriorMind www.priormind.com	"increase your attention span" "tDCS has been widely used to treat depression…"
TCT* www.trans-cranial.com	"when only the best in tDCS therapy will do"
Super Specific Devices* http://www.superspecificdevices.com	"personal tDCS device"

*Website contains some form of a medical or health-related disclaimer.

The more complex question, however, is whether language such as "power your mind" and "increase your attention span" implies an intended structure/function claim. The FDA and courts have struggled to interpret the meaning of "intended to affect the structure or any function of the body..." as a large number of products—from high-heeled shoes to chairs to treadmills—can be said to be intended to affect the body's structure or function. In general, both the FDA and courts have recognized that interpreting the statute literally would lead to a large number of consumer products coming under FDA regulation. For example, in one case, the D.C. Circuit court noted that Congress surely did not mean for there to be a broad reading of "intended to affect the structure or function..." because otherwise a multitude of products—anything that "stimulates the senses"—could be considered a medical device or drug.[31]

Instead, courts have leaned toward a narrow interpretation of the statute, in which a structure/function claim must have a medical or therapeutic connotation. Three cases in particular, related to seizures of wrinkle remover creams in the 1960s, have served to clarify this interpretation. In *United States v. An Article...Sudden Change*, an appeals court ruled that the question of whether a product is to "intended to affect the structure or function of the body" hinged on whether the claim may be said "to constitute a representation that the product will affect the structure of the body in some medical or drug-type fashion."[32] In *United States v. An Article of Drug...Helene Curtis Magic Secret*, a district court also upheld that a "drug connotation" was necessary for a claim to be considered a structure/function one.[33] In *United States v. An Article of Drug . . . Line Away*, an appeals court ruled that the Line Away product

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[31] Action on Smoking and Health v. Harris, 655 F.2d 236, 240 (D.C. Circuit 1980).

[32] United States v. An Article . . . Sudden Change, 409 F.2d. 734 (2d Cir. 1969).

[33] United States v. An Article of Drug... Helene Curtis Magic Secret, 331 F. Supp. 912 (D. Md. 1971).

was a drug, because its structure/function claims had therapeutic implications.[34] Though the latter three cases relate to drugs, the "intended to affect…" clause is identical for drugs and medical devices.

Indeed, in a 2002 letter, FDA Chief Counsel Daniel Troy stated that the Food, Drug, and Cosmetic Act regulates only those devices whose claims have medical or therapeutic connotations.[35] In the letter, which can be said to reflect the FDA's most recent explication of its position on intended use and structure/function claims, the FDA determined that an implantable radio-frequency identification (RFID) chip intended for health applications was considered a medical device, whereas the same chip intended for use only in security and personal identification applications was not. Thus, even an implantable device—one that clearly affects the structure or function of the body in some manner—was considered a medical device by the FDA only when its intended use was medically related.

With regard to consumer tDCS devices, would "brain optimization" or "cognitive enhancement" claims can be considered to have medical or therapeutic connotations? Indeed, the issue of what sorts of "optimization" claims are permissible for consumer devices has become a pressing one in recent years, due to the increase in wearable technology devices and smartphone-based health applications. In at least some industries, it is thought that "wellness" claims (e.g. "supports sleep") as opposed to therapeutic ones (e.g., "reduces insomnia") will place a product outside the definition of a medical device. For example, at the 2014 Neurogaming conference, a panel of neurotechnology investors emphasized the importance of distinguishing between

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[34] United States v. An Article of Drug . . . Line Away, 415 F.2d 369 (3d Cir. 1969)

[35] Letter from FDA Chief Counsel Daniel E. Troy to Jeffrey N. Gibbs (October 17, 2002).

wellness and therapy claims for avoiding FDA regulation.[36] Indeed, many consumer electroencephalography (EEG) devices—which, as mentioned in the introduction, monitor rather than stimulate the brain's activity—seem to have strategically marketed their devices for "improving mental fitness" and "optimizing brain performance."[37] However, it should be noted that the lack of formal enforcement action on the part of the FDA in the consumer neurotechnology arena (i.e., with regard to both tDCS and EEG devices) does not necessarily indicate that the FDA shares this view.

To address the regulatory status of health-related wearable technology devices, the FDA published a draft guidance on January 20, 2015, entitled "General Wellness: Policy for Low Risk Devices."[38] Although guidances are non-binding, the FDA has in recent years increasingly used them to reflect its latest thinking to industry. The draft guidance—which, it should be emphasized, is not the final version of the guidance, nor will it be binding or enforceable when it is finalized—indicates that FDA does *not* intend to enforce device provisions for "general wellness products" presenting a low risk to safety. The draft guidance defines a general wellness product in terms of intended use claims: 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. Among the examples of acceptable wellness claims provided are those relating to

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[36] Neurogaming 2014, "Investing in Neurogaming: Panel Discussion," May 7, 2014, video recording available at https://www.youtube.com/watch?v=fz95kEx3zx4 (accessed July 7, 2014).

[37] See, e.g., Muse, http://www.choosemuse.com/; Emotiv Insight, https://emotiv.com/insight.php; Neurosky, http://neurosky.com/; Melon http://www.thinkmelon.com/; and FocusBand http://www.ifocusband.com/ (accessed between January and May 2015).

[38] U.S. Food and Drug Administration, "General Wellness: Policy for Low Risk Devices Draft Guidance for Industry and Food and Drug Administration Staff," January 20, 2015, https://www.federalregister.gov/articles/2015/01/20/2015-00756/general-wellness-policy-for-low-risk-devices-draft-guidance-for-industry-and-food-and-drug (accessed May 4, 2015).

"mental acuity," "concentration," "problem-solving," and "relaxation and stress management."[39] Furthermore, the draft guidance indicates that even certain structure/function claims are permitted under the umbrella of "wellness claims:" examples of acceptable claims include those related to improving muscle size, toning the body, enhancing cardiac function, and improving sexual performance, among others.[40] Thus, at first glance, the draft guidance seems to indicate that the FDA does not intend to enforce regulations for tDCS devices marketed for wellness purposes.

However, the draft guidance also provides a second criterion: the product must be a low-risk device. According to the draft guidance, 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."[41] The draft guidance also states that in determining whether a device is low risk, the manufacturer should consider whether a similar device is "actively regulated" by the FDA. Though the guidance provides a number of examples of low-risk devices (mobile apps, wearable heart-rate monitors) and non-low-risk devices (cosmetic implants, laser technology products), electrical brain stimulation devices are not mentioned. Would consumer tDCS products be classified as low-risk devices? On the one hand, tDCS has been consistently shown to have relatively mild side effects (e.g., surface skin burns, headaches, and dizziness)[42] and the FDA has

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[39] Ibid., 3.
[40] Ibid., 4.
[41] Ibid., 5.
[42] Andre Russowsky Brunoni et al., "A Systematic Review on Reporting and Assessment of Adverse Effects Associated with Transcranial Direct Current Stimulation," *International Journal of Neuropsychopharmacology* 14, no. 8 (September 1, 2011): 1133, doi:10.1017/S1461145710001690.

identified health risks in similar technologies.[43] On the other hand, no serious or chronic adverse events have been reported in the literature.[44]

The recent letter from the FDA to Thync regarding the classification of its device supports the notion that the FDA does not view consumer neurotechnology devices that have intended uses related to wellness or recreation as medical devices. Prior to going to market, Thync submitted a 513(g), requesting information from the FDA regarding how it would classify its product.[45] According to the company, the FDA exempted the product from medical device requirements such as pre-market approval and clearance, as the product was intended for recreational purposes.[46] It should be noted, however, that the same decision might not hold true for manufacturers who do not limit their claims to recreational use. Furthermore, it is worth

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[43] In draft guidance for TENS devices for aesthetic purposes, the FDA identified two health issues: "electrical hazards that may result in user discomfort or injury" and "adverse reactions to the skin-contacting materials." US Food & Drug Admin., "Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Aesthetic Purposes," April 5, 2010, http://www.fda.gov/RegulatoryInformation/Guidances/ucm199067.htm (accessed January 5, 2015).

[44] Fregni et al., "Regulatory Considerations."

[45] Interview with Jamie Tyler, CEO of Thync, (February 12, 2015). The company submitted a 513(g) "Request for Information" to the FDA, which is a "means of obtaining the agency's views about the classification and the regulatory requirements" applicable to a particular device. See U.S. Food & Drug Admin., "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act," April 6, 2012, http://www.fda.gov/RegulatoryInformation/Guidances/ucm209841.htm (accessed January 5, 2015).

[46] The Thync press release accompanying the launch of its device included the following statement: "Based on its intended use in lifestyle applications, the FDA exempted the Thync System from medical device regulations requiring pre-market notification (clearance) or approval." Thync Press Release, "Thync Launches First Wearable to Shift Your State of Mind, Consumer Product Delivers Calm and Energy within Minutes," (June 2, 2015) http://www.thync.com/resources/press-release/thync-launches-first-wearable-to-shift-your-state-of-mind (accessed June 12, 2015).

pointing out that the communication between the FDA and Thync has not been made public; all information regarding the FDA's letter has come from the company itself.

Still, one question remains: if the definition of a medical device is based on its intended use—and neither on risk level nor mechanism of action—could a consumer device making only wellness or recreational claims (and not disease or medical-related structure/function ones) fall under the scope of FDA regulation? Furthermore, how can the draft guidance pose risk level as a criterion for regulation, if risk level only defines the regulatory process once a device is considered to be within the jurisdiction of the FDA? Answering this question requires an examination of how courts have construed the FDA's statutory authority with regard to medical devices, which is the topic of the next section.

II. Judicial interpretation of "intended use" and medical devices

When determining the intended use of a product, the FDA has historically relied almost exclusively on manufacturers' claims as represented on the product's labeling and advertising.[47] For example, in two cases from the 1950s, district courts upheld the focus on marketing claims, finding that cigarettes making disease prevention[48] or weight-loss claims[49] came under the FDA's jurisdiction, whereas cigarettes that lacked such claims fell outside it. (Both of these cases came prior to the Medical Device Amendments of 1976, and the courts in each case considered the

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[47] For a comprehensive overview of intended use as it relates to medical devices, see Gary E. Gamerman, "Intended Use and Medical Devices: Distinguishing Nonmedical Devices from Medical Devices under 21 U.S.C. 321(h)," *George Washington Law Review* 61 (1992), 806. See also Hutt et al., *Food and Drug Law*, 92-97.

[48] *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J 1953).

[49] *United States v. 354 Bulk Cartons... Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959).

cigarettes to be drugs, not devices.) Indeed, today there are many "dual use" products that are identical in technology but regulated differently based on intended use as represented by the manufacturer intent. For example, exercise equipment marketed for medical purposes is regulated by the FDA,[50] but exercise equipment for recreational use is regulated by the Consumer Product Safety Commission.[51] Other dual use products include bed rails,[52] razors and binoculars.[53]

Though the FDA has focused almost exclusively on marketing language to establish intended use, a close read of 21 C.F.R. Section 801.4 ("meaning of intended uses") shows that the FDA can consider a variety of factors: intent may be shown by the "circumstances surrounding the distribution of the article" or "oral and written statements" by the manufacturers and their representatives.[54] Indeed, the courts have affirmed the FDA's extensive powers in this regard: in one case, the Seventh Circuit upheld the FDA's reliance on instruction booklets, financial arrangements, and individuals' testimonies in determining the intended use of a product.[55] In another, a district court agreed that the FDA could rely upon the "circumstances surrounding the distribution of the article" to determine that a product was a drug, even in the absence of explicit labeling.[56] Furthermore, according to 21 C.F.R. Section 801.4, if the FDA can

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[50] See, e.g., 21 C.F.R §§ 890.5350-5410, defining various kinds of FDA-regulated exercise equipment as those "intended for medical purposes."

[51] See later in this chapter for further discussion of the Consumer Product Safety Commission.

[52] U.S. Food & Drug Admin., "Bed Rail Safety: FDA and CPSC Activities," http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362867.htm (accessed June 4, 2015).

[53] Gamerman, "Intended Use and Medical Devices," 833-835.

[54] 21 C.F.R § 801.4

[55] United States v. An Article of Device... Toftness Radiation Detector, 731 F.2d 1253, 1257 (7th Cir. 1984).

[56] The product was a unlabeled balloon filled with nitrous oxide, and the "circumstances surrounding the distribution" were that the defendants were selling balloons outside a rock

demonstrate 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" it can deem the device misbranded.[57] With these broad criteria, the FDA would likely be well within its authority to take action against many small-scale tDCS manufacturers.

Even if a consumer tDCS device makes no explicit or implied medical-related claims, can the way that consumers actually use the product be sufficient to imply an intended use? This question has previously been raised in cases regarding cigarette regulation.[58] In the late 1970s, a citizen action group, Action on Smoking and Health (ASH), attempted to compel the FDA to regulate cigarettes, arguing that the way in which consumers actually used cigarettes demonstrated that the product's "intended use" was to "affect the structure or function of the body."[59] The FDA refused to regulate, citing the absence of manufacturers' health claims.[60] In 1980's *Action on Smoking and Health (ASH) v. Harris*, the D.C. Circuit ruled that while it may be possible to demonstrate intention by showing actual consumer use, the standard was high, as it had to be shown that consumers were using a product "nearly exclusively" for a given

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concert. The court found this information sufficient to establish intended use, and nitrous oxide was therefore considered a drug. United States v. Travia, 180 F. Supp. 2d 115 (D.D.C 2001).

[57] 21 C.F.R § 801.4. This particular line has most notably applied to the off-label use of drugs: it is legal for physicians to prescribe a drug (or device) for an indication other than that for which it has been approved by the FDA, but a manufacturer cannot advertise, label, or otherwise represent the drug (or device) for a purpose other than approved by the FDA (21 C.F.R. § 801.4). This rule has been recently challenged on First Amendment grounds: for review see Stephanie M. Greene and Lars Noah, "Debate: Off-Label Drug Promotion and the First Amendment," *University of Pennsylvania Law Review* 62 (June 24, 2014): 239–67.

[58] For overview see Margaret A. Boyd, "Butt Out!! Why the FDA Lacks Jurisdiction To Curb Smoking of Adolescents and Children," *Journal of Contemporary Health Law and Policy* 13 (1996): 169–97. See also Hutt et al., *Food and Drug Law*, 139-145 (on struggles over tobacco regulation).

[59] Hutt et al., *Food and Drug Law*, 140.

[60] See history as set out in Action on Smoking And Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980).

intention.[61] The court noted that "ASH did not establish, and arguably cannot establish, the near-exclusivity of consumer use of cigarettes with the intent 'to affect the structure or any function of the body of man...'"[62] However, even if ASH had been able to demonstrate that consumers were indeed using cigarettes exclusively to affect the structure or function of the body, the court would have had to confront the question of whether the structure/function use had medical or therapeutic connotations. Exercise machines for recreational purposes, for example, are used by consumers "nearly exclusively" to affect the structure or function of the body, yet they are not regulated as medical devices.

The question of whether the "actual and foreseeable use" of cigarettes could be sufficient to demonstrate an intended structure/function use was raised again in 1995, when the FDA, under Commissioner David Kessler, attempted to regulate tobacco.[63] The tobacco industry challenged the FDA, and the case ultimately went to the Supreme Court.[64] In *Food and Drug Administration v. Brown & Williamson* (2000), the Court rejected the FDA's assertion of jurisdiction over cigarettes but did not address the question of "actual and foreseeable use" vs. "intended use," and the matter has never been subsequently resolved in court.[65] However, it should be noted that in the 2002 letter from the FDA Chief Counsel mentioned in the previous

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[61] Ibid., 237.
[62] Ibid.
[63] Food and Drug Administration 60 Fed. Reg. 41,314, (August 11, 1995).
[64] Hutt et al., *Food and Drug Law*, 140-141.
[65] Food and Drug Administration v. Brown & Williamson Tobacco Corp. 529 U.S. 120 (2000). It was not until Congress passed the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA, Pub. L. No. 111-131) that tobacco came under the jurisdiction of the FDA.

section, the FDA took the position that "[f]oreseeability by the manufacturer does not suffice to establish intended use."[66]

Thus, intended use has most often been determined with relation to marketing claims (although the FDA is fully within its power to consider a broad range of factors) and "actual or foreseeable use" has not been sufficient to determine intended use. While the FDA and courts have favored a narrow interpretation of "intended use," recognizing that a literal reading of the structure/function definition would open up the door for a large number of consumer products to come under its jurisdiction, it is important to note that courts are often willing to give deference to the FDA's statutory interpretations. For example, in *United States v. An Article of Drug... Bacto-Unidisk (1969)*, the Supreme Court upheld the FDA's decision to classify an antibiotic sensitivity disc as a drug rather than a device, because doing so would subject the product to more stringent requirements.[67] The Court reasoned that Congress had not meant for the statute to be read narrowly: rather, the FD&C Act "is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health."[68] Subsequent opinions, such as the dissent in *Brown & Williamson*, have quoted this line when reasoning in favor of a liberal interpretation of the FD&C Act.[69] However, it is unlikely that a similar "public health" argument could be made with regard to consumer tDCS, as it would have to be demonstrated that tDCS posed a

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[66] Letter from FDA Chief Counsel Daniel E. Troy to Jeffrey N. Gibbs (October 17, 2002), 5.

[67] United States v. An Article of Drug...Bacto-Unidisk, 394 U.S. 784 (1969). The case took place prior to the passage of the Medical Device Amendments, when devices, unlike drugs, did not have to undergo pre-market approval.

[68] Ibid., 798.

[69] In his dissent, Justice Breyer argued that cigarettes should indeed be regulated by the FDA, because (a) the purpose of the FD&C Act is to protect public health; and (b) cigarettes are certainly are intended to affected the structure or function of the body. Food and Drug Administration v. Brown & Williamson Tobacco Corp. 529 U.S. 120 (2000). (Breyer, J., dissenting).

significant public health risk—and according to one recent empirical study, the home use of tDCS "does not seem to pose an imminent risk or danger to the public."[70]

Importantly, when attempting to both understand and predict the actions of the FDA, it should be emphasized that the agency does not act consistently over time; instead there is variation across different leaderships and agency actions. Thus it is impossible to draw a single coherent picture of how the FDA (and courts) have acted. For example, in at least one instance, the FDA seemed to contradict its stance that structure/function claims must be medically related: in July 2000 it sent a warning letter to a company marketing a battery-powered facial mask called Rejuvenique, which applied electrical stimulation to the face. In the warning letter—which, it should be noted, is not final agency action—the FDA wrote that regardless of the manufacturers' claims, "because the Rejuvenique is intended to affect the structure or function of the body by providing electrical current to various facial muscles to repeatedly contract them, it is a device..."[71] The company's lawyers responded with a 15-page letter, arguing that the product was not a medical device because the FDA classifies devices based on intended use, not mechanism of action.[72] Evidently, however, the company decided it was in their best interest to work with the FDA rather than litigating, because one year later the Rejuvenique was cleared via the 510(k) process.[73]

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[70] See Jwa, "Early Adopters," 25.

[71] Larry D. Spears for Steven D. Niedelman, Acting Director, Office of Compliance, Food and Drug Administration, *Warning Letter to Salton, Inc.,* July 12, 2000, http://www.casewatch.org/fdawarning/prod/2000/salton.shtml (accessed January 12, 2015).

[72] Georgia C. Ravitz, Counsel for Salton, Inc., *Re:Rejuvenique Facial Toning System*, to Mr. William F. Defibaugh, Compliance Offer, Center for Devices and Radiological Health, August 11, 2000, http://media.corporate-ir.net/media_files/nys/sfp/salton_rejuv.pdf (accessed January 12, 2015).

[73] 510(k) Summary - Rejuvenique® Facial Toning System, August 8, 2001, http://www.accessdata.fda.gov/cdrh_docs/pdf/k011935.pdf (accessed January 12, 2015); Note, however, that this pathway was somewhat unusual because a 510(k) is granted when the device

The Rejuvenique case is particularly informative, as it exemplifies the typical negotiations between government agency and manufacturer following a warning letter. While the Rejuvenique manufacturer could have challenged the FDA in court, it chose the faster and cheaper option of working with the agency. Indeed, practical business considerations may be the best predictor of how a company will engage with the FDA. Many companies that have a product of unclear regulatory status—especially if they are investor-backed or are looking for funding—will open a dialogue with the FDA early in the development process, so as not to risk later regulatory action. Indeed, it is hard to imagine that venture capital-backed companies such as Thync and Halo Neuroscience would have been able to raise millions of dollars without a solid regulatory plan. (As noted in the previous section, Thync was in contact with the FDA prior to going to market;[74] press mentions of Halo Neuroscience have indicated that the company intends to work with the agency.)[75] By contrast, a small-scale tDCS consumer device manufacturer without the funds for legal counsel would probably attempt to place its device outside of the scope of FDA regulation. A manufacturer of this kind who received a warning letter or notice of violation from the FDA could in theory litigate (assuming that its product does not have an medical or disease-related intended use according to all the factors set out in 21 C.F.R. Section 801.4), but in practice it would not likely be worth the time or money. The section

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is similar in both "intended use" and "technological characteristics." Here the intended use was cosmetic, not therapeutic.

[74] Interview with William (Jamie) Tyler, co-founder and chief scientific officer (CSO) of Thync, February 12, 2015.

[75] Ben Popper, "The Halo Headband Wants to Make You Smarter by Shocking Your Brain," *The Verge*, April 30, 2014, http://www.theverge.com/2014/4/30/5668086/halo-neuroscience-brain-stimulation-funding-andreessen (accessed December 4, 2014); John Biggs, "Halo, The Brain-Improving Wearable, Raises $1.5 Million," *TechCrunch*, May 1, 2014, http://social.techcrunch.com/2014/05/01/halo-the-brain-improving-wearable-raises-1-5-million/ (accessed December 4, 2014).

below illustrates what happened when the state of California—acting on an email from an engineer at the FDA—sent a notice of violation to a small-scale consumer tDCS manufacturer.

III. Regulatory action to-date—the California Department of Public Health and TDCS Device Kit, Inc.

Thus far, the only instance of regulatory enforcement against a consumer tDCS device has come at a state level, from the California Department of Public Health (CDPH), which in May 2013 took action against a company called TDCS Device Kit, Inc., for violating California's Sherman Food Drug, and Cosmetic Law.[76] According to California state law, medical devices that are not federally approved for market in the United States can be considered misbranded and/or adulterated under the Sherman Law.[77] Furthermore, the Sherman Law requires anyone manufacturing a medical device in California to obtain a license from the CDPH.[78]

According to the CDPH report, the investigation of TDCS Device Kit was initiated following receipt of an email and five-page analysis from a biomedical engineer at the FDA's Center for Devices and Radiological Health.[79] The company, which was based in California, had been selling a "Home TDCS Device Kit" via its website (www.tdcsdevicekit.com). The FDA engineer had concluded that the "Home TDCS Device Kit" was a Class III medical device and would require 510(k) clearance to be legally marketed in the US, as the company's website

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[76] State of California Department of Public Health, Food and Drug Branch, Medical Device Safety Unit, *Medical Device Investigative Report*, TDCS Device Kit, Inc., inspection date May 7, 2013.

[77] Cal. HSC. Code § 109875 *et seq.* See discussion later in this chapter regarding the overlap between federal and state medical device laws.

[78] Cal. HSC. Code § 111615.

[79] The engineer was in the Office of Device Evaluation/Division of Neurological and Physical Medicine Devices/Physical Medicine and Neurotherapeutic Devices Branch (CDRH/ODE/DNPMD/PNDB).

implied that the device could be used to treat a variety of disorders. Although the company never explicitly claimed that its own device had medical benefits, its website did contain several paragraphs about tDCS, with sentences such as: "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 May 2013, an investigator from the CDPH contacted the president of TDCS Device Kit, Richard O'Rourke, who believed that his product did not require CDPH clearance, since the product was a kit that was assembled by the user. A few days later, the same investigator met O'Rourke and inspected the manufacturing facility; the company was issued a notice of violation that day for non-compliance with California's Sherman Food, Drug and Cosmetic Law for manufacturing medical devices without a license from the CDPH.[80] Two weeks later, the CDPH issued TDCS Device Kit a second notice of violation, this time with eleven items related to "selling and delivering misbranded, adulterated, and unapproved medical devices." According to the notice of violation, the device was unapproved by the FDA; it was adulterated in that it did not comply with good manufacturing practices and performance standards; and it was misbranded in that the manufacturing establishment was not licensed by the FDA or the CDPH, and the label failed to bear adequate warnings, directions, and other information.[81]

The company subsequently stopped selling the devices, and a sentence was added to its website, noting that the kits were "unavailable at this time." O'Rourke, however, was reluctant to issue a recall, and evidently did not take action to meet with the FDA or medical device regulatory counsel to negotiate a plan to secure approval for the device. Therefore, the CDPH

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[80] Cal. HSC. Code § 111615.

[81] State of California Department of Public Health, Food and Drug Branch, Medical Device Safety Unit, *Medical Device Investigative Report*, TDCS Device Kit, Inc., inspection date May 7, 2013.

moved forward, issuing a press release (**Fig 4.1**) on June 28, 2103, entitled "CDPH Warns Consumers Not to Use TDCS Home Device Kit."[82] The next month, TDCS Device Kit sent out a recall email to over 200 customers. The investigation was officially closed in October 2013, following a CDPH determination that the firm's recall efforts were adequate.[83]

There are several contextual points of interest in this case. First, it remains an open question why the FDA engineer conducted his or her own analysis, yet forwarded the issue to the CDPH. One possibility is that the FDA engineer did not have evidence of the product being sold across state lines; the FDA's jurisdiction lies only in interstate commerce, not in intrastate commerce.[84] Another possibility is that it was simpler to hand the case off to the state and not engender complex federal regulatory processes. In response to a query regarding the frequency of FDA referrals for medical device investigations, the CDPH noted that such referrals occur "occasionally."[85]

Second, all items in the eleven-item notice of violation referred to the device as a "*prescription* medical device" (emphasis added). The fifth item on the notice of violation was based entirely on this characterization, stating that the device was misbranded because the label failed to bear the statement "Caution: federal law prohibits dispensing without a prescription…" or similar language. However, there is no clinical use of tDCS that is FDA-approved, either for prescription or over-the-counter use. When queried about the use of the term, the CDPH noted

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[82] California Department of Public Health, *CDPH Warns Consumers Not to Use TDCS Home Device Kit*, June 28, 2013, http://www.cdph.ca.gov/Pages/NR13-029.aspx (accessed December 4, 2014).

[83] State of California Department of Public Health, Food and Drug Branch, Medical Device Safety Unit, *Medical Device Investigative Report*, TDCS Device Kit, Inc., inspection date October 7, 2013.

[84] Section 301 of the FD&C Act.

[85] E-mail from Ronald Owens, Office of Public Affairs, California Department of Health, to Anna Wexler (February 13, 2015), on file with author.

that when "additional information was obtained, it was determined the product was an unapproved new medical device as opposed to a prescription medical device."[86] Indeed, the second, shorter CDPH report does not mention the word "prescription," but it also does not make note of the initial error.



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.

Figure 4.1. Press release issued by the California Department of Public Health on June 28, 2013, warning consumers against using the TDCS Home Device Kit.

Third, even though TDCS Device Kit never made a specific disease or structure/function claim for its product, the report states that treatment claims were "implied" by the website. Thus, if statements about the clinical effects of tDCS appear on a website that sells a consumer tDCS device, representatives from the FDA and the state of California have inferred that the product is a medical device. Furthermore, designing and marketing a consumer tDCS device as a "kit" made no meaningful difference. Thus, several manufacturers that currently sell consumer tDCS devices may be liable to receive notices of violation (at the state or federal level) for unapproved,

[86] E-mail from Ronald Owens, Office of Public Affairs, California Department of Health, to Anna Wexler (February 2, 2015), on file with author.

adulterated, or misbranded medical devices. As noted in Part II, several manufacturers link to, or mention, research regarding the therapeutic effects of tDCS.

Fourth, according to the CDPH report, the FDA engineer's five-page analysis concluded that the device was a Class III device that would require a 510(k) clearance before marketing. This implies that the FDA engineer had characterized the device as substantially equivalent to an existing pre-amendment Class III device, which as mentioned in Part II, is a device that poses the highest risk of injury and illness. The existing Class III device most similar to tDCS is a cranial electrotherapy stimulation (CES) device, which according to the FDA's definition, "applies electrical current to a patient's head to treat insomnia, depression, or anxiety."[87] The main difference between the two is that while tDCS uses direct current, CES uses alternating current. The assumption of substantial equivalence to CES would explain the CDPH report's (incorrect) observation that tDCS "is typically used to treat depression and other mood disorders." It would also explain the use of the term "prescription" in the CDPH's violation notice, as CES is currently a prescription-only device.

The comparison of tDCS to CES is especially interesting in light of the ongoing battles about whether CES should be categorized as a Class II or Class III device. As mentioned earlier, the vast majority of non-invasive electrical stimulation devices for medical purposes are categorized as Class II devices, and CES manufacturers have long attempted to have the CES device reclassified from a Class III to Class II. In recent years, however, the FDA has tried unsuccessfully, and against heavy resistance, to *increase* the burden on CES manufacturers.[88] In

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[87] 21 C.F.R. § 882.5800.

[88] In 2011 the FDA issued a proposed rule to require the filing of a PMA (or a notice of completion of a product development protocol, PDP) for CES devices. In response, three petitions were filed by CES manufacturers, requesting reclassification of CES devices into Class II. The petitions were referred to a 2012 Neurological Device Panel, which agreed that the

June 2014, in response to a flood of public comments, the FDA stated that it planned to reclassify the device as Class II, although it has yet to follow through with this reclassification.[89] It is likely that the particular CES troubles are a consequence of being grandfathered in under the 1976 Medical Device Amendments and automatically categorized as a Class III device; CES was therefore never required to submit a premarket application demonstrating safety and efficacy. The lack of premarket application for CES also explains the FDA engineer's surprising determination that the "Home TDCS Device Kit" was substantially equivalent to an existing Class III device and would require 510(k) clearance, as most new Class III devices cannot be cleared via the 510(k) process. The engineer likely had CES in mind, because the only instance where a new Class III device can be cleared via the 510(k) process is if it can demonstrate substantial equivalence to a "preamendment" device that was automatically classified as Class III, such as CES.[90]

In sum, the CDPH case shows that contrary to common perception, the FDA has been involved in the regulation of consumer tDCS devices; however, it should be emphasized that the FDA engineer's email and analysis does not represent the formal position of the FDA.[91] Though there was initial uncertainty on the part of the CDPH regarding the status of consumer tDCS

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devices should require PMAs and remain in Class III. In April 2013 (around the time the FDA emailed the CDPH) the FDA issued an order to require additional pre-market approval for CES devices. See Background section, U.S. Food & Drug Admin., Neurological Devices; "Withdrawal of Proposed Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator Devices," 79 Fed. Reg. 33,712 (June 12, 2014), to be codified at 21 C.F.R. 882.

[89] Ibid.

[90] See *infra* note 63.

[91] Under 21 C.F.R. 10.85(k), a statement by an FDA employee represents only the best personal judgment of that individual and "does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed." 21 C.F.R. 10.85(k), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.85 (accessed December 4, 2014).

devices, state and federal regulators still considered the product to be a medical device based on manufacturer's statements about the therapeutic effects of tDCS. Importantly, the use of the term "kit" did not offer any protection. Finally, the only documented case to-date of the FDA's involvement in tDCS indicates that at least one engineer in its offices has viewed tDCS for medical purposes as a Class III device. While this will likely be surprising for researchers who have assumed that tDCS for medical use would be a Class II device, the report should be taken with a grain of salt, as the FDA engineer's analysis is not representative of the agency's formal position. Indeed, another device similar to tDCS—one that provides direct current stimulation to the head for migraine prevention—was recently classified by the FDA as a Class II device.[92]

IV. Safety and advertising regulations for consumer products

If the FDA does not recognize consumer tDCS devices as medical devices (or opts not to enforce existing regulations), such products would still be subject to a multitude of consumer product safety and advertising laws. For example, the Federal Trade Commission (FTC) has the authority to take relevant administrative action for "unfair or deceptive" business practices.[93] The FTC interprets the term "deceptive" broadly—to include "sales of hazardous… products…without adequate disclosures"—and therefore issues related to the sale of consumer

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[92] U.S. Food & Drug Admin., Medical Devices; Neurological Devices; Classification of the Transcutaneous Electrical Nerve Stimulator to Treat Headache, 79 Fed. Reg. 37,946 (July 3, 2014) to be codified at 21 C.F.R. 882, https://www.federalregister.gov/articles/2014/07/03/2014-15625/medical-devices-neurological-devices-classification-of-the-transcutaneous-electrical-nerve (accessed February 7, 2015).

[93] 15 U.S.C. § 45(a)(1).

tDCS products could fall under its scope.[94] While the FTC regulates the advertising of consumer products as well as over-the-counter drugs and medical devices, the FDA maintains regulatory authority over the advertising of restricted (i.e., prescription) drugs and medical devices, and for the labeling of all products under its jurisdiction.[95] Thus, if the FDA classifies consumer tDCS products as *unrestricted* medical devices, oversight of their advertising would fall under the FTC and labeling under the FDA; if such devices are considered consumer products, oversight of both advertising and labeling would fall under the broad brush of the FTC. Two recent FDA guidances—the wellness device draft guidance mentioned in Part II, and a 2015 guidance regarding health-related mobile applications—seem to shift a regulatory burden to the FTC by placing a large class of wellness products outside the scope of FDA regulation.[96] Indeed, the FTC recently filed a complaint against a company marketing a computer game that claimed to improve cognition in children.[97] It also has pursued action against various mobile medical health apps in recent years, such as ones that have claimed to treat acne and diagnose melanoma.[98]

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[94] Federal Trade Commission, "FTC Policy Statement on Deception," http://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception (accessed December 4, 2014).

[95] Although the FDA and FTC have overlapping jurisdiction, since 1954 they have operated under a Memorandum of Understanding. However, it should be noted that the Memorandum is only an informal division of authority. Working Agreement Between Federal Trade Commission and Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971), http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm (accessed January 5, 2015). See also discussion in James M. Serafino, "Developing Standards for Health Claims-The FDA and the FTC," *Food & Drug Law Journal* 47 (1992), 335-337.

[96] U.S. Food & Drug Admin., "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff," (Feb. 9, 2015), http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf (accessed December 4, 2014).

[97] Federal Trade Commission, Press Release, "Makers of Jungle Rangers Computer Game for Kids Settle FTC Charges that They Deceived Consumers with Baseless 'Brain Training' Claims," January 20, 2015, http://www.ftc.gov/news-events/press-

With regard to safety, the Consumer Product Safety Commission (CPSC) is tasked with protecting the public from "unreasonable risks of injury associated with consumer products,"[99] and regulates products such as table saws, cribs, and carbon monoxide detectors. The CPSC has the authority to ban products, develop safety standards, and facilitate product recalls. All medical devices (and other products regulated by the FDA) fall outside the scope of the CPSC.[100] It should be noted, however, that as a matter of practice, some authorities may be reluctant to take enforcement action over a product that may fall under the primary jurisdiction of another agency. For example, if a product has the appearance of a medical device, an agency such as the CPSC may be hesitant to assert jurisdiction.

Another federal agency, the Federal Communications Commission (FCC), regulates the radio frequency output of various wireless technology devices, ensuring that they meet certain standards. While most tDCS devices from small-scale vendors do not incorporate wireless technology, both the Foc.us and the Thync devices have FCC certification, as they can be controlled wirelessly from a smartphone.[101] The FCC and the FDA in some cases have

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releases/2015/01/makers-jungle-rangers-computer-game-kids-settle-ftc-charges-they (accessed March 27, 2015).

[98] Federal Trade Commission, Press Release, "Acne Cure Mobile App Marketers Will Drop Baseless Claims Under FTC Settlements," September 8, 2011, https://www.ftc.gov/news-events/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under (accessed December 5, 2014); and Federal Trade Commission, Press Release, "FTC Cracks Down on Marketers of 'Melanoma Detection' Apps," February 23, 2015, https://www.ftc.gov/news-events/press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detection-apps (accessed April 8, 2015).

[99] Consumer Product Safety Act (Codified at 15 U.S.C. §§ 2051–2089).

[100] U.S. Consumer Product Safety Commission, "Products Under the Jurisdiction of Other Federal Agencies," http://www.cpsc.gov/en/Regulations-Laws--Standards/Products-Outside-CPSCs-Jurisdiction/ (accessed December 10, 2014).

[101] The application for FCC certification for the Foc.us devices (submitted by European Engineers Limited, FCC ID: 2AAH6DLIG1) and for the Thync device (FCC ID: 2AELZ-1000) are publicly viewable via an "Equipment Authorization Search" on the FCC website: https://apps.fcc.gov/oetcf/eas/reports/GenericSearch.cfm (accessed December 4, 2014).

overlapping jurisdiction, as they both regulate radiation-emitting products. For example, the FCC certifies cell phones and ensures that they meet certain radio frequency standards, whereas the FDA is responsible for potential cell phone-related health issues.[102]

In addition to federal regulations, individual states also have health, safety, and medical device laws. According to section 521 of the FD&C Act, the FDA's medical device regulations preempt (i.e., supersede) state laws.[103] Though the overlap between federal and state regulations is complex, in general, a state law cannot interfere with FDA regulations (e.g., it cannot set lesser criteria for what constitutes a medical device). However, in some cases a state can apply additional rules or more stringent requirements. For example, the first notice of violation issued to TDCS Device Kit was related to a state requirement (lack of licensing from the California Department of Public Health), not a federal one. Furthermore, the FDA has jurisdiction only over interstate commerce, not intrastate commerce.[104] Currently all US-based consumer tDCS device manufacturers are selling their products on an interstate level, but if every part of a device were to be manufactured and sold entirely within a single state—which, of course, is highly unlikely—the product would fall under state, and not FDA, jurisdiction. States also have their own consumer protection laws (often for unfair or deceptive business practices) that would be applicable in the realm of consumer tDCS.

With regard to the importation of foreign tDCS devices into the US (such as those from the Hong Kong-based companies TCT Research Limited and PriorMind, both of which make

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[102] U.S. Food & Drug Admin., "Radiation-Emitting Products - Cell Phones," http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm (accessed December 10, 2014).

[103] Section 521(a) of FD&C act, as codified in 21 C.F.R. § 808. For discussion see Hutt et al., *Food and Drug Law,* 1280-1282.

[104] Section 301 of the FD&C Act.

explicit medical claims), the FDA imposes identical requirements on both foreign and domestic devices.[105] The FDA works with the Department of Homeland Security to inspect food, drugs, cosmetics and medical devices, and the government has broad powers to detain or seize imports.[106] However, the FDA recognizes that it is not practical to inspect every item imported into the US, and they have therefore been permissive with small quantities of drugs or devices imported for personal use. According to the FDA's Regulatory Procedures Manual, the agency exercises enforcement discretion even for items that are in clear violation of FDA regulations. However, the manual notes that although the FDA "may use discretion to allow admission of certain violative items, this should *not* be interpreted as a license to individuals to bring in such shipments."[107] The FDA is more likely to take enforcement action when the product presents a health risk, if it is being actively promoted to US customers, or if it is being shipped repeatedly and/or in large quantities.

Finally, the Better Business Bureau (BBB), a non-profit non-governmental organization, plays a major role in what it is referred to as industry "self-regulation."[108] The BBB interfaces between companies and consumers to settle complaints outside of court; it has already helped

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[105] Section 801(a) of the FD&C Act.

[106] See Hutt et al., *Food and Drug Law,* 1450 for discussion of different outcomes for seizure as compared to refusal of admission.

[107] US Food and Drug Administration, Regulatory Procedures Manual, 9-2, Coverage of Personal Importations, available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm (accessed December 4, 2014).

[108] Council of Better Business Bureaus, Mission and Vision, http://www.bbb.org/council/about/vision-mission-and-values/ (accessed January 15, 2015); FTC Commissioner Maureen K. Ohlhausen has defined self-regulation as a "broad concept that includes any attempt by an industry to moderate its conduct with the intent of improving marketplace behavior for the ultimate benefit of consumers." Maureen K. Ohlhausen, "Remarks at the BBB Self-Regulation Conference," June 24, 2014, 2, available at http://www.ftc.gov/system/files/documents/public_statements/410391/140624bbbself-regulation.pdf (accessed December 10, 2014).

one consumer with a complaint about the Foc.us device.[109] The BBB also has a National Advertising Division, which monitors companies' advertising claims and attempts to resolve matters through settlements.[110] Thus, even if consumer tDCS devices are not regulated as medical devices by the FDA, they would still be subject to numerous federal and state consumer product laws.

Conclusion

This chapter has offered an in-depth, empirical perspective on the regulation of consumer tDCS devices in the United States. Rather than a "regulatory gap," there are multiple, distinct pathways by which consumer tDCS devices can be regulated in the United States. An examination of the existing consumer device market illustrated the complex array of various tDCS devices and the shift from DIY devices to direct-to-consumer ones. A review of the statutory language of the FD&C Act as well as related judicial and agency interpretations demonstrated the importance of considering the precise language of the law (and the intended use claims made for each consumer tDCS device) as well as how the courts have construed the FDA's authority. Although it is unclear whether the FDA or states will attempt to assert jurisdiction over small-scale consumer tDCS manufacturers, if regulatory action is initiated, such

[109] BBB Business Review, European Engineers Limited, (see "Complaint Resolution Log") http://www.bbb.org/greater-san-francisco/business-reviews/home-electronics/european-engineers-limited-in-redwood-city-ca-459140/complaints (accessed December 4, 2014).

[110] National Advertising Division, http://www.bbb.org/council/the-national-partner-program/national-advertising-review-services/national-advertising-division/ (accessed January 13, 2015).

small-scale manufacturers may be able to challenge the FDA in limited circumstances,[111] though in practice this is unlikely to be a successful or worthwhile endeavor. In addition, an analysis of the state regulatory action taken against TDCS Device Kit revealed one FDA engineer's interpretation that a consumer tDCS product was a Class III device; it also provided an indication of the level of scrutiny that states and federal bodies might adopt in determining what constitutes an "implied" therapeutic use claim. Finally, I have shown that if the FDA does not regulate consumer tDCS products as medical devices, such products would still be subject to a multitude of consumer safety and advertising regulations, although enforcement may not be vigorous.

Taken together, existing authorities provide diverse regulatory options. For example, products such as the Foc.us and tDCS device kits could be regulated as consumer devices, and therefore would be subject to the consumer safety and advertising laws outlined in the previous section. Foreign device manufacturers who ship consumer tDCS devices to the US (such as TCT Research Limited and PriorMind) might not encounter regulatory issues if they ship in limited quantities to individuals for personal use. Companies with greater resources, such as Thync and Halo Neuroscience, may be more likely to work with the FDA; as mentioned above, according to Thync's press release, the FDA exempted the company from obtaining approval or clearance for its device.

Separate from consumer tDCS devices, medical and investigational devices have their own regulatory pathways. Neuroconn could continue to provide its tDCS device to clinicians and researchers for investigational purposes only, under the FDA's investigational device exemption. Scientists could continue to repurpose iontophoresis devices for use in research studies as long as

[111] Since 21 C.F.R. Section 801.4 allows the FDA to consider a broad range of factors in determining intended use, I use "limited circumstances" here to refer to a situation wherein a disease claim or medical-related structure/function claim could not be construed based on all the factors set out in that section.

such devices are deemed to be non-significant risk devices by their local Institutional Review Board. With regard to treatment, psychiatrists and other medical professionals could continue to repurpose iontophoresis devices for "off-label" use for either cognitive enhancement or treatment; such a practice is legal in the United States.[112] In the future, a company could demonstrate the safety and efficacy of its device for a specific clinical use (e.g., depression) and see it approved or cleared as a prescription-only medical device. Thus, while all of the above mentioned examples involve some form of tDCS, each is subject to different forms of oversight.

Given the multitude of regulation covering various forms of tDCS devices, it is unclear how additional regulation might fit into the picture. Indeed, as I mentioned at the outset, many scholars have conflated the lack of enforcement with the lack of regulation. Furthermore, much of the existing literature has neglected to consider current legal frameworks and factors such as the practical feasibility of implementation (i.e., the procedures, costs, and length of time required to modify regulation), the precise targets of regulation (exactly which devices additional regulation would affect, and how); and possible social implications (such as the possibility that home users might go further "underground" in response to a regulatory push). Indeed, modifying a regulatory framework to questionably encompass a small sliver of devices that have yet to cause any serious adverse effects seems both impractical and unrealistic.

Rather than focusing on the enforcement of existing regulation[113]—which would not affect the use of home-built devices, the Thync device, and iontophoresis devices—a more productive method might be to begin with a review of existing devices and the populations who use them, outlining the relevant issues of concern surrounding consumer non-invasive brain

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[112] Margaret A. Boyd, "Butt Out!! Why the FDA Lacks Jurisdiction To Curb Smoking of Adolescents and Children," *Journal of Contemporary Health Law and Policy* 13 (1996): 169–97.

[113] In most cases, a federal or state agency cannot be compelled to enforce existing regulation. However, complaints may be filed with the various regulatory authorities.

stimulation. While there has been a large body of literature on the ethics of cognitive enhancement drugs (e.g. inequality with regard to distribution, compelled use), the bulk of the conversation surrounding consumer tDCS devices has focused on issues of safety and risk. However, further clarification is necessary when using these terms, as even a device that complies with regulatory standards may not be "safe" under certain usage practices (e.g., long-term use of the Thync device); whereas a device that does not meet technical output standards may be safe when used in a specific manner (e.g., a "DIYer" using a home-built device). In other words, *who* is using the device is just as important as *what* device they are using. Furthermore, it is crucial to differentiate between short-term safety issues (e.g., side effects such as skin irritation and headaches) and long-term unknowns (e.g., the possibility of deleterious cognitive effects).

Looking ahead, it is clear that electrical brain stimulation will soon become available to a larger audience than it ever has before. If Thync's initial results are borne out—and its device does have the same effect as a glass of wine or a cup of coffee—then the technology could be profoundly transformative in ways that we cannot yet grasp. Rather than adopting an alarmist approach to the new reality of consumer brain stimulation, this unfamiliar terrain must be navigated with practical, grounded assessments of social and regulatory issues.

CHAPTER 5

The medical battery in the United States (1870-1920): electrotherapy at home and in the clinic

In 1892, A. D. Rockwell, a New York-based physician and one of the leaders in the field of electrical medicine, spoke at the American Electrotherapeutic Association about the threats to the credibility of the field, or as he put it, "hindrance[s] to the right appreciation and the right use of electricity."[1] Although Rockwell noted that both "self-confessed charlatans" and dubious medical colleagues presented challenges for electrotherapeutics, he felt that more pernicious threats were posed by two other groups: "members of the regular profession who freely use electricity" presumably without sufficient training, and the general public, "who either with or without advice make use of this agent as commonly and as confidently as they take their morning bath or daily friction."[2]

Expounding upon the public's use of electrotherapeutics, Rockwell lamented that "anyone can buy a battery of some sort, for the market is glutted with machines of the most inexpensive and worthless construction."[3] Indeed, Rockwell was correct: in the late nineteenth and early twentieth century, the advent of mail-order catalogues meant that a plethora of electrotherapy products—such as electric belts, socks, and hairbrushes—were widely available

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[1] A. D. Rockwell, "The Uses and Abuses of Electricity in Medicine," *Journal of the American Medical Association* 20, no. 3 (January 21, 1893), 72.

[2] Ibid.

[3] Ibid., 73.

for direct purchase by consumers; many of these products were marketed with the promise of curing everything from cancer to headaches.[4] But it is not these products that were the target of Rockwell's frustration; rather, his ire is directed toward an item he refers to as a "battery."

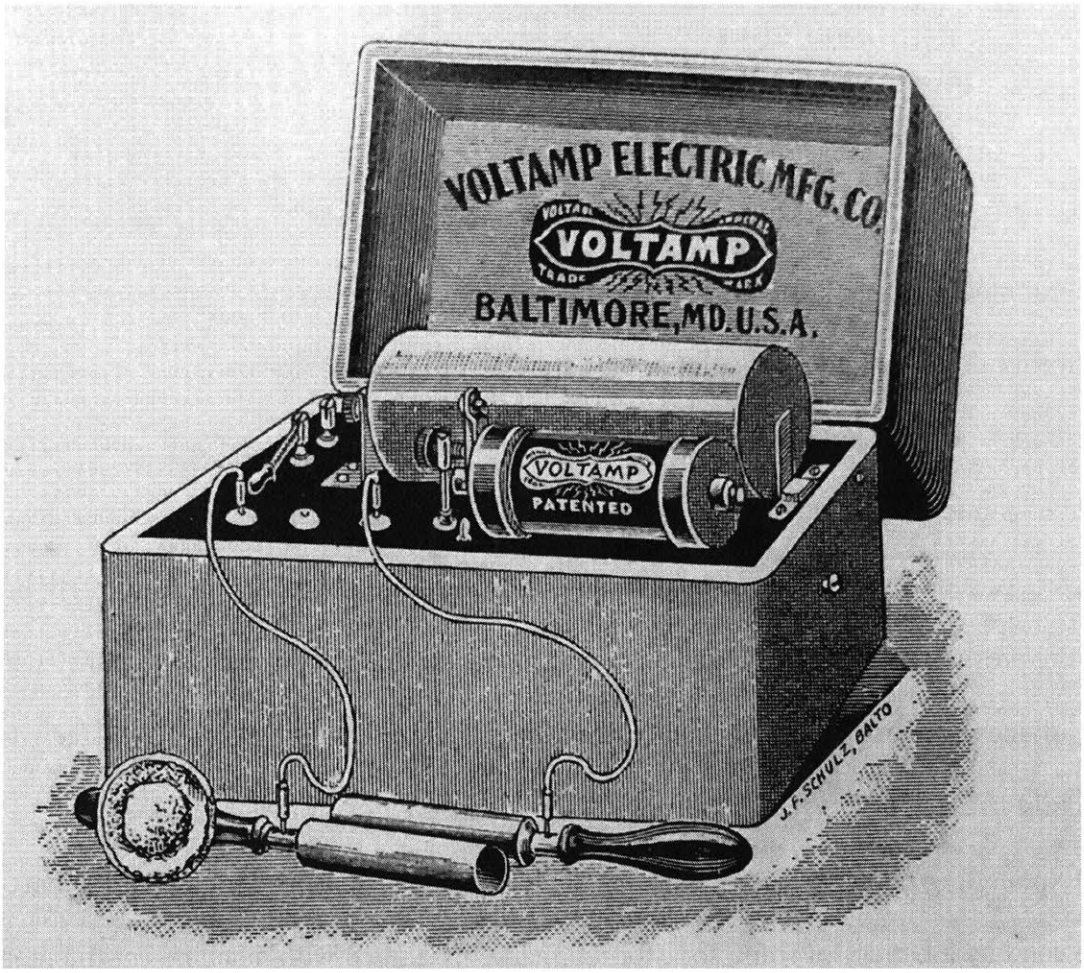


Figure 5.1. Medical battery No. 4 from the Voltamp Electric Manufacturing Co., as advertised in the company's 1904 catalogue. Bakken Library Collection.

The battery—more commonly known as a "medical battery"—was a simple shock-producing device, consisting of a battery and an iron core encased in a wooden box (**Fig. 5.1**).[5]

[4] Carolyn Thomas de la Peña, *The Body Electric: How Strange Machines Built the Modern American* (New York: New York University Press, 2003), 105-121.

Most medical batteries were approximately the size of a shoebox, though "pocket" medical batteries could be as small as a paperback book and high-end medical batteries with extra features could be as large as a carry-on suitcase. They usually provided both direct and alternating current and were used to administer low levels of electrical stimulation to the body to treat a variety of diseases. For physicians interested in electrotherapeutics, the medical battery was often the entry-level device offered in an electromedical instrument catalogue. But medical batteries were also sold directly to the public by electric novelty and supply companies, individual instrument makers, and even companies that manufactured medical instruments for physicians. For Rockwell, the public's use of the medical battery undermined the notion of electricity as a serious scientific and medical technique that required years of training and expertise.

In some ways, the issues raised by the medical battery were not unique to electrotherapeutics: the increase in direct-to-consumer health products in the nineteenth century (sometimes referred to as the rise of the medical marketplace) challenged physicians' authority over healthcare. Historians Anne Digby, Takahiro Ueyama, Joseph Gabriel and others have chronicled how physicians in Britain and the United States (US) attempted to position the medical profession in opposition to entrepreneurialism.[6] Any doctor who advertised his or her practices, held a patent on a medicine, or who was involved in profit making was liable to be

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[5] Dean P. Currier, *Guide to Electrotherapy Instruments and History of Their American Makers,* (West Conshohocken, PA: Infinity Publishing, 2013). This book, which is a 500-page guide for antique collectors, is the most comprehensive work to-date on the medical battery.

[6] Anne Digby, *Making a Medical Living: Doctors and Patients in the English Market for Medicine, 1720-1911* (Cambridge University Press, 2002); Takahiro Ueyama, *Health in the Marketplace: Professionalism, Therapeutic Desires, and Medical Commodification in Late-Victorian London* (Society for the Promotion of Science and Scholarship, 2010); and Joseph M. Gabriel, *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry* (University of Chicago Press, 2014).

labeled as a quack.[7] Another defining feature of quackery was the sale (or recommendation) of so-called "patent medicines"[8] whose ingredients were kept secret by their manufacturers. When the American Medical Association (AMA) was founded in 1847, it adopted a Code of Ethics that framed an "ethical" medical profession in opposition to the practices of quackery; any "concealment" regarding medicines was considered "inconsistent with beneficence and professional liberty."[9]

But whereas one of the defining features of quackery with regard to medicines was secrecy of ingredients, the same criteria did not hold true for electrotherapeutic devices: anyone who purchased a consumer electrotherapy device could open up the product and see how it worked, and magazines and books offered step-by-step instructions for constructing a medical battery.[10] For electrical medicine, then, overt commercialism (i.e., companies who advertised and sold directly to the public) and exaggerated claims were other indicators of quackery.[11] Another

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[7] Digby, *Making a Medical Living*, 61; Gabriel, *Medical Monopoly*, 57-63.

[8] Despite the name, such medicines were rarely patented. See Gabriel, *Medical Monopoly*, 17-18.

[9] American Medical Association, *Code of Ethics of the American Medical Association, Adopted May 1847* (Philadelphia : T.K. and P.G. Collins, printers, 1848), 16 (Chapter 2, Article 1, Section 4). See also Robert Baker, "The Historical Context of the American Medical Association's 1847 Code of Ethics," in *The Codification of Medical Morality*, ed. Robert Baker, Philosophy and Medicine Volume 49.

[10] "Amateur Mechanics," *Popular Mechanics* 11, no. 1 (1909), 36; Selimo Romeo Bottone, *Electrical Instrument Making for Amateurs, a Practical Handbook* (London, Whittaker & co.; New York, D. Van Nostrand, 1888); Norman Hugh Schneider, *Induction Coils: How to Make, Use, and Repair Them Including Ruhmkorff...*, 2nd ed. (Spon & Chamberlain, 1901); and Frederick Charles Allsop, *Induction Coils and Coil-Making; a Treatise on the Construction and Working of Shock, Medical and Spark Coils* (London & New York: E. & F N. Spon; Spon & Chamberlain, 1894).

[11] As Dr. Samuel Monell, a founder and chief instructor at the New York School of Special Electro-Therapeutics, put it: "no medical writer who has won recognition as a competent authority in the field of electro-therapeutics has ever *over*-stated the value of electric currents in medicine... Experienced medical men in this branch of practice seek ultra-conservatism, and shun exaggeration as science itself shuns quackery." Samuel Howard Monell, *High Frequency*

marker was the sale of electrotherapy products that were not used by the medical profession: no regular physician would ever imagine writing about electric socks or brushes in a medical journal—indeed, it was unclear whether they even provided an electric current—and such products were written off as nostrums.[12]

But the medical battery occupied a more complex space at the nexus of medicine, consumerism, and quackery.[13] Because electrical treatment via the medical battery was considered a legitimate electrotherapeutic technique—as evidenced by numerous mentions of it in books and articles written by regular physicians who practiced electrotherapeutics—the product itself, even when sold directly to consumers, could not be dismissed as quackery. While there were indeed those who sold the medical battery directly to consumers with cure-all claims—and such companies were therefore likely to be labeled as quacks—there were many

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Electric Currents in Medicine and Dentistry (New York: W. R. Jenkins company, 1910), 128-129.

[12] Ibid., 129-130.

[13] Many scholars have discussed the difficulties in defining "quackery." See, e.g., the first chapter of Roy Porter, *Health for Sale: Quackery in England, 1660-1850* (Manchester: Manchester University Press, 1989); Erika Janik, *Marketplace of the Marvelous: The Strange Origins of Modern Medicine* (Boston: Beacon Press, 2014), 1-23; and Eric W. Boyle, *Quack Medicine: A History of Combating Health Fraud in Twentieth-Century America* (Santa Barbara, CA: Praeger, 2013). See also Stewart H. Holbrook, *The Golden Age of Quackery* (New York: The Macmillan Company, 1959); James Harvey Young, *American Health Quackery* (Princeton: Princeton University Press, 1992); Arthur Wrobel, ed., *Pseudo-Science and Society in Nineteenth-Century America* (Lexington: University Press of Kentucky, 1987); Robert K. Waits, *The Medical Electricians: George A. Scott and His Victorian Cohorts in Quackery* (Sunnyvale, California: CreateSpace Independent Publishing Platform, 2013; and William H. Helfand, *Quack, Quack, Quack: The Sellers of Nostrums in Prints, Posters, Ephemera & Books* (New York: Grolier Club, 2002). Indeed, the term "quackery" is slippery to define; it has been alternately used to describe products and procedures as well as the people who manufacture or promote them. The notion of "quackery" also depends on whether a therapy is accepted by those with the most authority in a given field. Indeed, perhaps the best definition of "quacks" comes from Everett Hughes, who according to sociologist Paul Starr, defined them as "practitioners who continue to please their customers but not their colleagues." Paul Starr, *The Social Transformation Of American Medicine: The Rise Of A Sovereign Profession And The Making Of A Vast Industry*, Reprint edition (New York: Basic Books, 1982), 23.

retailers selling medical batteries to consumers *without* cure-all claims and with minimal advertising. Thus in many ways the sale of the medical battery to the laity (and its subsequent use in home settings) represented a separate issue than that of quackery; indeed, in Rockwell's speech, he distinguished the threats presented by charlatans from those posed by the public's use of the medical battery.

Yet Rockwell was one of the very few to speak out about the issue; on the whole there was no outcry amongst physicians regarding the use of electricity at home. In fact, every reputable electrotherapy instrument manufacturer sold at least one model of the medical battery for "family" use, and physicians could recommend or even purchase such products on behalf of their patients. That the "family battery" remained in the catalogues of reputable electrotherapy instrument manufacturers in the United States for approximately 50 years (between 1870 and 1920) suggests that there was a significant demand for the product for this period of time. Thus, while physicians did not publicly promote or even write about the home use of electricity, I will suggest here that they were likely more involved in the practice than they appeared in print.

This chapter explores how the medical battery blurred the lines between medicine, consumerism, and quackery in the United States in the late nineteenth and early twentieth century. In many ways it follows the work of Lori Loeb and Peter Bartrip, who have shown that the presumed gulf between the medical profession on the one hand, and quackery (and consumerism) on the other, was often not as large as regular physicians professed it to be. Loeb, for example, has argued that many British physicians were quietly involved in recommending patent medicines to their patients, despite the medical profession's official stance against them.[14] She has also shown how many individuals who were derided as "quacks" by the medical

[14] Lori Loeb, "Doctors and Patent Medicines in Modern Britain: Professionalism and Consumerism," *Albion* 33, no. 3 (October 2001): 404–25.

profession were in fact upstanding citizens who embraced the rising commodification of healthcare.[15] Along similar lines, Bartrip has demonstrated how the *British Medical Journal* (BMJ) financially benefitted from running advertisements for patent medicines even as it was actively campaigning against them.[16] Thus, as Bartrip notes, "ethical rhetoric was not always in step with marketplace reality."[17] In a similar vein, this chapter highlights discrepancies between the professional ideals of electrotherapeutics and physicians' actual practices.

While much scholarship has focused on irregular medical practitioners and consumer electrotherapy products that were dismissed by the regular profession as quackery, this chapter centers on the sale and use of the only direct-to-consumer electrotherapeutic product, the medical battery, that was viewed as legitimate by physicians practicing electrical medicine in the US in the late nineteenth and early twentieth century. It should be emphasized, however, that electrotherapy was not uniformly accepted by the medical profession; physicians who practiced electrical medicine were liable to find themselves facing "sarcastic remarks and sneers" from their medical colleagues.[18] Yet the practice did achieve a certain measure of professional acceptance: by the 1890s electrotherapy had become part of the curriculum in some medical schools,[19] and the proceedings of the annual conference of the American Electrotherapeutic

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[15] Lori Loeb, "George Fulford and Victorian Patent Medicine Men: Quack Mercenaries or Smilesian Entrepreneurs?," *Canadian Bulletin of Medical History / Bulletin Canadien D'histoire de La Médecine* 16, no. 1 (1999): 125–45.

[16] Peter Bartrip, "Secret Remedies, Medical Ethics, and the Finances of the British Medical Journal," in *The Codification of Medical Morality*, ed. Robert Baker, Philosophy and Medicine 49 (Springer Netherlands, 1995).

[17] Ibid., 192.

[18] William Harvey King, "Some of the Causes Which Retard the More Rapid Progress of Electro-Therapeutics," *Journal of Electrotherapeutics* 10 (1892), 66. See also Lisa Rosner, "The Professional Context of Electrotherapeutics," *Journal of the History of Medicine and Allied Sciences* 43, no. 1 (January 1, 1988), 68.

[19] Timothy Kneeland and Carol Warren, *Pushbutton Psychiatry: A Cultural History of Electric Shock Therapy in America* (Walnut Creek, CA: Left Coast Press, 2008), 29. Indeed, in

Association (AEA) were published in the pages of the esteemed *Journal of the American Medical Association* (JAMA). A number of electrotherapy clinics admitted physicians for training purposes[20] and there was even an electrotherapy correspondence course for those located in more remote areas.[21]Thus, when I refer to the medical profession and regular physicians in the context of electrotherapeutics, I am referring to those medical professionals—usually possessing medical degrees from respected institutions—who both practiced electrotherapy and would have been welcome at American Medical Association (AMA) meetings.

Despite the apparent historical popularity of the medical battery, little scholarship has been devoted to its manufacture and use, particularly in the United States.[22] Indeed, the term "medical battery" in historical literature is perhaps most strongly associated with the case of C.

1892, W. F. Osbourne, the manager of the eastern office of the *Western Electrician*, reflected on the rise of electrotherapy in the mainstream medical profession: "Twenty years ago work in this line was considered a disreputable thing for a regular physician, and the subject was never mentioned in any of the medical colleges or journals. To-day all the medical colleges deal with it more or less, and you can seldom find an issue of a medical journal that does not contain something in reference to it." W. F. Osbourne, "Correspondence: New York Notes," *Western Electrician*, Vol. 11, (17 September 1892), 153.

[20] See, e.g., Margaret A. Cleaves, "The Record of Four Years (1895-1899) in an Exclusively Electro-Therapeutic Clinic," Bakken Library Collection.

[21] Kneeland and Warren, *Pushbutton Psychiatry*, 29. Note, however, that the correspondence course, from the National College of Electrotherapeutics, was later liable to charges of quackery from the AMA. See National College of Electrotherapeutics, Box 0232-05, AMA Historical Health Fraud Archive; also see "National College of Electro-therapeutics," Editorial, *New York Medical Journal*, June 3, 1899 (republished in the International Record of Medicine and General Practice Clinics, Vol. 69, 786).

[22] By contrast, much work has been devoted to the overall practice of electrotherapeutics and its theoretical underpinnings in the late nineteenth and early twentieth century, particularly in Europe. For example, Iwan Rhys Morus has written extensively about the practice of electrotherapeutics and its rise to legitimacy in Victorian England, and Andreas Killen has suggested a link between German modernization, the rise of the diagnosis of "nervous" disease, and electrical treatments. See Iwan Rhys Morus, *Shocking Bodies: Life, Death and Electricity in Victorian England* (Stroud: The History Press, 2011); Iwan Rhys Morus, "Marketing the Machine: The Construction of Electrotherapy as Viable Medicine in Early Victorian England," *Medical History*, 36 (1992); and Andreas Killen, *Berlin Electropolis: Shock, Nerves, and German Modernity* (Berkeley, CA: University of California Press, 2006).

B. Harness, whose London-based Medical Battery Company was successfully sued for fraud in 1892 by a customer who had purchased an electric belt.[23] Here, however, I use the term "medical battery" as it was commonly used in the U.S. in the late nineteenth and early twentieth century, in reference to simple electrotherapy apparatuses designed to provide low levels of current for electric treatment. As sales records from companies and reports from consumers are largely nonexistent, I have relied upon trade catalogues and newspaper advertisements, as well as surviving medical batteries, to reveal how different actors marketed and utilized the medical battery in multiple ways.

I begin by presenting a brief overview of the history of the use of electricity in medicine, covering early uses of electric fish and initial uses of electricity in medicine in the eighteenth and nineteenth centuries in both Europe and America. Next I focus on the "golden age of electrotherapy" in the United States in the late nineteenth and early twentieth century, beginning with the broader social and cultural currents that led to the rise of consumer electrical devices. I then explore the medical battery market, characterizing how the wide variety of consumer-and physician-oriented companies differentially marketed the device. After considering the "family battery" and the (lack of) debate over the acceptability of self-treatment with electricity, I discuss the decline of the medical battery in the 1910s and note its contemporary revival in antique markets.

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[23] For discussions of the case, see Lori Loeb, "Consumerism and Commercial Electrotherapy: The Medical Battery Company in Nineteenth-Century London," *Journal of Victorian Culture,* 4, 2 (1999); and Takahiro Ueyama, "Capital, Profession and Medical Technology: The Electro-Therapeutic Institutes and the Royal College of Physicians, 1888–1922," *Medical History* 41, no. 02 (April 1997): 150–81, doi:10.1017/S0025727300062360.

I. Early history of electricity in medicine

The therapeutic effects of electricity were noted in Roman times, fifteen-hundred years prior to the development of the concept of "electricity." Sometime around 47 AD, a prominent physician named Scribonius Largus wrote *Compositiones medicae* (a compendium of medical treatments).[24] In the work, Scribonius notes that live torpedo fish can cure headaches and gout.[25] After Scribonius, a Greek physician named Dioscorides wrote about the use of the torpedo fish to treat headaches and anal prolapse (or hemorrhoids, depending on one's interpretation).[26] Later, in the mid-to-late second century, a well-known physician named Galen also wrote about the use of torpedo fish for treating headache and anal prolapse.[27] All three of these writings, but particularly Galen's, were repeated in various forms over the ensuing centuries.[28] However, almost no new advances were made regarding medical electricity until the middle of the eighteenth century.

Interestingly, the proposed use of electricity in medicine did not follow from philosophical inquires into the properties of electric fish, but rather emanated from a search to find the usefulness for the newly discovered phenomenon of "electricity."[29] The term "electricity" comes from the Greek word for amber, and is credited to British physician William Gilbert, who experimented with the attractive properties of various substances in the late

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[24] Stanley Finger and Marco Piccolino, *The Shocking History of Electric Fishes: From Ancient Epochs to the Birth of Modern Neurophysiology* (Oxford: Oxford University Press, 2011), 45-46. Note that the exact year of composition of the text is debated; for a brief overview of the key points of the controversy, see Ianto Jocks, "The Compositiones Medicamentorum of Scribonius Largus" (MRes thesis, University of Glasgow, 2013), 8-9.

[25] Finger and Piccolino, *The Shocking History of Electric Fishes*, 45-46.

[26] Ibid., 47-49.

[27] Ibid., 50.

[28] Ibid.

[29] Ibid., 175.

sixteenth century.[30] By the middle of eighteenth century, a variety of apparatuses had been developed that used friction to create electricity.

Historians attribute the earliest mention of the potential use of electricity in medicine to German professor Johann Gottlob Krüger, who told his students in a 1743 lecture that the "best effect [for electricity] would be found in paralyzed limbs."[31] Krüger's conjecture likely stemmed from the fact that it was commonly known at the time that electric shocks could cause twitching of the muscles. The next year, one of Kruger's students, Christian Gottlieb Kratzenstein, found that electric stimulation helped a woman overcome a muscle contraction in her finger.[32]

Just a few years later, the Leyden jar was invented simultaneously in both Holland and Germany; the apparatus represented a major advance in electricity, as for the first time it allowed (static) charge be accumulated, "stored" and then later released at will.[33] The discovery of the Leyden jar spurred further scientific investigations as well as experimental medical applications, and in the ensuing years many European physicians used electricity harnessed from Leyden jars to administer electrotherapy to paralyzed individuals. It was theorized that in paralyzed limbs, the "life fluid" of electricity was diminished or blocked, and perhaps function could be restored through electrical stimulation.

In 1756, the first textbook in English on medical electricity was published,[34] and thereafter reports of the use of medical electricity appeared in medical journals in England,

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[30] Ibid., 163, and Margaret Rowbottom and Charles Susskind, *Electricity and Medicine: History of Their Interaction* (San Francisco: San Francisco Press, 1984), 1-2.

[31] Finger and Piccolino, *The Shocking History of Electric Fishes*, 175.

[32] Ibid.

[33] Rowbottom and Susskind, *Electricity and Medicine*, 7. The Leyden jar is an early version of what came to be known as a capacitor.

[34] Paola Bertucci, "Revealing Sparks: John Wesley and the Religious Utility of Electrical Healing," *The British Journal for the History of Science* 39, no. 03 (September 2006): 341–62, doi:10.1017/S0007087406008363, 345.

France, Germany,[35] and other countries.[36] Electricity was administered in hospitals and asylums in England,[37] and according to some scholars, "by the 1770s and 1780s medical electricity had achieved a certain measure of official recognition in Britain."[38] It was not an obscure treatment, either: according to one scholar, "By 1780, virtually every Parisian would have heard of the use of electricity to cure nervous disorders such as paralysis."[39]

The electrotherapy apparatuses of the late eighteenth century were hand-built by specialized instrument makers, and were often accompanied by pamphlets containing instructions of how to apply electricity to treat specific ailments.[40] Sometimes the information from the booklets was sourced from the public: in 1747, a British instrument maker, John Neal, requested that individuals send in reports of electrical cures that would then be included in a booklet.[41] Based on the number of reprints of various pamphlets, it seems that the devices enjoyed a good measure of popularity: for example, the booklet accompanying Edward Nairne's machines went through eight different editions between 1783 and 1796, and was translated into both French and German.[42]

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[35] Oliver Hochadel, "'My Patient Told Me How to Do It': The Practice of Medical Electricity in the German Enlightenment"," in *Electric Bodies: Episodes in the History of Medical Electricity*, ed. Paola Bertucci and Giuliano Pancaldi (Bologna: Università di Bologna, 2001); see also Finger and Piccolino, *The Shocking History of Electric Fishes*, 177-178.

[36] Rowbottom and Susskind, *Electricity and Medicine,* 21.

[37] Ibid., 23; Paola Bertucci, "A Philosophical Business, Edward Nairne and the Patent Medical Electrical Machine (1782)," *History of Technology* 23 (2001), 49.

[38] Rowbottom and Susskind, *Electricity and Medicine,* 23.

[39] François Zanetti, "Curing with Machines: Medical Electricity in Eighteenth-Century Paris," *Technology and Culture* 54, no. 3 (2013): 503–30, doi:10.1353/tech.2013.0102, 514.

[40] Bertucci, "A Philosophical Business."

[41] John Neal, *Directions for gentlemen, who have electrical machines, how to proceed in their experiments* (London, 1747), discussed in Paola Bertucci, "Therapeutic Attractions: Early Applications of Electricity to the Art of Healing," in *Brain, Mind and Medicine: Essays in Eighteenth-Century Neuroscience*, ed. Harry Whitaker, C. U. M. Smith, and Stanley Finger (Springer US, 2007), 277.

[42] Bertucci, "A Philosophical Business," 46.

Instrument makers, physicians, and clergymen were drawn to electricity because they hoped it would become a universal and cheap treatment for a wide variety of maladies.[43] John Wesley, who later went on to co-found Methodism, was an early proponent of electrical treatment.[44] In *The Desideratum, or Electricity Made Plain and Useful* (1759), he refers to electricity as an "unexpensive and speedy Remedy" that can restore sick individuals to "Ease, Health, Strength, generally in a few Minutes, frequently in a Moment."[45] Wesley was one of the first to provide electrical treatments in his "dispensaries,"[46] hospital-like institutions that were frequented by the poor.[47] According to one scholar, there was a "do-it-yourself ethos"[48] to medical electricity, and it was "commonly regarded as one of the possible self-remedies for use at home." However, one could also visit both "regular" and "irregular" medical practitioners for treatment.[49]

While electricity was a popular therapy in eighteenth century Europe, there are few reports of similar treatments in colonial America.[50] The one major exception comes from Benjamin Franklin, whose surviving letters detail his extensive experiments, both philosophical and medical, into the nature of electricity. After reading reports from Europe about the success of

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[43] Bertucci, "Revealing Sparks," 345.

[44] Ibid., 355.

[45] John Wesley, *The Desideratum: or, electricity made plain and useful* (London: Baillière, Tindall, and Cox, 1759), preface.

[46] Bertucci, "Revealing Sparks," 353.

[47] Charles E. Rosenberg, "Social Class and Medical Care in 19th Century America: The Rise and Fall of the Dispensary," in *Sickness and Health in America: Readings in the History of Medicine and Public Health*, ed. Judith Walzer Leavitt and Ronald L. Numbers (Madison: University of Wisconsin Press, 1978), 309.

[48] Bertucci, "Revealing Sparks," 346-347.

[49] Bertucci, "Therapeutic Attractions," 271. For a discussion of the differences between regular and irregular practitioners in the eighteenth century, see Roy Porter, "Laymen, Doctors and Medical Knowledge in the Eighteenth Century: The Evidence of the Gentleman's Magazine," in *Patients and Practitioners: Lay Perceptions of Medicine in Pre-Industrial Society*, ed. Roy Porter (Cambridge: Cambridge University Press, 2003), 283-314.

[50] Rowbottom and Susskind, *Electricity and Medicine,* 29.

electrical medical treatments, Franklin decided to see for himself if it was effective.[51] He administered electricity to a patient with hysteria, who subsequently returned to health.[52] According to the patient, Franklin sent her home with a "globe and bottle" so that she could electrify herself "everyday for three months."[53] However, Franklin found little success in using electricity to treat other disorders, such as palsies (which at that time mostly referred to disorders related to loss of muscle movement),[54] writing that he "never knew any Advantage from Electricity in Palsies that was permanent."[55]

Although electricity was mostly used to treat movement disorders in the late eighteenth century, there are some reports of it being used to treat mental disorders as well. While Giovanni Aldini, Galvani's nephew, is credited in most academic tDCS publications with being the first to use electricity on the brain to treat mental disorders (particularly melancholy) in 1804, historians have pointed out that there are earlier reports.[56] For example, John Birch, who founded the electrical department at St. Thomas's Hospital in London, reported treating two individuals for melancholy in 1792 by using electric shocks applied to the head.[57] In addition, in a book

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[51] Sherry Ann Beaudreau and Stanley Finger, "Medical Electricity and Madness in the 18th Century: The Legacies of Benjamin Franklin and Jan Ingenhousz," *Perspectives in Biology and Medicine* 49, no. 3 (2006): 330–45.

[52] Stanley Finger, *Doctor Franklin's Medicine* (University of Pennsylvania Press, Philadelphia, PA: 2006), 104-107.

[53] Ibid., 106.

[54] Ibid., 80-101; Beaudreau and Finger, "Medical Electricity and Madness," 333.

[55] Benjamin Franklin, "An account of the effects of electricity in paralytic cases," *Philosophical Transactions of the Royal Society*, 50 no. 2 (1758):481-483, quoted in Beaudreau and Finger, "Medical Electricity and Madness," 334.

[56] See, e.g., Finger, *Doctor Franklin's Medicine*, 113; and Beaudreau and Finger, "Medical Electricity and Madness."

[57] Beaudreau and Finger, "Medical Electricity and Madness," 339.

published in 1802, an American physician named T. Gale described success in using "gentle shocks" of electricity to treat several cases of madness.[58]

In the nineteenth century, electrical therapies continued to evolve alongside knowledge of electricity. Just as the Leyden jar sparked an increase in medical and philosophical experiments in the mid-1700s, so too did Alessandro Volta's invention of the crude battery in 1800 spur a new wave of interest in electricity.[59] The "voltaic pile," as his invention became known, consisted of a series of alternating pairs of copper and zinc discs, separated by brine-soaked cloth. When a wire was connected to each end of the pile, a steady, direct current was produced.[60] This type of electricity later came be to known as "galvanism," in reference to the work of fellow Italian scientist Luigi Galvani whose experiments a decade earlier Volta had built upon.[61] Galvani, who had been using frog preparations in his many experiments on electricity, had come across a unique phenomenon: when a frog's legs were draped over an iron railing, and then a brass hook—that was fixed into the frog's spinal cord—was pressed against the railing, the frog's legs twitched.[62] Though Galvani had previously demonstration that muscle contractions could be caused by stimulation with "artificial" electricity from electrostatic machines as well as from atmospheric electricity, this discovery, and his subsequent

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[58] T. Gale, *Electricity, or ethereal fire, considered...* (Troy, MI: Moffitt & Lynn, 1802), quoted in Beaudreau and Finger, "Medical Electricity and Madness," 339-340. Interestingly, the extended subtitle of Gale's book, describes medical electricity as the "best family physician ever extant."

[59] Rowbottom and Susskind, *Electricity and Medicine,* 47-49. It is possible that Volta invented the voltaic pile earlier, but he first described it in a March 1800 letter to the Royal Society of London. Finger and Piccolino, *The Shocking History of Electric Fishes*, 335-337.

[60] Rowbottom and Susskind, *Electricity and Medicine,* 47-49.

[61] Note, however, that Volta was not happy about the use of the term "galvanism" to describe the electricity produced by the voltaic pile. See Finger and Piccolino, *The Shocking History of Electric Fishes*, 344.

[62] Ibid., 315-316; Rowbottom and Susskind, *Electricity and Medicine*, 38-41.

experiments, demonstrated that twitching could be caused *without* artificial or atmospheric electricity.[63]

Galvani attributed the phenomenon to the existence of "animal electricity," a fluid he posited flowed through the nerves of the body. Initially, Volta accepted Galvani's interpretation and commended his work,[64] but after conducting additional experiments, Volta came to believe that it was the close contact of two different metals—the brass and the iron—that played a key role in causing the frog's muscle contractions.[65] The ensuing debate between the two scientists over the nature of electricity is one of the most oft-repeated stories in the history of science, and the tale is usually concluded by noting that the invention of the voltaic pile "proved" Volta's theory to be correct. However, historians of science have argued that this is a misleading summation, as both men's theories were indeed partially correct.[66]

The development of the voltaic pile allowed for a constant source of electricity to be generated on-demand, and at the turn of the century physicians began experimenting with the medical effects of this new "galvanic" treatment. In an 1826 book on the medical effects of galvanism, English medical practitioner Michael La Beaume noted that galvanic treatments had been reported by physicians in Germany, England, and France for a wide array of diseases, such

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[63] Finger and Piccolino, *The Shocking History of Electric Fishes*, 314-316; Rowbottom and Susskind, *Electricity and Medicine,* 38-42.

[64] Finger and Piccolino, *The Shocking History of Electric Fishes*, 327-328.

[65] Rowbottom and Susskind, *Electricity and Medicine,* 43.

[66] For an excellent, in-depth research that challenges common perceptions of Galvani, Volta, and their respective experiments, see Marco Piccolino and Marco Bresadola, *Shocking Frogs: Galvani, Volta, and the Electric Origins of Neuroscience* (New York: Oxford University Press, 2013). The book questions the portrayal of Galvani as a hapless discoverer; clarifies that Volta initially supported (and praised) Galvani; and argues that rather than Volta being "right," in fact both Galvani and Volta were correct in some respects but incorrect in others. See also Finger and Piccolino, *The Shocking History of Electric Fishes*, 307-350.

as palsies, deafness, cramps, epilepsy, and asthma.[67] Though La Beaume enthusiastically reported that galvanic treatments were employed in the Americas, contemporary historians have been more circumspect in their assessments, suggesting that reports of electrotherapy in the US in the first part of the nineteenth century are "occasional and unsystematic."[68]

In the updated preface to the third edition of his book, published in 1848, La Beaume—who now self identified as a "Medical Galvanist and Electrician to the Queen"—reflects that in the twenty years since the publication of the first edition of his work, the public had become more familiar with electricity and galvanism. He credits this familiarity largely to the exhibition of electricity in "public places of instruction and amusement."[69] Indeed, electricity in the late eighteenth and early nineteenth century was characterized by performance and spectacle;[70] according to historians, "the electrification of the human body became a source of public entertainment."[71] In one oft-repeated demonstration that was conducted in the eighteenth century, a young boy was suspended from the ceiling on silk cords and "electrified" with static electricity; sparks would then be elicited from his body.[72] Other demonstrations involved shocks being passed through large groups of people holding hands.[73]

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[67] Michael La Beaume, *On Galvanism, with Observations on Its Chymical Properties and Medical Efficacy in Chronic Diseases* (London: Highley, 1826), 17-20.

[68] Timothy W. Kneeland and Carol A. B. Warren, *Pushbutton Psychiatry: A Cultural History of Electric Shock Therapy in Americ*a (Walnut Creek, CA: Left Coast Press, 2008), 22.

[69] Michael La Beaume, *On Galvanism and Its Efficacy in the Cure of Indigestion, Torpid and Obstructed Liver and Bowels, Asthma, Dropsy, &c* (London: Simpkins and Marshall, 1848), 3.

[70] Finger and Piccolino, *The Shocking History of Electric Fishes*, 167; Bertucci, "Therapeutic Attractions," 271-272; Kneeland and Warren, *Pushbutton Psychiatry*, 10-11.

[71] Kneeland and Warren, *Pushbutton Psychiatry,* 10.

[72] Finger and Piccolino, *The Shocking History of Electric Fishes*, 164-165; Rowbottom and Susskind, *Electricity and Medicine,* 8.

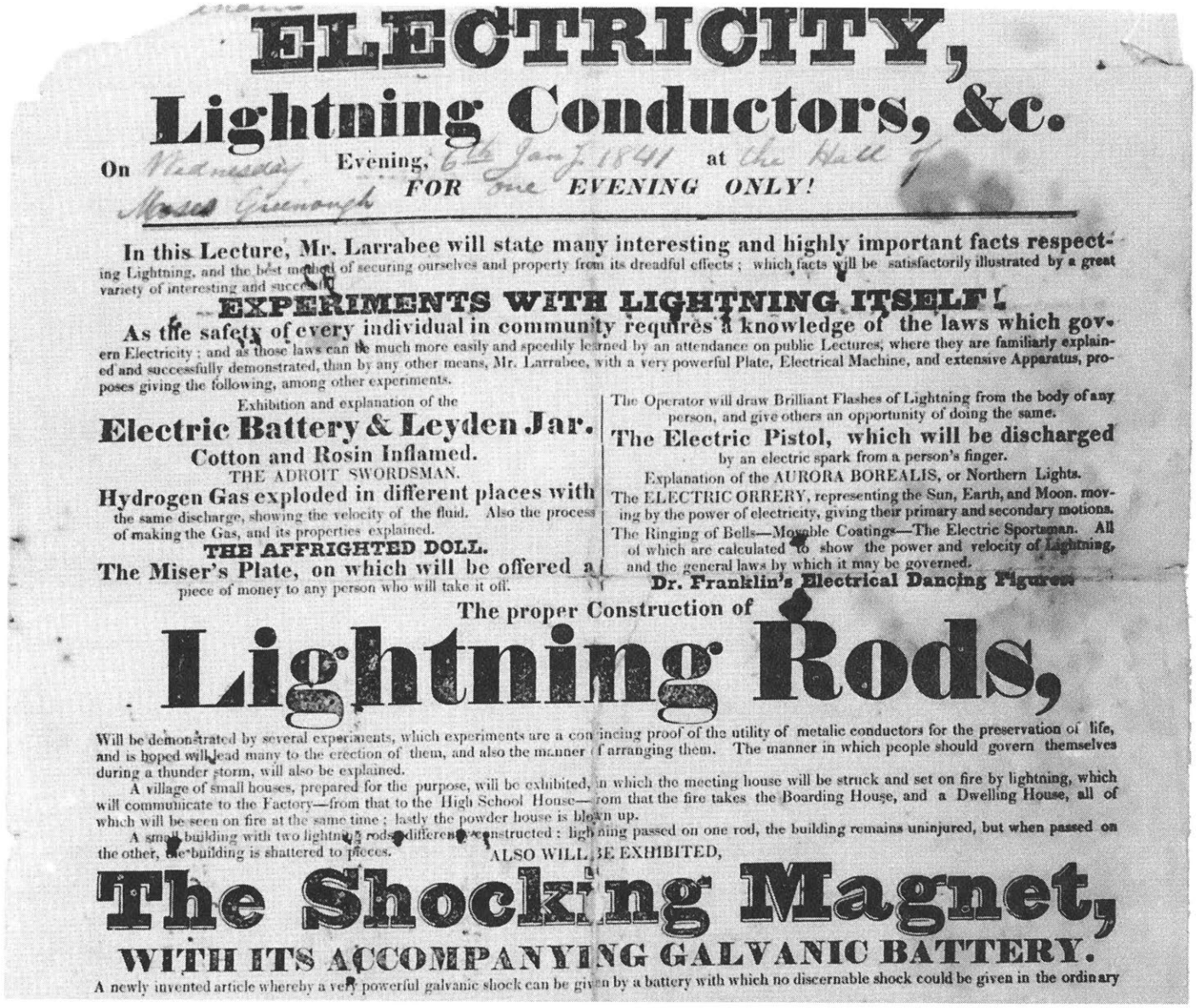
[73] Rowbottom and Susskind, *Electricity and Medicine,* 8-9.

The display of electricity onstage continued through the nineteenth century in both the United States and Europe. Entertainers would travel from city to city, performing one-night shows that combined short lectures about electricity with sensational displays of sparks and shocks. One poster from an unspecified US location in 1841, for example, advertised an entertaining evening of "Electricity, Lightning Conductors, &c" **(Fig. 5.2)**. Twelve-and-a-half cents bought admission to the show, in which a Mr. Larabee discharged sparks from the human body, created fire with "lightning rods," and demonstrated the wonders of the electric battery and the Leyden jar.

Mr. Larabee's show also featured exhibitions of the "Mysterious Agency of Electro-Magnetism," with displays that illustrated how an iron core could be turned into a powerful magnet by winding it with a coil of wire, and then running current through the wire. Indeed, the relationship between electricity and magnetism had become a major topic of study among European scientists in the 1820s.[74] In 1831, ten years prior to Mr. Larabee's show, English scientist Michael Faraday had discovered that when he ran current through a wire wrapped around an iron core (which "magnetized" the core), a current could be induced in a second wire that was also wrapped around the core—but only when there was a change in the primary current.[75] In other words, when the current flowing through the first wire was steady (as it is when flowing through a battery), there was no change in the magnetic "flux" of the iron core, and therefore no current was induced in the second wire. However, each time the current was turned on and off, there was a momentary change in the level of "magnetic flux" of the iron core, and a current was briefly induced in the second coil. Thus, changes in magnetic flux could induce current in a nearby coil. Importantly, a battery was not required to create changes in

[74] Ibid., 55-57.
[75] Ibid., 57.

magnetic flux: merely moving a permanently magnetized object around a wire coil had the same effect, and was sufficient to induce current in the coil.



ELECTRICITY,

Lightning Conductors, &c.

On Wednesday Evening, 6th Jan'y 1841 at the Hall of Moses Greenough

FOR ONE EVENING ONLY!

In this Lecture, Mr. Larrabee will state many interesting and highly important facts respecting Lightning, and the best method of securing ourselves and property from its dreadful effects; which facts will be satisfactorily illustrated by a great variety of interesting and successful

EXPERIMENTS WITH LIGHTNING ITSELF!

As the safety of every individual in community requires a knowledge of the laws which govern Electricity; and as those laws can be much more easily and speedily learned by an attendance on public Lectures, where they are familiarly explained and successfully demonstrated, than by any other means, Mr. Larrabee, with a very powerful Plate, Electrical Machine, and extensive Apparatus, proposes giving the following, among other experiments.

Exhibition and explanation of the

Electric Battery & Leyden Jar.

Cotton and Rosin Inflamed.

THE ADROIT SWORDSMAN.

Hydrogen Gas exploded in different places with the same discharge, showing the velocity of the fluid. Also the process of making the Gas, and its properties explained.

THE AFFRIGHTED DOLL.

The Miser's Plate, on which will be offered a piece of money to any person who will take it off.

The Operator will draw Brilliant Flashes of Lightning from the body of any person, and give others an opportunity of doing the same.

The Electric Pistol, which will be discharged by an electric spark from a person's finger.

Explanation of the AURORA BOREALIS, or Northern Lights.

The ELECTRIC ORRERY, representing the Sun, Earth, and Moon, moving by the power of electricity, giving their primary and secondary motions.

The Ringing of Bells—Movable Coatings—The Electric Sportsman. All of which are calculated to show the power and velocity of Lightning, and the general laws by which it may be governed.

Dr. Franklin's Electrical Dancing Figures.

The proper Construction of

Lightning Rods,

Will be demonstrated by several experiments, which experiments are a convincing proof of the utility of metalic conductors for the preservation of life, and is hoped will lead many to the erection of them, and also the manner of arranging them. The manner in which people should govern themselves during a thunder storm, will also be explained.

A village of small houses, prepared for the purpose, will be exhibited, in which the meeting house will be struck and set on fire by lightning, which will communicate to the Factory—from that to the High School House—from that the fire takes the Boarding House, and a Dwelling House, all of which will be seen on fire at the same time; lastly the powder house is blown up.

A small building with two lightning rods differently constructed: lightning passed on one rod, the building remains uninjured, but when passed on the other, the building is shattered to pieces.

ALSO WILL BE EXHIBITED,

The Shocking Magnet,

WITH ITS ACCOMPANYING GALVANIC BATTERY.

A newly invented article whereby a very powerful galvanic shock can be given by a battery with which no discernable shock could be given in the ordinary

Figure 5.2. Broadside advertisement for electricity show, 1841. Bakken Ephemera Collection.

Therefore, in addition to electricity that could be generated by friction (referred to at the time as "static" or "Franklinic" electricity, after Benjamin Franklin) or batteries ("galvanic" or direct current), the advances of the 1830s led to a method of using mechanical forces—by

rotating a magnet around a coil—to create electrical current. However, unlike galvanic current, which flows in one direction, the current that could be induced in a coil by changing magnetic flux (which came to be known as "faradic" or alternating current) oscillated back and forth, depending on the magnet's position. Scientists and physicians such as Guillaume Duchenne of France, who later became known as the father of electrotherapy,[76] spent the ensuing decades studying the therapeutic and physiological effects of faradic current.[77] In the mid-nineteenth century a variety of small, hand-cranked "electro-magnetic" machines were developed to produce faradic current; these devices were the precursors of the object that came to be known as the medical battery.

II. The "golden age of electrotherapy" (1870-1920) and the rise of consumer electrical devices

Before delving into the medical battery, which flourished in the period that has become known as the "golden age of electrotherapy" (1870-1920), it is worth taking stock of the broader social and cultural currents in mid- to late-nineteenth century America—particularly those related to medicine, electricity, and consumerism—that set the stage for the widespread embracement of electrical therapy, both by consumers and medical practitioners. Though similar developments occurred in the European context, the remainder of this chapter turns its focus to the use of electricity in medicine in America.[78]

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[76] See, e.g., Helena Knotkova and Dirk Rasche, eds., *Textbook of Neuromodulation: Principles, Methods and Clinical Applications* (New York: Springer, 2014), preface.

[77] Rowbottom and Susskind, *Electricity and Medicine*, 71-88.

[78] For more on developments in the European context, see, e.g., Killen, *Berlin Electropolis*; Lori Loeb, "Consumerism and Commercial Electrotherapy"; Iwan Rhys Morus, *Shocking Bodies*; and Iwan Rhys Morus, "Marketing the Machine."

In mid-nineteenth century America, medicine was not exclusively in the realm of the physician. In fact, since colonial times, medical care had been viewed as "common sense" knowledge passed down through families, and it was often women who were responsible for tending to those who were sick.[79] There was an emphasis on self-reliance, especially in rural areas. In colonial times, guides such as John Tennant's *Every Man His Own Doctor* (1736) and William Buchan's *Domestic Medicine* (1771) contained detailed instructions of how to treat various diseases.[80] In the nineteenth century, new self-treatment books, such as *Gunn's domestic medicine, or, Poor man's friend, in the hours of affliction, pain and sickness* (1830) offered up-to-date information on home medical care.[81]

Those who were sick could also seek out the care of a doctor, who would often make home visits. However, there was no guarantee that the doctor had a medical education: by some estimates, in the 1840s and 1850s, only one-fifth to one-third of physicians had attended medical school or had received another kind of formal training.[82] Even if a doctor had attended a medical school—the first one was established at the College of Philadelphia in 1765[83]—there were no

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[79] Starr, *Social Transformation Of American Medicine*; Janik, *Marketplace of the Marvelous*, 8-10; Charles E. Rosenberg, *Our Present Complaint: American Medicine, Then and Now* (Baltimore: John Hopkins University Press, 2007); Bertucci, "Revealing Sparks," 346-347.

[80] John Tennant, *Every Man His Own Doctor, or the Poor Planter's Physician* (Williamsburg, 1734) and William Buchan, *Domestic Medicine, or the Family Physician* (Philadelphia, 1771), as discussed in Starr, *Social Transformation Of American Medicine,* 32-34, and footnote 5, p. 452.

[81] John C. Gunn, *Gunn's Domestic Medicine, Or, Poor Man's Friend, in the Hours of Affliction, Pain and Sickness* (Knoxville, 1830).

[82] Paul Starr cites surveys from New England and Tennessee in the early 18th century in "Medicine, Economy and Society in Nineteenth-Century America," *Journal of Social History* 10, no. 4 (June 20, 1977), 591.

[83] Note that this is now the University of Pennsylvania School of Medicine. See, e.g., "School of Medicine: Historical development, 1765-1800," Penn University Archives & Records Center, accessed December 26, 2015, http://www.archives.upenn.edu/histy/features/1700s/medsch.html

standardized curriculums,[84] and medical degrees were widely available through the mail via "correspondence courses."[85] Anyone could set up a clinic and call himself a doctor. According to one author, the nineteenth century "was a time when healers of all kinds—regular, irregular, quacks, and everything in between—vied for public favor as the criteria for practicing medicine seemed to be no criteria at all."[86]

It wasn't until the late nineteenth and early twentieth century that medicine began to undergo a dramatic shift as physicians attempted to solidify their authority and draw professional boundaries. By the turn of the century, each state had passed medical licensing laws.[87] The American Medical Association (AMA), a professional association of physicians that had formed in the mid-nineteenth century, consolidated its power, increasing its membership from 8,000 in 1900 to 70,000 by 1910.[88] Medical education gradually became standardized, due in large part to Abraham Flexner's scathing 1910 report on the poor quality of most medical schools.[89] By the early twentieth century, the medical profession had largely succeeded in its efforts to crack down on "irregular" or unqualified practitioners.[90]

In addition to shifts in medicine, in the late nineteenth century another major social transformation was beginning to take place: the "electrification" of America. No longer merely a novelty relegated to traveling showmen, electricity began to creep into homes and the fabric of daily life. When the town of Wabash, Indiana, set up the state's first public lighting display in

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[84] Ronald L. Numbers, "The Fall and Rise of the American Medical Profession," in *Sickness and Health in America: Readings in the History of Medicine and Public Health*, ed. Judith Walzer Leavitt and Ronald L. Numbers (Madison: University of Wisconsin Press, 1978), 225–36, 225.

[85] de la Peña, *Body Electric*, 96.

[86] Janik, *Marketplace of the Marvelous*, 3.

[87] Numbers, "American Medical Profession," 229.

[88] Starr, *Social Transformation Of American Medicine,* 110.

[89] Numbers, "American Medical Profession," 232.

[90] Ibid.

1880, approximately 10,000 visitors travelled to witness the spectacle.[91] According to the local newspaper, "People stood overwhelmed with awe, as if in the presence of the supernatural."[92] In the 1890s, spectacular lighting displays were the major draw at world fairs[93], and in the ensuing decades, public lighting came to the main streets of America, with each inaugural display accompanied by much fanfare.[94]

Electricity brought more than just lighting: at the turn of the century, the advent of elevators, trolleys, and telephones rapidly revolutionized public infrastructure, transportation, and communication. Inside the home, too, electricity brought major changes to domestic routines. A home that was connected to the electrical grid could make use of newly invented household appliances such as washing machines, hot water heaters, vacuum cleaners, and electric stoves.[95] However, the adoption of domestic electricity was gradual: though electricity appeared in public places and well-off homes in the 1890s, most houses were not wired until the late 1920s.[96]

Electricity also dramatically transformed methods of production: automatic machines, running on newly invented electric motors and sensors, increasingly replace skilled labor. Given the constant availability of power (and electric light), factories no longer had to shut down at night, and could produce goods twenty-four hours a day. Mass production methods allowed

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[91] David Nye, *Electrifying America: Social Meanings of a New Technology* (Cambridge: MIT Press, 1990), 3.

[92] *Wabash Plain Dealer*, 1880, as quoted in Nye, *Electrifying America,* 3.

[93] Nye, *Electrifying America,* 37-47.

[94] Ibid., 57. For more on the rise of public lighting in America, see John A. Jakle, *City Lights: Illuminating the American Night* (Baltimore: Johns Hopkins University Press, 2001).

[95] Nye, *Electrifying America,* 18-20.

[96] Ben Wattenberg, *Statistical History of the United States* (New York: Basic Books, 1977), as quoted in Nye, *Electrifying America,* 16, and footnote 50, p.395.

companies to manufacture a huge variety of consumer goods at relatively cheap prices.[97] In the 1880s and 1890s, mail order companies (e.g., Montgomery Ward and Company, and Sears, Roebuck and Company) printed huge catalogues that offered tens of thousands of products, such as clothing and accessories, household appliances, toys and games, machine tools, building materials, home decor, furniture, and farming equipment.[98] Moreover, one did not need to live in a city to purchase such products: the rapid expansion of railroads in the 1850s and 1860s meant that these items were available even to those living even in remote, rural areas.[99] According to one historian, with the advent of mail order catalogues, "it needn't really matter whether one lived in city or country, for the good life could be purchased by mail wherever one made one's home."[100]

One class of products offered for sale in mail order catalogues (and advertised in newspapers and magazines) were medicines, which were often marketed as "cure-alls." For example, the 1902 Sears catalog offered products such as obesity powders ("a boon to fat people"), "sure cures" for the "tobacco habit" and opium habits, wonder heart cures, a "Mexican

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[97] Nye, *Electrifying America,* 13-14. For more on the effects of mass production on big business, see Alfred D. Chandler, *The Visible Hand* (Harvard University Press, 1993) and David Hounshell, *From the American System to Mass Production, 1800-1932: The Development of Manufacturing Technology in the United States* (Baltimore: John Hopkins University Press, 1985). For works on the rise of the consumer society (albeit in England) see, e.g., Neil McKendrick, John Brewer, and J. H. Plumb, *The Birth of a Consumer Society: Commercialization of Eighteenth Century England* (London: HarperCollins Publishers Ltd, 1984); and John Benson, *The Rise of Consumer Society in Britain, 1880-1980* (London: Longman Group United Kingdom, 1994). For contemporary views on consumer culture in America, see, e.g., George Ritzer, *The McDonaldization of Society*, 8th ed. (SAGE Publications, 2014); and Juliet B. Schor, *Born to Buy: The Commercialized Child and the New Consumer Culture* (New York: Scribner, 2005).

[98] William Cronon, *Nature's Metropolis: Chicago and the Great West* (New York and London: W. W. Norton & Company, 1991), 336-337; see, for example, Catalogue No. 112, Sears, Roebuck & Co, 1902, digital archive accessed on December 14, 2015, https://archive.org/details/catalogueno11200sear.

[99] Cronon, *Nature's Metropolis*, 68.

[100] Ibid., 338.

Headache and Neuralgia Cure," and Siberian catarrh snuff.[101] One page of the catalogue was devoted entirely to pills: blood pills, nerve and brain pills, "wonderful little liver pills," cathartic pills, and even "Dr. Worden's Female Pills," for curing every kind of "female trouble" (**Fig. 5.3**).[102] Tonics, tinctures, syrups, bitters, wines and teas were advertised for the cure of everything from consumption to rheumatism to scrofula.[103] Until 1906, there was no federal or state regulation that prevented manufacturers from exaggerating —or outright misrepresenting— their products' ingredients and supposed benefits.[104]



Figure 5.3. Dr. Worden's Female Pills from the 1902 Sears, Roebuck & Co. catalogue.

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[101] Catalogue No. 112, Sears, Roebuck & Co, 1902, 440, digital archive accessed on December 14, 2015, https://archive.org/stream/catalogueno11200sear#page/438/mode/2up

[102] Ibid., 440.

[103] Ibid., 441-451.

[104] The 1906 Pure Food and Drugs Act made it illegal to introduce "misbranded" or "adulterated" food and drugs interstate commerce. Drugs were also required to state, on the product label, if they contained narcotics (e.g., opium or marijuana). See Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, *Food and Drug Law: Cases and Materials*, 4th ed. (St. Paul, MN: West Academic, 2014), 6-9. For more on the history of regulatory efforts to combat what were known as "patent medicines," see Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*, first edition (Princeton: Princeton University Press, 2010); Boyle, *Quack Medicine*; and Philip J. Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation* (New York: Alfred A. Knopf, 2003).

Against this mid-to-late nineteenth century backdrop—with its lack of professionalization of medicine, the gradual rise of electrification, and the surge in availability of cheap consumer goods—electrical devices for medical purposes entered the consumer market. Device manufacturers capitalized both on the excitement about electricity and lack of knowledge on the part of the public: "Brewster's Medicated Electricity," for example, purportedly consisted of a battery in a glass bottle, "combined with vegetable compounds" that generated "a vapor which is a safe, convenient, and speedy method of obtaining relief from Nervous Headache, Catarrh, Hay Fever, Neuralgia."[105] Electric combs and hairbrushes were sold to cure baldness, nervous headaches, and other diseases; an "electric flesh brush" was marketed as a cure-all.[106] Electric insoles were touted as a treatment for rheumatism, gout, cold feet, and all kinds of pains and aches.[107] There was an electric garter for women that would "subdue all cramps and stiffness of joints," among other benefits, and there were electric corsets to "ward off disease."[108] Various companies sold ladies' electric "spinal appliances" and unisex "lung appliances."[109] Voltaic-electric porous plasters were marketed as remedies for dyspepsia, bilious colic, cramps and

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[105] "Brewster's Medicated Electricity," undated pamphlet, Bakken Ephemera Collection.

[106] "Improved Electro-Magnetic Hair Brush and Comb," New York and London Electric Association, undated, Bakken Ephemera Collection; "Riley's Electric Comb Battery," 1899, Bakken Ephemera Collection. See also various reprints of advertisements in Waits, *The Medical Electricians*, 254-289.

[107] See, e.g., Ohio Electric Insoles, p. 5 in "Illustrated Catalogue of the Leading Electric Novelties and Appliances," Ohio Electric Works, undated, Bakken Ephemera Collection; and ad for Dr. Bridgeman's Electro-Magnetic Belts, Corsets, Supporters, Braces, Insoles, and Appliances, *Harper's Magazine,* ca. 1891, Bakken Ephemera Collection. There are, however, many more examples, from the Pall Mall Electric Co, Electric Appliance Co, and Fletcher & Fletcher Co., to name a few.

[108] Dr. Scott's Electric Corset, ca. 1879, periodical unknown, reprinted in Waits, *Medical Electricians*, 253; see similar advertisement in *Century Illustrated*, ca. 1881-1882, also reprinted in Waits, *Medical Electricians*, 259.

[109] See e.g., p. 11 of the "German Electric Belts and Appliances," German Electrical Agency, 1893, Bakken Library Collection; and ladies' spinal appliances on p. 80 of the "Catalogue of Owen Electric Belt and Appliances," The Dr. A Owen Electric Belt and Appliance Company, 1892, Bakken Library Collection.

pains. "Electric-magnetic" rings and pendants,[110] often consisting of nothing more than alternating metals—supposedly activated when in direct contact with skin—were sold to a willing public, as were electro-massage machines.[111]

Electric belts (**Fig. 5.4**) were one of the most popular consumer electrotherapeutic devices.[112] European inventor J. L. Pulvermacher is credited with introducing the belts to the American market for the first time in 1875,[113] though he had described early prototypes, galvanic chains, in the 1850s in Europe.[114] The chains were based on the principles of the voltaic pile: each link was comprised of alternating copper and zinc wires wrapped around wooden dowels, and when the chain was soaked in a acidic fluid such as vinegar, a small (direct) electric current was generated.[115] The J. L. Pulvermacher company, which continued doing business in both Europe and the US even after the death of its founder in 1884,[116] initially sold all kinds of galvanic chains but later moved to belts, which were made of cloth and contained a small pouch to hold the galvanic chain. Subsequent versions of electric belts—both by Pulvermacher and other manufacturers—utilized dry cell batteries, thus eliminating the need to soak the chains in

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[110] Dr. Bridgman's Electro-Magnetic Ring, *Scribner's*, December 1892, reprinted in Waits, *Medical Electricians*, 288; also see advertisement for Electro-Chemical Ring (Toledo, Ohio), undated, Bakken Ephemera Collection. For pendants, see, e.g., advertisement for the London Galvanic Generator, *Harper's Weekly*, October 30, 1880, reprinted and discussed in *Medical Electricians*, 65.

[111] See, e.g., "Dr. John Butler's Electro-Massage Machine (or Electric Manipulator) for Curing Disease at Home," ca. 1889, Bakken Library Collection.

[112] For more on electric belts, see de la Peña, *Body Electric*, 108-121; Waits, *Medical Electricians*; Kneeland and Warren, *Pushbutton Psychiatry*, 39-40; Carolyn Thomas de la Peña, "Designing the Electric Body: Sexuality, Masculinity and the Electric Belt in America, 1880-1920," *Journal of Design History* (2001):275-289.

[113] de la Peña, *Body Electric*, 110.

[114] Waits, *Medical Electricians*, 47; Rowbottom and Susskind, *Electricity and Medicine,* 64.

[115] Waits, *Medical Electricians*, 48; de la Peña, *Body Electric*, 110; Rowbottom and Susskind, *Electricity and Medicine,* 64-68.

[116] Waits, *Medical Electricians*, 46-54.

vinegar before use. Some later belts even had the capability of inducing an alternating current,[117] which would create a more distinct "shocking" sensation than the direct current (which would have felt more like a light tingling, if at all perceptible).

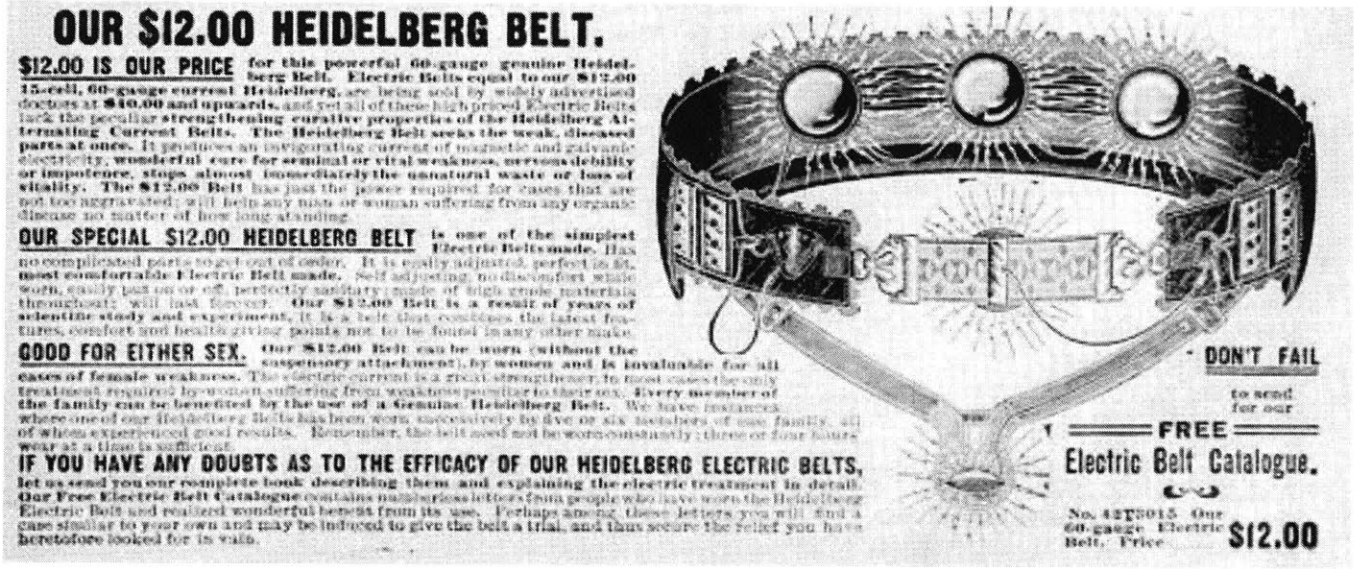


Figure 5.4. A $12 electric belt in the 1902 Sears, Roebuck & Co catalogue.

Advertisements for electric belts often featured illustrations of naked women and men wearing belts, with bolts of lightning sometimes emanating from their bodies. Low-end electric belts sold for a few dollars, but deluxe models, which provided more current, could cost as much as $75 (nearly $2,000 in today's dollars).[118] More common was the $10-20 price range, though manufacturers often had several different models at varying price points: for example, the 1902

[117] Catalogue No. 112, Sears, Roebuck & Co, 1902, 472, digital archive accessed on January 8, 2016, https://archive.org/stream/catalogueno11200sear#page/472/mode/2up. The alternating current was induced via an interrupter that would effectively "pulse" the direct current, thereby inducing alternating current in a second coil.

[118] Dollar values estimated according to the "Consumer Price Index (Estimate) 1800-," Federal Reserve Bank of Minneapolis, accessed January 8, 2016, https://www.minneapolisfed.org/community/teaching-aids/cpi-calculator-information/consumer-price-index-1800. The $75 belt was Dr. McLaughlin's Invigorator, Bakken Artifact Collection.

Sears catalogue featured three different models of the Heidelberg belt ($4, $12, and $18).[119] While some companies sold electric belts through mail order catalogues, others circulated pamphlets that functioned as all-in-one advertisements, instructional guides, and product catalogues.[120] If an individual expressed interest, via mail, in an electric belt, manufacturers would go to great lengths to make a sale, sending lengthy follow-up letters for months[121] and even years after an initial expression of interest.[122] Belts were also sold via local agents through door-to-door sales.[123]

The J. L. Pulvermacher Company advertised its belts as being "self-applicable, for the cure of nervous and chronic diseases without medicine."[124] Other companies, too, marketed their belts as cure-alls, though some belts, particularly those marketed to men, insinuated that the products were effective at treating sexual dysfunction (many belts came with a "suspensory" attachment). Today, the surviving electric belt advertisements—mostly newspaper ads and pamphlets printed in black and white—belie the belts' colorful and flashy appearance. They were often made of satin-like fabric in bold colors—rich hues of blue, maroon, red, and white—suggesting that they were not intended to be worn inconspicuously beneath one's clothes, but rather, like a luxurious robe, to be donned in the privacy of one's home. A listing for the

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[119] Catalogue No. 112, Sears, Roebuck & Co, 1902, 471-472, digital archive accessed on January 8, 2016, https://archive.org/stream/catalogueno11200sear#page/470/mode/2up

[120] The Bakken Library Collection contains many such pamphlets, such as those from the German Electric Agency, The Owen Electric Belt and Appliance Company, Pulvermacher's Electric Belts and others.

[121] For example, Dr. McLaughlin to Mr. G. O. Gjevre, 24 Jan and 18 May 1906, Bakken Ephemera Collection.

[122] E. M. Crump to Electra-Vita, 15 June 1911; and the Electra-Vita Co to E.M. Crump, 16 and 26 June 1911, 3 and 24 July 1911, 24 Aug 1911, 18 May 1912, and 2 Feb 1914. American Medical Association, Health Fraud Archives, Box 0230-03.

[123] de la Peña, *Body Electric*, 111.

[124] "Electricity - Nature's Chief Restorer," Pulvermacher Galvanic Co, 1882, Bakken Ephemera Collection.

Heidelberg belt in the 1902 Sears catalogue recommended that individuals wear it for three or four hours a day.[125]

Although sales figures for electric belts are difficult to come by, the number of manufacturers—and the multiple editions of pamphlets they published—suggests that the belts were a popular item for many decades.[126] Electric belts continued to be sold well into the 1910s, but declined in the 1920s.[127] However, for the most part, the belts were not sold in medical catalogues directed to physicians. The one exception was the McIntosh Company, a highly regarded manufacturer of electrotherapeutic equipment. An electric belt appeared in the company's 1879, 1881 and 1885 catalogues,[128] and it was offered in the catalogues of retailers who sold medical and surgical equipment as late as 1891 and 1893.[129] However, the company clearly felt the need to distinguish its product from other electric belts on the market. The copy accompanying the belt in one catalogue stated: "We do not offer the McIntosh Electric Belt as in any sense a 'cure-all.' Neither do we offer it in competition with the so-called 'cheap' electric belts with which the market is flooded."[130]

Indeed, the mainstream medical profession often dismissed electric belts and other consumer electrical products as "quackery," and those who sold them as "quacks" or

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[125] The text accompanying the $12 Heidelberg belt in the 1902 Sears catalogue states: "Remember, the belt need not be worn constantly; three or four hours' wear at a time is sufficient." Catalogue No. 112, Sears, Roebuck & Co, 1902, 471, digital archive accessed on January 8, 2016, https://archive.org/stream/catalogueno11200sear#page/470/mode/2up

[126] For example, the New York-based German Electric Agency published multiple versions of its pamphlets over the years; the Bakken Library Collection has five from 1889-1901.

[127] de la Peña, *Body Electric*, 111.

[128] *Illustrated Catalogue of McIntosh Combined Galvanic and Faradic Battery.* (McIntosh Galvanic and Faradic Battery Co., 1881 and 1885), Bakken Library Collection, and Currier, *Guide to Electrotherapy Instruments*, 274.

[129] Currier, *Guide to Electrotherapy Instruments*, 218.

[130] *General catalogue*, (St Paul: Noyes Brothers & Cutler, 1891), Bakken Library Collection.

"charlatans." Belts are largely absent from medical guides on electrical treatment, though the McIntosh belt did have at least one advocate in the mainstream medical profession: Dr. Solomon Solis Cohen, who in *A System of Physiologic Therapeutics: Electrotherapy* discussed the belt's usefulness. He was careful to distinguish the McIntosh belt from "the majority of belts" which had "merely a suggestive value."[131] It is worth noting that electric belts—which often did reliably provide a current—were considered a step above the electric brushes and garments, which often contained nothing more than steel inserts. But overall, electrical devices that were marketed directly to consumers for therapeutic purposes were never sanctioned by regular medical practitioners.[132]

III. The medical battery (1870-1920)

Compared to the colorful electric belts, the medical battery—which came encased in a variety of nondescript oak, mahogany, walnut, and cherry wood boxes—was rather understated in appearance (**Fig 5.1**). The smallest "pocket" medical batteries were the size of a thick paperback book; larger apparatuses, mostly sold to physicians, were the size and weight of a modern-day toolbox. Though the medical battery shares roughly the same historical timeline as

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[131] Solomon Solis Cohen, *A System of Physiologic Therapeutics: Electrotherapy* (Philadelphia: P. Blakiston's Son & Co, 1901), 146-147.

[132] According to Dr. Homer Clark Bennett, "The ordinary so-called electric belt is a fake pure and simple, made to sell, and then to disintegrate." *The Electro-Therapeutic Guide: Or, A Thousand Questions Asked and Answered*, 9th ed. (Lima, Ohio: Literary Department of the National College of Electro-therapeutics, 1912), 143. It wasn't just physicians who deemed the belts to be fake: in 1893 the editors of *Electricity* wrote: "... we assert that these electric belts, electric hair-brushes, electric headache cures, electric light baths etc., etc., are unqualified frauds upon the public... They are frauds, or else the therapeutical and electrical authorities are all wrong." *Electricity*, 16 August 1893, p 52. See Waits, *Medical Electricians*, 207-208, for further discussion.

the electric belt, it differs from it and other consumer electrical products in one major respect: it was the one device that was legitimized, or sanctioned, by medical professionals. For nearly five decades—from the 1870s into the late 1910s—the medical battery was simultaneously used by regular physicians, irregular practitioners, and consumers.

Although the medical battery took off in earnest in the 1880s and 1890s, there were earlier precedents for the devices. For example, from the mid-1850s to the 1870s, there were a variety of "electro-magnetic" machines sold directly to consumers. These devices—which built off the principles that Faraday had discovered in 1831— featured hand cranks that rotated magnets around coils to produce current.[133] The strength of the current was determined by the speed at which the crank was turned, and an individual grasping the hand-held electrodes connected to the machine would feel a shock. One of the most popular was Davis and Kidder's Magneto Electric Machine for "nervous diseases" (**Fig. 5.5**).[134]

The first true medical batteries, however, used wet-cell batteries—instead of hand cranks—to induce current. The design of the machine was conceptually similar to the experimental setup that Faraday used when he discovered the principles of induction: a battery was connected to a wire that was wrapped an iron core, and a second wire—not connected to the battery or the first wire—was also wrapped the iron core. When the battery was turned on, a direct current was produced in the first wire, thereby magnetizing the iron core. In the mid-1830s and onward, a variety of methods to rapidly "pulse" the direct current were developed; the pulsed

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[133] Currier, *Guide to Electrotherapy Instruments,* 4, and Dean P. Currier, "A Biographical History of Induction Coils," published on the online website "Quackatorium" in 2001, archived version accessed on December 16, 2015 https://web.archive.org/web/20030817194513/http://www.radiantslab.com/quackmed/Deanbio.html.

[134] Robert Greenspan, *Medicine: Perspectives in History and Art* (Alexandria, Va: Ponteverde Press, 2006), 525.

current caused rapid changes in the magnetic flux of the iron core, thereby inducing an alternating current in the second wire.[135] Most medical batteries—which it should be emphasized, refer not just to the physical battery itself but the entire apparatus—allowed a user to receive the primary or direct galvanic current (which came in pulses); the secondary or faradic current; or a combination of both. (Even though most batteries provided both direct and alternating current, they were sometimes referred to as "faradic batteries.") By connecting a variety of electrode attachments to the battery, it was thought that current could be passed through parts of the body and cure a whole host of diseases.

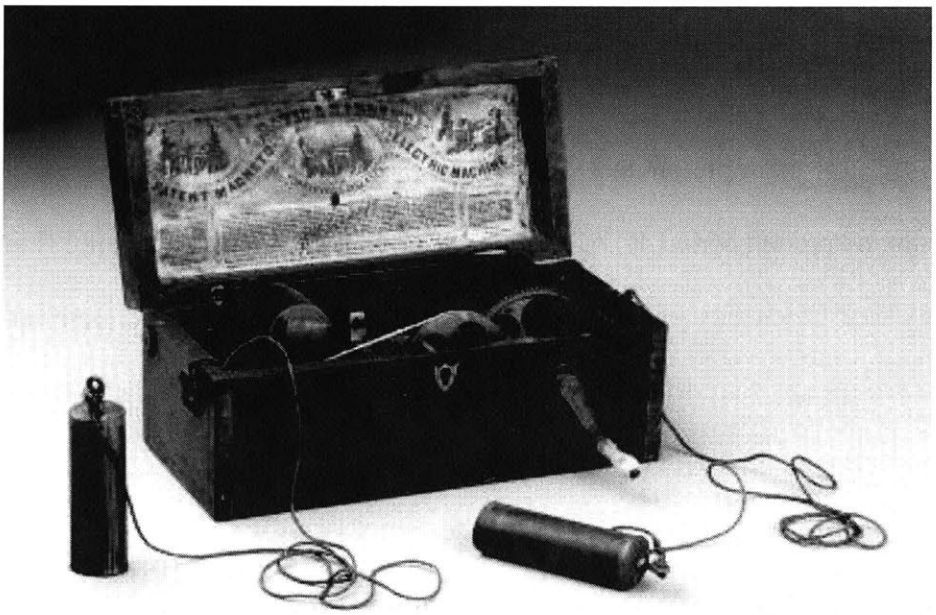


Figure 5.5. Davis and Kidder's Magneto Electric Machine (ca. 1854), a precursor to the medical battery. Courtesy of the New York Historical Society.

[135] These automatic current interrupters were known as rheotomes. See Currier, *Guide to Electrotherapy Instruments,* 20-21, for diagrams and description of how they worked.

The early medical batteries of the 1850s and 1860s were made by individual instrument makers, largely in Boston and New York.[136] They were used by a handful of regular practitioners, such as George Beard and A. D. Rockwell, who co-authored an 1867 book on the medical uses of electricity.[137] Though several other works on electrical medicine were published in America in the 1850s and 1860s, their work, which in later editions was entitled *A Practical Treatise on the Medical and Surgical Uses of Electricity*, became the standard reference for physicians interested in electrical treatment.[138] The authors advocated the use of electrical current to treat neuralgia, rheumatism, dyspepsia, chorea, paralysis and other diseases. According to some historians, the publication of Beard and Rockwell's book marked "the legitimation of electricity in treating mental illness in America."[139]

Electrical medicine was equally embraced by irregular practitioners, particularly female homeopathic doctors.[140] For example, in an 1850 ad from the *Lincoln Democrat*, an "Electropathic physician" named Mrs. J.R. Albee advertised that she had a "Galvanic Battery for the medical application of Electricity" which "restores vitality to the system, and many obstinate cases of disease that would not yield to the medicine of the most skillful Physicians, have been overcome and perfectly cured."[141] In undated trade card that is likely from the same time period,

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[136] Currier, *Guide to Electrotherapy Instruments,* 30-63.

[137] The first edition was Beard, George Miller, and A. D. Rockwell. *Medical Use of Electricity; with Special Reference to General Electrization as a Tonic in Neuralgia, Rheumatism, Dyspepsia, Chorea, Paralysis, and Other Affections Associated with General Debility. With Illustrative Cases.* New York: Wood, 1867.

[138] By the ninth edition, which was over 600 pages long, Rockwell had dropped Beard's name as a co-author (Beard had passed away in 1883). A.D. Rockwell, *The Medical and Surgical Uses of Electricity.* (New York : William Wood and Company, 1896).

[139] Kneeland and Warren, *Pushbutton Psychiatry,* 28.

[140] For a discussion of gender in early electrotherapy, see Kneeland and Warren, *Pushbutton Psychiatry*, 27-28.

[141] Ad for Mrs. J. R. Albee, *Lincoln Democrat*, Newcastle Maine, December 25, 1850, Bakken Ephemera Collection.

Mrs. D. Norwood, a "Medical Clairvoyant" based in South Easton, Pennsylvania, advertised that she treated diseases "by Electric Battery."[142]

Emma Hardinge Britton, a self-described spiritualist and clairvoyant, offered electrical treatments in her Boston office for $3 and home treatments for $5.[143] She also wrote *The Electric Physician, or, Self Cure Through Electricity* (1875), a guide for electrical treatments for everything from liver complaints to paralysis to constipation.[144] Her husband, William Britton, manufactured an early version of a home medical battery. An ad for his battery appears in final pages of his wife's book, where it was advertised as alternative to regular medicine: "any family can possess themselves of an universal and unfailing source of health, and forever dispense with drugs and medical attendance."[145]

Electrical treatments at this time were also commonly provided in conjunction with massage services.[146] Virginia K. Orvis of Williamsport, Pennsylvania, provided both spa treatments—turkish bath, wet shampoo, massage, manicure—and a host of electrical treatments, such as a "dry electrical shampoo," "local electrical treatments," and "general galvanic or faradic treatment, with massage."[147]

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[142] Undated trade card for Mrs. D. Norwood, Medical Clairvoyant, Bakken Ephemera Collection.

[143] Emma Hardinge Britten, *The Electric Physician, Or, Self Cure through Electricity : A Plain Guide to the Use of Electricity, with Accurate Directions for the Treatment and Cure of Various Diseases, Chronic and Acute* (Boston : W. Britten, 1875), http://archive.org/details/electricphysicia00brit.

[144] Ibid.

[145] Ibid.

[146] This was also the case in Europe. For example, the Grand Hotel Lido in Venice, Italy, had a "Hydro Electrotherapeutical Establishment" that provided baths, massages, and electric cures. "Lido-Venice Hydro Electrotherapeutical Establishment," undated, Bakken Ephemera Collection.

[147] Undated trade card for Virginia K. Orvis, Medical Electrician, Bakken Ephemera Collection.

Up until the early 1890s, most medical batteries were of the wet-cell variety, which like the voltaic pile, required the addition of a conductive fluid. By the early 1890s, medical batteries began to use dry cells that consisted of a paste rather than a wet solution—which made them much more attractive to consumers, as there was less of a possibility of spilling or corrosion.

Although the medical battery came to prominence concomitantly with electric belts and other consumer electrotherapy products, it seems to have dwarfed them in at least some measures of popularity. While sales figure are largely nonexistent, in the course of my research on trade catalogues at the Bakken Museum (in Minneapolis, MN), digitized versions of the magazine *Electrical World* and *American Electrician,* and secondary literature on electrotherapeutics, I counted roughly two dozen electric belt manufacturers in the US in the late nineteenth and early twentieth century.[148] By comparison, using similar same measures, I counted over 150 companies that sold their own brand of medical battery in the United States between 1870 and 1920, as well as over a hundred additional retailers that distributed these brands. Although these measures are skewed towards museum collecting and journal digitization practices—and absent sales records it is impossible to reach any definitive conclusions—they suggest that there was far more demand for the medical battery than for the electric belt. Indeed, this is not surprising, as the medical battery effectively had two markets—physicians and consumers—whereas electric belts were purchased almost exclusively by consumers.

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[148] This figure is my own conservative estimate, based on both primary sources (Bakken Library, Ephemera, and Artifact Collections; American Medical Association's Historical Health Fraud Archives) and digital archival research, as well as secondary sources (de la Peña, *Body Electric*, 108-120; Waits, *Medical Electricians*, 203-21; Dean P. Currier, "Components of the Electrical Belt," Quackatorium, accessed December 26, 2015, https://web.archive.org/web/20030819021239/http://www.radiantslab.com/quackmed/deanbeltcomp.html); and Currier, *Guide to Electrotherapy Instruments*.

IV. Medical batteries for physicians

From 1870 to 1920, there were approximately a dozen companies that sold their own brand of high-end medical batteries for physicians, primarily located in New York, Chicago, Philadelphia, and Baltimore. These companies sold electromedical products through secondary retailers for surgical and medical supplies, as well as directly to physicians via illustrated catalogues.[149] The catalogues became a source of reference for physicians, as they often contained a brief history of the use of electricity in medicine, an overview of its present-day uses, and a glossary of terms.[150] The final pages of catalogues were often devoted to fawning testimonials from physicians. From the catalogues, physicians could learn about the different tools available for treatment, and details such as which electrode was most appropriate for use on which part of the body.[151] Physicians interested in learning about electrical treatment could also turn to one of the dozens of books on the practice of electrotherapeutics.

The medical literature published at the time referenced two main techniques of applying current. In "general" faradization or galvanization, one electrode was placed beneath the patient's feet (although sometimes both the patients' feet and the electrode were submerged in water) while the second electrode was rubbed over the body, either by the patient or physician. (Central galvanization, depicted in **Fig. 5.6**, was a variation in which the stable electrode was

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[149] "General catalogue - Noyes Brothers & Cutler, Importers and wholesale dealers in drugs" (St Paul: Noyes Brothers & Cutler, 1891), Bakken Library Collection.

[150] See, e.g., "Illustrated Catalogue of McIntosh Combined Galvanic and Faradic Battery." (McIntosh Galvanic and Faradic Battery Co., 1881), http://archive.org/details/IllustratedCatalogueOfMcintoshCombinedGalvanicAndFaradicBattery; also see Currier, *Guide to Electrotherapy Instruments*, 213.

[151] For more on how physicians (albeit in Britain) utilized medical trade catalogues in the late nineteenth and early twentieth century, see Claire L. Jones, "(Re-)Reading Medical Trade Catalogs: The Uses of Professional Advertising in British Medical Practice, 1870–1914," *Bulletin of the History of Medicine* 86, no. 3 (2012): 361–93, doi:10.1353/bhm.2012.0056.

placed above the stomach instead of beneath the feet.)[152] General faradization or galvanization was thought to target the body as a whole, and was often recommended as a treatment when an illness was systemic in nature. By contrast, "local" faradization or galvanization was advised when a pain or illness was situated in a particular part of the body. For example, for constipation, electricity was applied to the bowels, for sunstroke and fevers, it was applied to head; and for ovarian tumors, it was applied to the ovaries. Though the specific type of electrode placements varied across diseases (and according to different physicians), in "local" applications, both electrodes were usually stationary.[153]

Current was generally not recommended for more than 10-20 minutes for general applications, and several minutes for local applications. Treatment was prescribed several times a week, or even daily. Though caution was frequently urged when applying electricity near the head, there was no particular focus on brain-based applications; the brain was viewed as an organ like any other. Overall, electrical treatments were deeply rooted in somaticism—that is, current was applied to whatever part of the body was ailing—and it was believed that electricity could "loosen" any unhealthy blockages and promote circulation.[154]

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[152] A.D. Rockwell, *The Medical and Surgical Uses of Electricity.* (New York : William Wood and Company, 1896), 236-237.

[153] Batteries that provided just galvanic (direct) and not faradic (alternating) current were sold to home consumers, but to a lesser extent. Many batteries that offered purely galvanic current were marketed for hair removal purposes. See Rebecca Herzig, "Subjected to the Current: Batteries, Bodies, and the Early History of Electrification in the United States," *Journal of Social History* 41, no. 4 (2008): 867–85, doi:10.1353/jsh.0.0013.

[154] John Greenway, "'Nervous Disease' and Electric Medicine." In *Pseudo-Science and Society in Nineteenth-Century America*, edited by Arthur Wrobel, (Lexington, KY: University Press of Kentucky, 1987), 52-55.

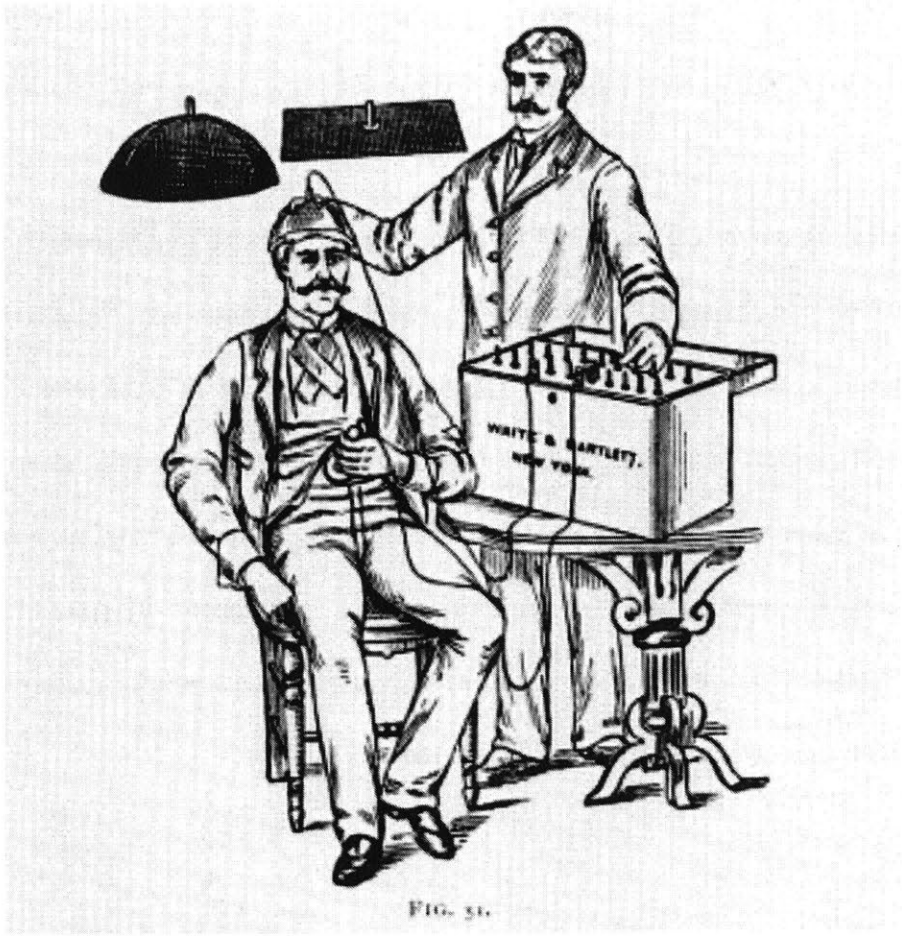


Figure 5.6. Central galvanization, as depicted in A. D. Rockwell's *The Medical and Surgical Uses of Electricity* (ninth edition, 1896).

The names of prominent electromedical instrument manufacturers appeared frequently in medical journals and in electrotherapy guides written by "regular" physicians. For example, in *Practical Electro-Therapeutics* (1888), Dr. William Hutchinson noted that the "best American instruments" were made by companies such as Flemming and McIntosh.[155] In *Clinical Therapeutics* (1885), Dr. C. L. Dana wrote that "Good faradic batteries are now made by a great many firms," such as Kidder, the Galvano-Faradic company, Waite & Bartlett, Stammers,

[155] See e.g., William Francis Hutchinson, *Practical Electro-Therapeutics* (Philadelphia: Records, McMullin & Co, 1888), 26.

Flemming, and McIntosh.[156] Physicians also recommended specific parts made by the companies, for example, by mentioning that they liked a certain brand of neck electrode[157] or voltmeter.[158]

The medical battery was just one of the items offered for sale in electrotherapeutic catalogues. The Waite and Bartlett catalogue from 1895, for example, featured a handful of static electricity machines, as well as several "wall cabinet" batteries (**Fig. 5.7**) for physician's offices, which cost $200-260 (approximately $5,000-7,000 in 2016 dollars) and could be ordered in oak or mahogany.[159] The catalogue offered eight different medical batteries, ranging in price from $10-66. In addition, Waite and Bartlett sold approximately one hundred different electrode attachments for their devices: including many that were specially shaped for different parts of the body (e.g., nasal, ear, rectal, and intra-uterine electrodes).

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[156] Dujardin-Beaumetz, *Clinical Therapeutics*, trans. E. P. Hurd (Detroit: G.S. Davis, 1885), 46. Note that this is an English translation of a French work, with certain parts replaced to suit American physicians. See p. 42, noting that the ensuing section is written by Dr. C. L. Dana.

[157] Hutchinson, *Practical Electro-Therapeutics*, 197.

[158] George W. Jacoby, *A System of Physiologic Therapeutics: Electrotherapy*, ed. Solomon Solis Cohen (Philadelphia: P. Blakistan's Son & Co, 1901), 162.

[159] "Illustrated Price List, Electro-Medical and Electro-Surgical Instruments," (New York: Waite & Bartlett Mfg Co, 1895-1896), accessed June 2, 2016, http://archive.org/details/illustratedprice00wait.

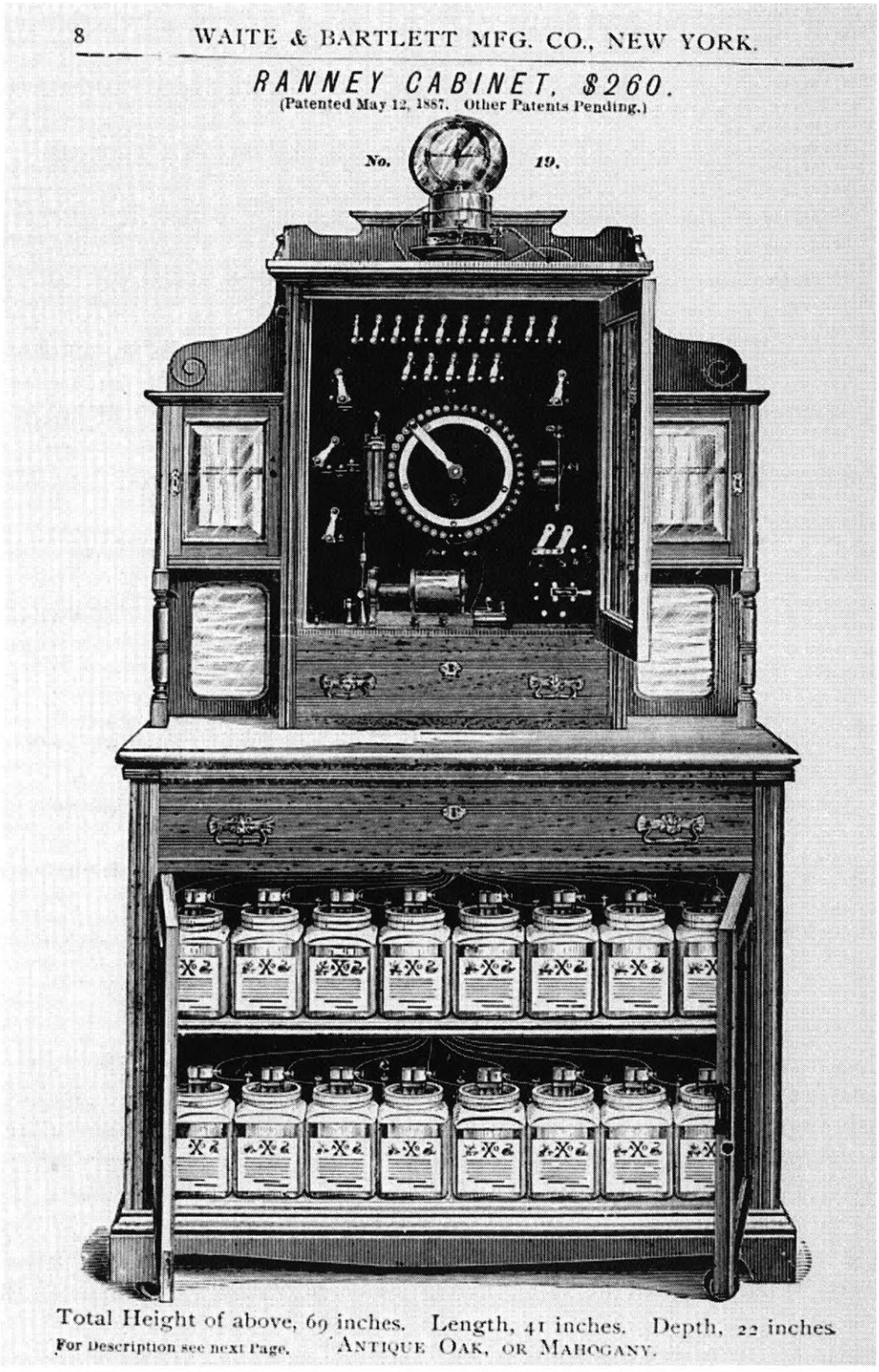


Figure 5.7. Physicians' wall cabinet battery from the 1895-1896 Waite & Bartlett catalogue.

Prominent electromedical instrument manufacturers such as Waite and Bartlett interacted closely with regular physicians as well as with professional organizations such as the American Electrotherapeutic Association (AEA).[160] They frequently attended the AEA's annual conferences, where they set up booths to display their latest wares.[161] In turn, the AEA created committees to test and review electrotherapeutic devices (such as medical batteries) and their components. Prior to each "test," companies with credibility in the eyes of the committees were invited to submit their products for review. For example, at the AEA's seventh annual meeting in 1897, the Committee on Meters reported on its recent test of several voltmeters (from Weston, Edison, Vetter, Chloride of Silver, Kidder, McIntosh, and Keystone).[162] Members from each company traveled to New York to be physically present for the test—presumably placing enough value on the outcome to make the trip.[163]

The relationship between the major electromedical instrument manufacturers and regular physicians was characterized by mutual dependence, similar to the symbiotic relationships Claire Jones has described between physicians and medical instrument manufacturers in the British context in the late nineteenth century.[164] Manufacturers relied on physicians for sales, and would

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[160] The American Electrotherapeutic Association (AEA) was created in 1891 with the aim of separating regular uses of electricity from that of quackery. As later AEA president Dr. Charles Rea Dickson put it, "[i]t was felt, and felt strongly, that electricity had been left too long to the charlatan, the incompetent, and the unscrupulous." "Eighth Annual Meeting of the American Electro-Therapeutic Association," *Electrical Engineer* 26, no. 54 (October 6, 1898): 347.

[161] For the record of presenters at the fourth annual meeting of the AEA, see Samuel Howard Monell, "An Electrical Exhibit," *The Medical Times and Register*, October 13, 1894, 237.

[162] American Electrotherapeutic Association, *Transactions of the American Electro-Therapeutic Association*, 10-27, accessed January 9, 2016, http://babel.hathitrust.org/cgi/pt?id=mdp.39015062239382

[163] Ibid.

[164] Claire L. Jones, *The Medical Trade Catalogue in Britain, 1870–1914* (Routledge, 2015).

sometimes appeal to the AEA, for example, by requesting that it select a standardized measurement for a particular component.[165] In turn, physicians depended on the manufacturers to make high quality products, and sometimes called on manufacturers to incorporate specific design features. Though I found no records of physicians being compensated for recommending specific brands, there are occasional mentions of physicians being sent components by manufacturers, presumably without cost.[166]

To a large extent, physician-oriented companies adhered to the ethics of the medical profession: they did not advertise their wares in popular outlets, relying instead on illustrated catalogues that were distributed to the medical profession. Descriptions of the medical battery and other electromedical products in these catalogues were dry, and focused on the technical aspects of the product: dimensions, weight, number of battery cells, and price. Whereas advertisements for consumer electrotherapy products were often accompanied by an illustration of an individual using the device, illustrations in medical device catalogues consisted of simple depictions of the products themselves.

V. Medical batteries for consumers

In contrast to electromedical instrument manufacturers, consumer-oriented companies frequently advertised their medical batteries in general interest magazines like *McBrides's* and *Popular Mechanics* as well as in local newspapers. The majority of consumer-oriented medical battery retailers were electrical supply and novelty companies that sold medical batteries

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[165] American Electrotherapeutic Association, *Transactions of the American Electro-Therapeutic Association* (Toronto: William Briggs, Wesley Buildings, 1897), 28, accessed January 9, 2016, http://babel.hathitrust.org/cgi/pt?id=mdp.39015062239382

[166] Hutchinson, *Practical Electro-Therapeutics*, 201.

alongside products such as motors, fans, burglar alarms, bells, electric neckties, and telegraph supplies. Unlike electromedical instrument manufacturers, who sold medical batteries with names like "No. 4 Office Battery" or the "No. 2 Battery," consumer-oriented companies often gave their batteries enticing names, such as "Home Comfort," "Solace" or "Relief."[167] Consumers could buy these medical batteries in their local general stores and drugstores, and many were available through mail order catalogues. The names of companies who sold medical batteries primarily to consumers do not appear in the pages of electrotherapeutic texts or records of the AEA's annual meetings.

For the home consumer, the faradic current was undoubtedly the most popular type of current; in fact, the term "faradic battery" was nearly synonymous with "medical battery" in the 1880s and 1890s, even though most medical batteries provided both galvanic and faradic current. Some pamphlets noted that the galvanic (primary) current should only be used in special cases by a physician.[168] It is not clear why the galvanic current took a backseat role to the faradic current for consumers (especially as it would have been more far comfortable to utilize). Although the answer may never be known, it is possible to speculate that the more salient physical sensations caused by the faradic current created a greater perception of effectiveness.

The medical batteries sold by consumer-oriented companies were often similar in price, or slightly cheaper, than the low-end models sold by electromedical instrument manufacturers: many fell in the $4-8 range, though top-of-the-line models could sell for as much as $12,[169] and rock-bottom medical induction coils—such as the Dunn-Martin Electric Company's "shocko"—

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[167] "Faradic Hints: the Faradic Current in the Treatment of Disease," Voltamp Electric Mfg Co (Baltimore, 1904), 18, Bakken Library Collection.

[168] See "Complete Guide for Domestic Treatment by Electricity: Explaining the Best Treatments in Plain Language for the Cure of Disease by Electricity." (Philadelphia: G.P. Pilling & Son, 1905), Bakken Library Collection.

[169] Currier, *Guide to Electrotherapy Instruments*, 458.

sold for just $1 (**Fig. 5.8**). Some electrical companies, like the Manhattan Electrical Supply Co, sold a variety of models of medical batteries for many years, whereas for others, the medical battery was a short-lived endeavor en route to a larger business in automobile or telephone products. The *Electrical World*, an electricity-related trade magazine, kept tabs on commercial activity in the electrical industry, reporting on the formations and closures of companies, product innovations, patents, and electrical fairs and exhibitions.



Figure 5.8. The $1 "shocko" medical battery from the Dunn-Martin Electric Co.

Outside of electrical supply and novelty companies, another class of consumer-oriented companies—often those who also sold electric belts and garments—sold medical batteries that were frequently billed as "cure-alls."[170] For example, in a 1907 ad in *Popular Mechanics*, the Detroit Medical Battery Company claimed that its medical battery cured "Rheumatism, Neuralgia, Constipation, Nervousness, Headache, Stomach Trouble or any other disease" (**Fig**

[170] "Electricity, when applied by an Automatic Medical Battery, will cure rheumatism," The Automatic Battery Co., *McBride's Magazine* 42, (1888), 54.

5.9).[171] The price range of these medical batteries was similar to those sold by electric companies (approximately $1-12). Free trials and money-back guarantees were just some of the gimmicks used to hook potential customers.

Some consumer-oriented companies explicitly positioned themselves in opposition to the medical profession, portraying the medical battery as an effective alternative to a pricey, time-consuming visit to the doctor. A catalogue from the German Electric Agency, which briefly sold a brand of P. G. Williams batteries, stated that it was their "aim to place in the hands of the public a battery with which they can cure themselves with little expense and without loss of time."[172] The Manhattan Electrical Supply Co even incorporated the anti-medical-establishment theme into the name of one its medical batteries, the "Anti-Doc Medical Apparatus." The company advertised the product heavily for at least seven years, noting that it cost "less than one application [of electricity] by your doctor."[173]

Though companies who sold medical batteries with cure-all claims and money-back guarantees could be dismissed as quacks, the medical battery itself, which was considered a legitimate therapeutic tool, was largely immune from such criticism. Rather than assailing the legitimacy of consumer medical batteries or their underlying therapeutic potential, medical practitioners criticized their *quality*. Dr. William Hutchinson wrote that the "numerous small induction machines in the market" were "valuable only as toys," and cautioned physicians to "let

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[171] This same advertisement for Detroit Medical Battery ran for several years (1906-1908) in *Popular Mechanics*. For sample see "Cure Yourself by Electricity," *Popular Mechanics* 9, no. 5 (1907), 591.

[172] "German Electric Belts and Appliances," (New York: German Electrical Agency, ca. 1901), 25. Bakken Library Collection.

[173] "Anti-Doc Medical Apparatus," Manhattan Electrical Supply Co, *The Railroad Telegrapher* 24 Part 2 (1907), 2154.

such playthings alone."[174] In the speech quoted at the start of this chapter, A. D. Rockwell criticized the plethora of batteries as being "of the most inexpensive and worthless construction."[175] Thus, in contrast to electric belts and brushes, which were considered to be quackery, the medical battery sold to consumers was instead portrayed as a cheap knock-off of a legitimate product.



Figure 5.9. Advertisement for the Detroit Medical Battery in the May 1907 issue of Popular Mechanics.

[174] Hutchinson, *Practical Electro-Therapeutics*, 16-17.

[175] A. D. Rockwell, "The Uses and Abuses of Electricity in Medicine," *Journal of the American Medical Association* 20, no. 3 (January 21, 1893), 73.

VI. Blurred Boundaries

It was not always easy to distinguish between a consumer and physician battery: the products were nearly identical, and some companies marketed *both* to physicians and consumers. For example, Herman C. Tafel, of Louisville, Kentucky, sold electrical instruments to consumers as well as medical and surgical supplies to physicians.[176] Some companies, such as the B. B. Bliss Electric Co., sold a consumer medical battery, yet advertised in medical journals.[177] Even the Jerome Kidder Manufacturing Company, one of the most reputable manufacturers of high-quality batteries for the medical profession, occasionally took out ads in consumer publications advertising that its product "conquered" disease.[178]

That some companies marketed medical batteries simultaneously to physicians and consumers is somewhat surprising, as it was far more common, both in the US and in Britain, for companies to align themselves with a single market.[179] Although in the late nineteenth and early twentieth century some British companies published catalogues of health products that were marketed both to physicians and consumers, the catalogues did not contain electromedical devices; instead they featured "sundries" like hot water bottles, belts, and hernia trusses, and were for the most part not marketed to treat disease.[180] In contrast, American companies who

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[176] James M. Edmonson, *American Surgical Instruments: The History of Their Manufacture and a Directory of Instrument Makers to 1900* (San Francisco: Norman Publishing, 1997), 193.

[177] "Doctor's Favorite: The Best Dry Cell Battery in the World," B. B. Bliss Elec. Co., *New Charlotte Medical Journal* 5 (1894), 98.

[178] Dr. Jerome Kidder's Electro-Medical Apparatuses, Jerome Kidder Manufacturing Co, *Electrical World* 2, December 1, 1883, 258.

[179] Claire L. Jones, *The Medical Trade Catalogue*, 54-57.

[180] According to historian Claire Jones, "a small number of catalogues produced in Britain between 1870 and 1914 promoted medical sundries as aids to health aimed at both doctors and their patients. Few of these catalogues contained products to directly treat an ailment

sold medical batteries to both physicians and consumers marketed their products with the implication, if not outright specification, of treating disease. The medical battery, then, occupied a unique space on the medical marketplace—while other electrotherapy products were sold only to physicians (e.g., wall cabinet batteries) or consumers (e.g., electric belts and brushes), the medical battery flourished for nearly 50 years in both the home and clinic.

In some ways, physicians who dabbled in electrotherapy became the beneficiaries of the rising consumerism, as the medical batteries sold to consumers were essentially the same as those sold to physicians—only cheaper. For example, the German Electric Agency, a well-known electric belt manufacturer, claimed that its line of P. G. Williams medical batteries were "first-class machines in every respect, equal to machines that formerly sold for $25 or $30. We offer them to the public at prices ranging from $3.50 to $12."[181] Such models would have been appealing to physicians who were interested in trying electrotherapeutics without making a sizable financial investment.

Although it is impossible to determine the extent to which physicians purchased consumer medical batteries, the criticism that emerged from some prominent physicians suggests that the practice was not uncommon. For example, Dr. Samuel Monell, a founder and chief instructor at the New York School of Special Electro-Therapeutics,[182] denounced the "honest but untaught" physicians who purchased such batteries and used them in "ignorance," for they were erroneously "attributing to mere toy devices the efficiency of costly scientific apparatus."[183] Then, when the medical battery failed to work, physicians (and patients) blamed electricity

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or cure a medical condition and no surgical or dental instruments or electro-medical apparatus were included in the product range." Claire L. Jones, *The Medical Trade Catalogue*, 54.

[181] "German Electric Belts and Appliances," (New York: German Electrical Agency, ca. 1901), 25. Bakken Library Collection.

[182] Samuel Howard Monell, *High Frequency Electric Currents*, title page.

[183] Ibid., 129.

"instead of the inferior apparatus."[184] Similarly, Dr. William Hutchinson felt that cheap medical batteries, and the untrained physicians who used them, were one of main reasons why electrotherapeutics had not achieved widespread acceptance amongst the medical profession at-large.[185] Both physicians attempted to draw boundaries between physician and consumer batteries by emphasizing the expense of a "real" medical battery: Hutchinson stated that a basic start-up outfit (comprised of several $30-35 batteries and accessories) would cost approximately a hundred dollars,[186] while Monell wrote that a "competent faradic apparatus costs from $50 upwards."[187]

Interestingly, every major electromedical instrument manufacturer had at least one battery for "families" in their catalogues. The product was almost always the only item in the entire catalogue that was directed at non-physicians. For example, among the eight batteries listed in the 1895 Waite and Bartlett catalogue, there were six "faradic" medical batteries for physician use, and two $10 medical batteries—the cheapest in the catalogue—one billed simply as a "Family Battery" and the other as an "Electro-Magnetic Machine – for Family Use."[188] Another major medical manufacturer, McIntosh, carried a similar "family faradic battery" (**Fig. 5.10**);[189] other manufacturers referred to their version of the same type of product as a "home battery" or a "domestic battery."[190] Though the name varied, the "family battery" was usually the

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[184] Ibid., 130.

[185] Hutchinson, *Practical Electro-Therapeutics*, 17.

[186] Ibid., 197.

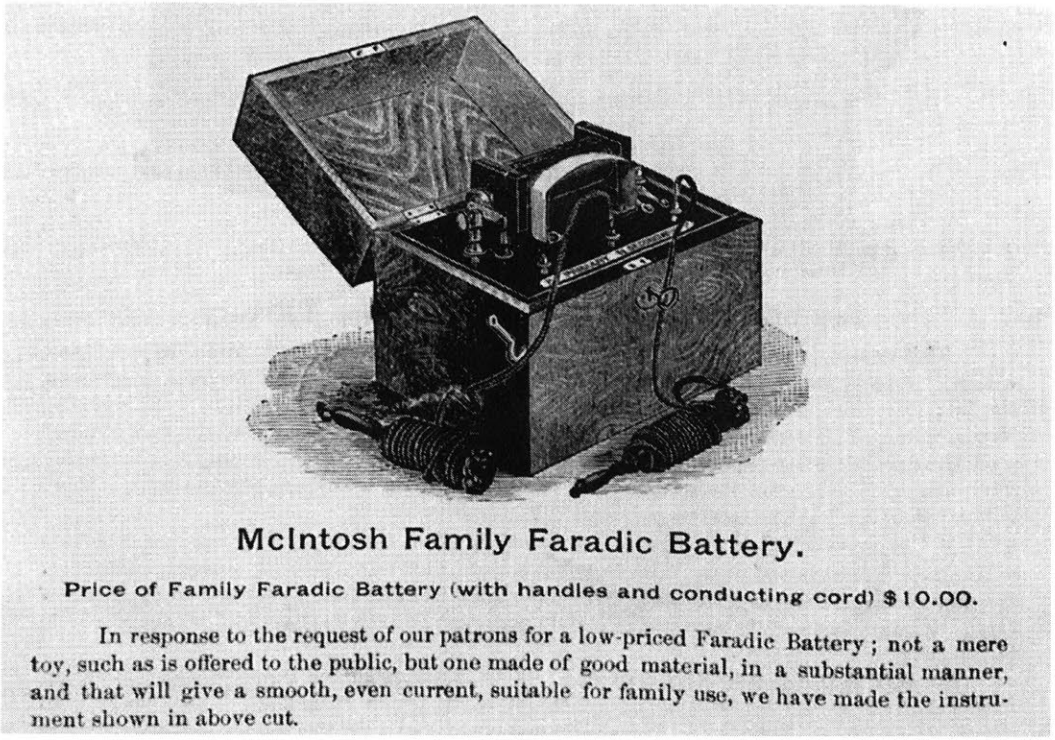
[187] Samuel Howard Monell, *High Frequency Electric Currents*, 131.

[188] "Illustrated Price List, Electro-Medical and Electro-Surgical Instruments," (New York: Waite & Bartlett Mfg Co, 1895-1896), 18, 46. Accessed June 2, 2016, http://archive.org/details/illustratedprice00wait.

[189] "Illustrated Catalogue of McIntosh Combined Galvanic and Faradic Battery," (McIntosh Galvanic and Faradic Battery Co., 1881), 19. Bakken Library Collection.

[190] For example, the Victor Electric Company sold a "Home Faradic Battery" and G. P. Pilling had a domestic faradic battery. "Catalogue no. 28 of Victor Electro-Surgical Apparatus,"

entry-level medical battery in most catalogues. Electromedical instrument manufacturers emphasized its affordability, quality ("made of good material") and ease of use ("It is so simple a child can use it").[191]



McIntosh Family Faradic Battery.

Price of Family Faradic Battery (with handles and conducting cord) $10.00.

In response to the request of our patrons for a low-priced Faradic Battery; not a mere toy, such as is offered to the public, but one made of good material, in a substantial manner, and that will give a smooth, even current, suitable for family use, we have made the instrument shown in above cut.

Figure 5.10. A "family" battery from the McIntosh Illustrated Catalogue, ca. 1885. Bakken Library Collection.

The line between what was considered a physicians' battery and a "family" battery was often murky. Sometimes the same model of medical battery was marketed *both* for physician and family use, such as Jerome Kidder's No. 4 "Office and Family Apparatus"[192] or Flemming's "No. 1 Faradic Battery," which as the company noted was "intended chiefly for the use of

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(Chicago, IL: Victor Electric Company, ca. 1905), 49; "Complete Guide for Domestic Treatment by Electricity" (Philadelphia: G.P. Pilling & Son, 1905), 30-31. Bakken Library Collection.

[191] "Illustrated Catalogue of McIntosh Combined Galvanic and Faradic Battery," (McIntosh Galvanic and Faradic Battery Co., 1881), 19; "A New Family Battery - The Lord Baltimore" by Chloride of Silver Dry Cell Battery Co., in "General catalogue: Noyes Brothers & Cutler," (St Paul: Noyes Brothers & Cutler, 1891), 438. Bakken Library Collection.

[192] "Electro-Allotropo-Physiology: Uses of Different Qualities of Electricity to Cure Disease" (New York: Dr. Kidder's Electrical Establishment, 1875). Bakken Library Collection.

physicians" but for "private family use it will be found especially valuable"[193] due to its simplicity and convenience. In other cases, the intended primary market for a medical battery shifted over time: Jerome Kidder's No. 3 battery was marketed for both office and family use in 1871, but the same product, in the company's 1874 and 1875 catalogues, was marketed just for physician use.[194] Electromedical instrument manufacturers also attempted to set their family batteries apart from the cheaper consumer batteries on the market. For example, McIntosh, a reputable electromedical instrument manufacturer, described its family battery as "not merely a toy, such as is offered to the public, but one made of good material in a substantial manner,"[195] and the Victor Electric Company stated that its family battery was "far superior to the small cheap outfits so extensively advertising to the laity, and that are nothing more or less than 'shocking' machines."[196]

To acquire a "family battery" from an electromedical instrument manufacturer, patients could purchase the medical battery directly via catalogues or physicians could order medical batteries on their patient's behalf.[197] As electromedical instrument manufacturers sometimes offered a discount of around ten to fifteen percent to medical professionals, it is possible that

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[193] "Illustrated Catalogue of Flemming's Electro-Therapeutic Apparatus, Electro-Surgical Apparatus, Electrodes, Etc," (Philadelphia: Press of Wm. H. Bartholomew, 1886), 23.

[194] "Dr. Jerome Kidder's Highest Premium, Vitalizing, Genuine Six and Nine Current Electro-Medical Apparatuses," (New York: Jerome Kidder's Electrical Manufactory, 1871), 7; "Electro-Allotropo-Physiology: Uses of Different Qualities of Electricity to Cure Disease" (New York: Jerome Kidder, 1874 and 1875). Bakken Library Collection.

[195] "Illustrated Catalogue of McIntosh Combined Galvanic and Faradic Battery," (McIntosh Galvanic and Faradic Battery Co., 1881), 19. Bakken Library Collection.

[196] "Catalogue no. 28 of Victor Electro-Surgical Apparatus," (Chicago, IL: Victor Electric Company, ca. 1905), 49.

[197] In some cases, individuals could purchase medical batteries locally: a 1900 article in the *National Druggist* indicates that although local druggists sold some medical batteries, they did not regularly keep them in stock. See "Medical Batteries," *The National Druggist*, Vol 30, 1900, p. 413. Digital archive accessed January 16, 2015, https://books.google.com/books?id=PWrnAAAAMAAJ

physicians made a small commission on sales to their patients. However, I did not come across any indication in the medical or popular literature of physicians profiting from the sales of family batteries to patients. Furthermore, in the numerous works of Monell, who was the most outspoken critic of the family battery (and of physicians who recommended it), no mention is made of physicians financially benefitting from sales of the family battery.

VII. The family battery and self-treatment with electricity

It is likely that the family battery was recommended by physicians to patients in much the same way as a medical device is "prescribed" today.[198] Indeed, the text accompanying family batteries in catalogues implies that physicians recommended that patients self-administer electricity to themselves; for example, the Pocket Faradic Battery No. 7, manufactured by the Chloride of Silver Dry Cell Battery Company, was advertised as being "used among Physicians, and recommended by them to patients for home use."[199] Those who purchased family batteries from electromedical instrument manufacturers probably received some form of guidance from their physician, as family batteries seldom came with treatment directions. By contrast, consumer medical batteries were often accompanied by an instructional pamphlet, like "the "Complete Guide for Domestic Treatment by Electricity" and "Medical Electricity at Home."[200] The latter

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[198] Though it is common to associate prescriptions with drugs, certain medical devices—such as a nebulizer for asthma treatment—require a prescription.

[199] "Keystone Electric Company Illustrated Catalogue and Price List," (Philadelphia: Keystone Electric Company, ca. 1903). Bakken Library Collection.

[200] "Complete Guide for Domestic Treatment by Electricity" (Philadelphia: G.P. Pilling & Son, 1905); O.G. Tradewell, "Medical Electricity at Home," (Signal Electric Mfg Co., undated) Bakken Artifact Collection.

pamphlet, for example, contained an alphabetical list of 75 diseases and conditions, and succinct directions on how to use electricity to treat them.[201]

That the family battery remained in the catalogues of major medical manufacturers between 1870 and 1920 suggests that the demand remained high for this product for a significant period of time. Put another way, it suggests that many physicians were recommending that patients self-administer electricity at home for treatment. This is somewhat puzzling, because in electrotherapeutic texts, mentions of the self-administration of electricity are almost entirely absent, and the practice is never recommended or advised. Similarly, articles in the *Journal of Electrotherapeutics* are mostly comprised of case studies of physicians applying electricity to a patient for a given indication.

Further evidence seems to indicate that many physicians were indeed recommending that their patients use a home medical battery, whether purchased from consumer-oriented outlets or from a reputable electromedical instrument manufacturer. For example, an 1892 editorial in *Western Electrician* lamented that "[m]any physicians will tell a patient to get 'a battery' and use it himself," even though "there is no more reason why a patient should use electric current of various nature without specific advice than that he should use surgical instruments."[202] A. D. Rockwell denounced physicians who order "the patient to get a battery and try electricity," even though he acknowledged that "the temptation on the part of the people to use electricity

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[201] For example, for the treatment of a nervous cough: prostate: "Apply the positive pole with the sponge electrode attached, to the back of the neck; apply the negative electrode against the front of the neck. This treatment should be ten or fifteen minutes in duration and should be given once or twice a day using the primary current." O.G. Tradewell, "Medical Electricity at Home," (Signal Electric Mfg Co., undated) 15.

[202] "Editorial," *Western Electrician* 11, no. 12 (September 17, 1892), 150.

themselves, and on the part of the profession to allow them to do so, is very strong."[203] But Monell was by far the most prolific crusader against the home use of electricity: in a variety of books and magazine articles from the late 1890s to 1910, he denounced physicians who recommended medical batteries to their patients.[204] He took issue specifically with family batteries, which he alternately called "worthless toy[s]," "delusions," "buzzing offenders," and "the worst enemy the cause of medical electricity has ever known," because they "deceive the public and retard progress."[205]

Why might physicians have been tempted to recommend the home use of electricity to their patients? In the late nineteenth century, many of their patients would likely have heard about the promising new technique of electrical medicine, both via the popular press as well as through the myriad consumer electrotherapy products on the market. Indeed, one of Monell's articles implies that patients would come to physicians to discuss whether electricity would be a suitable treatment.[206] Physicians would likely have wanted to be viewed as knowledgeable and up-to-date on the latest medical cures. While physicians who were interested in learning more about electrotherapeutics could enroll in a training course, doing so required a significant investment of both time and money, and courses were not readily available in rural areas. Another option was for physicians to purchase a cheap battery and administer treatment without

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[203] A. D. Rockwell, *The Medical and Surgical Uses of Electricity.* (New York: William Wood and Company, 1896), 228-229.

[204] Monell, *High Frequency Electric Currents*; Samuel Howard Monell, "Electro-therapeutics: The Present Faradic Muddle," *The Medical Times and Register*, July 21, 1894, 45-46 and "Electro-therapeutics: Electricity vs. Suggestion," *The Medical Times and Register*, June 23, 1894 403-404; and Samuel Howard Monell, *Elements of Correct Technique: Clinics from the New York School of Special Electro-Therapeutics* (New York: Edward R. Pelton, 1900), 282-293; Samuel Howard Monell, *Electricity in Health and Disease: A Treatise of Authentic Facts for General Readers* (New York: McGraw Publishing Company, 1907), 81.

[205] Monell, *High Frequency Electric Currents*, 130.

[206] Samuel Howard Monell, "Electro-therapeutics: A Question of Enterprise," *The Medical Times and Register*, January 19, 1895, 54.

formal training; as noted earlier, these "untrained" physicians were the target of criticism by Rockwell, Hutchinson, and Monell. An additional possibility was for physicians to recommend that patients apply electricity to themselves using a "family" battery. Given that physicians likely knew little more about electricity than their patients, this option would have certainly been appealing to a number of physicians.

Not surprisingly, the handful of physicians who did speak out against the home use of electricity were located in urban areas like New York and Providence, and held positions at the upper echelons of electrical medicine—Rockwell was one of fathers of electrotherapeutics, Monell ran a reputable electrotherapeutics training school in New York, and Hutchinson served as a the vice president of the AEA.[207] Their opposition to the self-administration of electricity reflected an underlying battle over the nature of electrical medicine: was electrotherapy akin to a drug, something that could be readily "taken" by consumers, or was it more like surgery, a specialized technique to be administered only by experienced professionals? The widespread accessibility of the medical battery to the public—both via consumer outlets and electromedical instrument manufacturers—represented a tacit endorsement of the former characterization; it advanced the image of the medical battery as a *product* to be purchased and used, rather than electrotherapy as a *technique* to be administered by experienced medical professionals. Indeed, Monell fought on behalf of the latter characterization, writing that "in a true sense there can be no family battery; there can only be a proper use of electrical remedies when trained physicians administer them."[208]

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[207] "A Memorial Sketch. William F. Hutchinson, M.A., M.D.," *The Boston Medical and Surgical Journal* 130 (February 22, 1894): 198–99.

[208] Monell, *Electricity in Health and Disease*, 81.

But Monell, who was the most vocal critic of the home use of the electricity, seemed to have been waging a solitary and ultimately rather fruitless battle against the family battery. On the whole, physicians were silent on the topic; indeed, there is a striking absence of debate or discussion on the topic. While physicians were easily united in their fight against "quackery," there was no public outcry against the home use of electricity. Given the cozy relationships that many physicians enjoyed with electromedical instrument manufacturers, it is telling that no pressure was exerted on these companies to halt sales of the "family battery," and the product continued to be sold by electromedical instrument manufacturers into the 1910s. Thus, taken together, existing evidence—both from the long life of the family battery and criticism that emerged from physicians like Monell—suggests that while the self-administration of electricity was not written about in medical books or journals, it was a practice that many physicians likely recommended to their patients.

VIII. Decline of the Medical Battery

In the 1880s and 1890s, *Electrical World* had frequently featured articles and trade notes about medical batteries: product innovations were described with excitement and optimism, and nearly every volume announced that new companies were entering the medical battery business. By 1905, however, mentions of medical batteries in the magazine had largely been replaced by articles about newer electrotherapeutic technologies, such as sinusoidal-wave producing devices (which produced a smoother type of alternating current via an electric motor,)[209] and high frequency devices. Though companies continued to carry older "galvanic" and "faradic" models

[209] Currier, *Guide to Electrotherapy Instruments,* 485.

of their medical batteries, by the 1910s, as on-the-grid electricity made its way into the home, using a battery—instead of plugging into the wall—seemed like an outdated approach.

The decline of the medical battery also followed that of electrotherapeutics as a whole. During World War I and after, medical schools removed electrotherapy courses from their curriculums, and journals began to reject articles about electrical medicine.[210] The *American Journal of Electrotherapeutics*, which had become the *Journal of Advanced Therapeutics* in 1902, changed its name to the *American Journal of Electrotherapeutics and Radiology* in 1916, reflecting interest in the applications of the newly discovered Roentgen rays (X-rays).[211] In 1927, the journal changed its name once again, to *Physical Therapeutics*.[212] Membership in the AEA declined to a new low by 1915, and by 1929 it had been subsumed under the American Physical Therapy Association.[213] In Europe, too, interest in electrotherapy had declined; according to one scholar, the field was largely "defunct" in Britain by the early 1920s.[214]

Some historians have attributed the decline of electrotherapeutics in the 1920s to the concurrent shift to psychology and psychoanalysis, which located "nervous" diseases in the mind rather than the body itself.[215] Electrical treatments, which were based on restoring depleted bodily energy, did not mesh with new theories of disease that centered on the subconscious

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[210] Kneeland and Warren, *Pushbutton Psychiatry*, 38.

[211] See record for "The Journal of Advanced Therapeutics," Hathitrust Digital Library records, accessed June 11, 2016, http://catalog.hathitrust.org/Record/000638395

[212] See record for "Physical Therapeutics," Hathitrust Digital Library records, accessed June 11, 2016, http://catalog.hathitrust.org/Record/000638388

[213] Kneeland and Warren, *Pushbutton Psychiatry*, 37-38.

[214] James Stark, in his work on Overbeck's Rejuvenator's, notes that: "John Senior has examined the context of neurology, concluding that by the start of the 1920s electrotherapy was largely defunct as an amateur, marginal practice." See James F. Stark, "'Recharge My Exhausted Batteries': Overbeck's Rejuvenator, Patenting, and Public Medical Consumers, 1924–37," *Medical History* 58, no. 4 (October 2014): 500. Stark references Senior's unpublished thesis: John Senior, 'Rationalising Electrotherapy in Neurology, 1860–1920' (unpublished PhD thesis: Oxford University, 1994).

[215] Kneeland and Warren, *Pushbutton Psychiatry*, 37.

mind.[216] Indeed, as Sigmund Freud's theories began to grow in popularity, the field of psychology staked its claim on mental diseases, and somatic diseases were incorporated under "physical therapy." Other historians, however, have suggested that the decline is partly attributable to the fact that a mechanism of action for electrical treatment was never clearly elucidated—and that the results of electrical treatment were always mixed.[217]

Even though physician interest in the medical battery dropped off in the 1910s and 1920s, the medical battery continued to be marketed directly to consumers. As late as October 1917, the *Electrical Record* recommended purchasing the medical battery as a "holiday gift."[218] Gradually, however, the medical battery came to be replaced by new versions of home electrotherapy products, such as vibrating machines,[219] high-frequency devices like the Violet Ray,[220] and so-called oxygen delivery systems like the Electropoise.[221] Other home electrotherapy products such as Overbeck's Rejuvenator,[222] and I-ON-A-CO,[223] which came to market in the mid-1920s, remained popular for over a decade.

The final nail in the coffin for consumer medical batteries was the AMA's anti-quackery campaign and related actions taken by regulatory authorities against companies that made unsubstantiated claims for their products. Though the crackdown on "quack" food and drugs had begun in earnest after the passage of the 1906 Pure Food and Drug Act, the law only provided

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[216] Greenway, "'Nervous Disease," 53.

[217] Ibid., 60-66.

[218] "Electrical Holiday Goods: Suggestions for the Selection of Appropriate Gifts, *Electrical Record and Buyer's Reference*, Vol. 22, October 1917, p. 82.

[219] Shelton Vibrator; "Health and Beauty," Shelton Electric Co, ca. 1910; and Wappler vibrators in "Wappler: Cautery and Light Apparatus and Accessories" (New York: Wappler Electric Mfg Co, 1914), 42-45. Bakken Library Collection.

[220] de la Peña, *Body Electric*, 121-126.

[221] Ibid.

[222] Stark, "'Recharge My Exhausted Batteries,'": 498–518.

[223] de la Peña, *Body Electric*, 125-136; Stewart H. Holbrook, *The Golden Age of Quackery* (New York: The Macmillan Company, 1959), 135-145.

for the regulation of food and drugs, not devices. To combat the "nostrums" that were still on the market, the AMA created a Propaganda Department (later renamed the Bureau of Investigation) in 1913 that investigated fraudulent medical products.[224] The Department worked closely with regulators such as the Department of Agriculture's Bureau of Chemistry (which enforced food and drug law prior to the establishment of the FDA); the Post Office Department, which had the authority to take action for fraudulent schemes run through the mail, and the Federal Trade Commission (FTC), which took action for "unfair trade practices."[225]

By the 1920s, any company that made unsubstantiated claims for their consumer electrotherapy products was susceptible to regulatory action. For example, in 1920 the FTC filed a complaint against the Electric Appliance Company of Burlington, Kansas, which had been making electric belts, electric insoles, and medical batteries. The complaint accused the company of circulating "false and misleading" advertisements about its products by claiming, among other things, that the belts preserved health and that the electric battery was "nature's vitalizer" and would "save doctor's bills."[226] The FTC ordered the company to "cease and desist" representing that "its products possess such curative qualities."[227] Evidently, however, the company remained in business for another decade and a half: in 1937 the FTC again ordered the company to "cease and desist" making "unfair representations."[228] It wasn't until 1938, however, that the

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[224] Boyle, *Quack Medicine*, 62.

[225] Ibid., 74-77.

[226] Federal Trade Commission v. The Electric Appliance Co., of Burlington, Kansas. Docket 340. March 19, 1920. Federal Trade Commission Decisions 2 (1920) 335-340.

[227] Ibid., 340.

[228] FTC, *Annual Report of the FTC for the Fiscal Year ended June 30, 1938* (Washington DC: US Government Printing Office, 1938), 57. The FTC's press release stated the following: "The Electric Appliance Company.... is directed to discontinue certain unfair representations regarding the value of its electric belts and insoles in the treatment of disease... Findings are that the respondent's products, advertised for use in treating nervous diseases, rheumatism, heart trouble and other ailments, do not have the curing qualities claimed for them. Neither the belts

government acquired real power to regulate "quack" devices, as the passage of the Federal Food Drug and Cosmetic Act gave the FDA authority to regulate medical devices that made therapeutic claims.[229]

Conclusion

The medical battery was used to provide electrical treatments in the home and clinic for nearly five decades (1870-1920). Though companies marketed medical batteries primarily to either consumers or physicians, this chapter has demonstrated that the lines between what was considered a consumer product and a medical device were often muddled. Some physician-oriented companies marketed their products directly to consumers; conversely, consumer-oriented companies advertised their products to physicians.

Most striking, however, was the existence of the "family battery," a product that was sold by every major electromedical instrument manufacturer, yet aimed at non-physicians for the purposes of self-administering electrical stimulation. Although mentions of patients self-administering electricity are almost entirely absent from medical textbooks and journals, existing evidence—both from the long life of the family battery as well as from criticism that emerged from a handful of physicians—suggests that many physicians were indeed recommending that their patients self-administer electricity at home, whether via the family or consumer battery. The handful of physicians who publicly advocated against the home use of the medical battery felt that its use by the laity threatened the image of electrotherapy as a skilled medical procedure. Yet

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not the insoles generate enough electricity to have any discernible effect on any part of the body, according to the findings." FTC Order for Press Release, November 27, 1937. AMA Health Fraud Archives, Box 0230-04.

[229] Hutt et al., *Food and Drug* Law, 10-11.

despite their objections, the medical battery remained in the hands of consumers well into the 1910s. The decline of the medical battery can be attributed to a constellation of factors, including shifting interest towards newer technologies, the disappearance of electrotherapeutics as a whole, changing conceptions of nervous disease, and the institution of regulations governing medical devices and advertising claims.

Interestingly, modern books and articles related to the history of electrical medicine rarely mention the use of galvanic or faradic electrotherapy in America in the late nineteenth and early twentieth century, and the little scholarship that exists on the topic is found mostly in cultural and social histories. While there are likely a number of reasons for this—one being that American physicians did not conduct studies of electrophysiology as did their European counterparts[230]—it is also possible that the anti-quackery campaigns of the 1920s retrospectively cast a pall over the legacy of late nineteenth and early twentieth century electrotherapeutics. Indeed, electrotherapeutics of the time period seems to be remembered more for quackery than for the work conducted by regular physicians. Furthermore, in antique markets today, medical batteries—which are currently traded and sold on places like eBay.com—are colloquially referred to as "quack devices" or "quack machines."[231] That the product has become synonymous with quackery in the world of collectors is an ironic final coda, because as I have shown throughout this chapter, the medical battery was the one consumer electrotherapy product *not* considered as such by regular medical professionals who practiced electrotherapy. Indeed, the medical battery occupied a unique position, flourishing for nearly five decades both in the

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[230] Rosner, "The Professional Context of Electrotherapeutics," 79.

[231] At any given time, there are hundreds of medical batteries for sale on the online auction site eBay.com, ranging in price from $50-300, depending on condition. There are so many surviving medical batteries that a second market has arisen just in their sale and trade, and a nearly 500-page book, Dean P. Currier's *Guide to Electrotherapy Instruments and History of their American Makers* (2013), serves as a detailed guide for medical battery collectors.

domain of medical practitioners and that of home consumers, blurring the boundaries between medicine and consumerism.

CHAPTER 6

Recurrent themes in the home use of electrical stimulation: tDCS and the medical battery (1870-1920)

Much of the print media coverage of transcranial direct current stimulation (tDCS) has focused on describing it in a positive light,[1] as a technique that is new, novel and innovative.[2] Articles related to the home (or do-it-yourself) use of tDCS refer to a "strange new world" where individuals use non-invasive electrical stimulation, instead of drugs, for self-improvement purposes.[3] In many media articles, tDCS technology seems to have appeared out of the ether, as if the current trend represents the first time electrical brain stimulation has been utilized.

The scientific literature does better, sometimes including a few introductory lines referencing tDCS's lineage.[4] The sentences point to many of the same key highlights in the

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[1] Veljko Dubljević, Victoria Saigle, and Eric Racine, "The Rising Tide of tDCS in the Media and Academic Literature," *Neuron* 82, no. 4 (May 21, 2014): 731–36, doi:10.1016/j.neuron.2014.05.003.

[2] Samuel K. Moore, "Psychiatry's Shocking New Tools," *IEEE Spectrum*, February 28, 2006, http://spectrum.ieee.org/biomedical/diagnostics/psychiatrys-shocking-new-tools.

[3] Greg Miller, "Inside the Strange New World of DIY Brain Stimulation," *WIRED*, May 5, 2014, http://www.wired.com/2014/05/diy-brain-stimulation/.

[4] See, e.g., Brian A. Coffman, Vincent P. Clark, and Raja Parasuraman, "Battery Powered Thought: Enhancement of Attention, Learning, and Memory in Healthy Adults Using Transcranial Direct Current Stimulation," *NeuroImage*, Neuro-enhancement, 85, Part 3 (January 15, 2014): 895–908, doi:10.1016/j.neuroimage.2013.07.083; Alberto Priori, "Brain Polarization in Humans: A Reappraisal of an Old Tool for Prolonged Non-Invasive Modulation of Brain Excitability," *Clinical Neurophysiology* 114, no. 4 (April 1, 2003): 589–95, doi:10.1016/S1388-2457(02)00437-6; Charlotte J. Stagg and Michael A. Nitsche, "Physiological Basis of Transcranial Direct Current Stimulation," *The Neuroscientist* 17, no. 1 (February 1, 2011): 37–53, doi:10.1177/1073858410386614; Kathrin S. Utz et al., "Electrified Minds: Transcranial

history of electrical medicine: the use of electric fish to treat headache and gout in Roman times; the late eighteenth century research of Luigi Galvani (on the electrical stimulation of frog muscles) and Alessandro Volta's invention of the "voltaic pile," a precursor to the modern battery; Giovanni Aldini's use of electricity to treat mental disorders in 1804; the development of electroconvulsive therapy (ECT) by Lucio Bini and Ugo Cerletti in 1938; and the use of weak direct current on animal brains in the 1960s. A 2001 paper by two German neurophysiologists, Michael Nietsche and Walter Paulus, is often credited with launching contemporary interest in the technique that has come to be known as tDCS.[5] Thus, the history of electrical brain stimulation is portrayed as a series of sporadic breakthroughs, with large gaps between certain years (e.g., 1804 to 1938).

According to historians, however, electricity (as we know it today) was first proposed for medicinal uses in 1743, and since that time has been continuously used both by individuals within the medical/scientific profession and those outside it.[6] In fact, electrical medicine was so popular in the United States and Europe between 1870 and 1920 that the period is often referred

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Direct Current Stimulation (tDCS) and Galvanic Vestibular Stimulation (GVS) as Methods of Non-Invasive Brain Stimulation in neuropsychology—A Review of Current Data and Future Implications," *Neuropsychologia* 48, no. 10 (August 2010): 2789–2810, doi:10.1016/j.neuropsychologia.2010.06.002.

[5] M. A. Nitsche and W. Paulus, "Excitability Changes Induced in the Human Motor Cortex by Weak Transcranial Direct Current Stimulation," *The Journal of Physiology* 527, no. 3 (September 1, 2000): 633–39, doi:10.1111/j.1469-7793.2000.t01-1-00633.x.

[6] Paola Bertucci and Giuliano Pancaldi, eds., *Electric Bodies: Episodes in the History of Medical Electricity* (Bologna: Università di Bologna, 2001); Stanley Finger and Marco Piccolino, *The Shocking History of Electric Fishes: From Ancient Epochs to the Birth of Modern Neurophysiology*, 1 edition (New York: Oxford University Press, USA, 2011); Marco Piccolino and Marco Bresadola, *Shocking Frogs: Galvani, Volta, and the Electric Origins of Neuroscience* (New York: Oxford University Press, 2013); and Margaret Rowbottom and Charles Susskind, *Electricity and Medicine: History of Their Interaction* (San Francisco: San Francisco Press, 1984).

to as the "golden age of electrotherapy."[7] During this time, electricity was administered by medical practitioners (both mainstream and alternative) in offices and clinics, but was also widely used by consumers for self-treatment in their own homes.[8]

Mainstream medical practitioners at the time acquired (and used) electrotherapy devices quite differently from consumers. Medical practitioners purchased stimulation devices from surgical and medical catalogues, and could learn about indications for use and stimulation protocols in medical textbooks and journals. Consumers, on the other hand, would often learn about electrotherapy products—such as electric socks, headbands, and belts— from newspaper and magazine advertisements, which proclaimed that electricity would provide relief for everything from nausea to rheumatism.[9]

While the vast majority of these direct-to-consumer products were dismissed as "quackery" by the mainstream medical profession, there was one stimulation device, known as the medical battery (**Fig. 6.1**), which was considered legitimate by physicians yet simultaneously used by consumers. As described in the previous chapter, the medical battery—a term that refers to the entire apparatus, not just the battery itself—consisted of a wooden enclosure, roughly the size of a shoebox, that contained a battery connected to a wire wrapped around an iron core, thus allowing for the production of both direct ("galvanic") and alternating ("faradic") current.[10] Electrodes were connected to the machine and placed at various sites on the body, and

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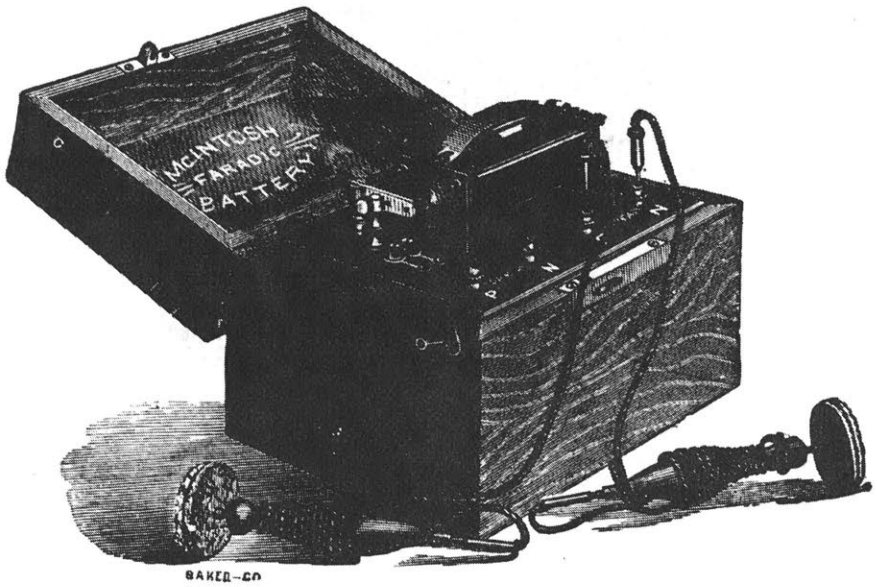
[7] Carolyn Thomas de la Peña, "The Golden Age of Electrotherapy," in *The Book of Touch*, ed. Constance Classen (Oxford: Berg Publishers, 2005); and L. A. Geddes, "A Short History of the Electrical Stimulation of Excitable Tissue. Including Electrotherapeutic Applications," *The Physiologist* 27, no. 1 Suppl (February 1984): S1–47.

[8] Carolyn Thomas de la Peña, *The Body Electric: How Strange Machines Built the Modern American* (New York: New York University Press, 2003).

[9] Robert K. Waits, *The Medical Electricians: George A. Scott and His Victorian Cohorts in Quackery* (Sunnyvale, California: CreateSpace Independent Publishing Platform, 2013).

[10] Dean P. Currier, *Guide to Electrotherapy Instruments and History of Their American Makers* (West Comshohocken, PA: Infinity Publishing, 2004).

stimulation was thought to cure a wide variety of ailments. As I noted in the previous chapter, between 1870 and 1920 in the United States, at least 150 different companies sold their own brand of medical battery, and over 100 additional distributors retailed these brands of medical batteries. The product was one of the most ubiquitous therapeutic items of the late nineteenth and early twentieth century, and today, so many of these objects survive that there is a flourishing market for them on Ebay.



McINTOSH PHYSICIANS' FARADIC BATTERY.

Figure 6.1. The McIntosh Physician's Faradic Battery, as depicted in an 1888 Noyes Bros. & Cutler medical catalogue. The battery itself is hidden from view inside the wooden box.

The medical battery bears a number of striking similarities to the modern-day use of tDCS. First, from a technical standpoint, a tDCS device is essentially a current-providing

component (such as a nine-volt battery) connected to two electrodes; more expensive devices offer methods of obtaining fine-grained control of the current. Today, many transcranial electrical stimulation devices provide both direct (tDCS) and alternating current (tACS). Similarly, although medical batteries were sometimes known as "faradic batteries," implying a strong connection to alternating current, in reality most provided both direct and alternating current (or a combination of both), although some provided only direct current (**Fig. 6.2**).

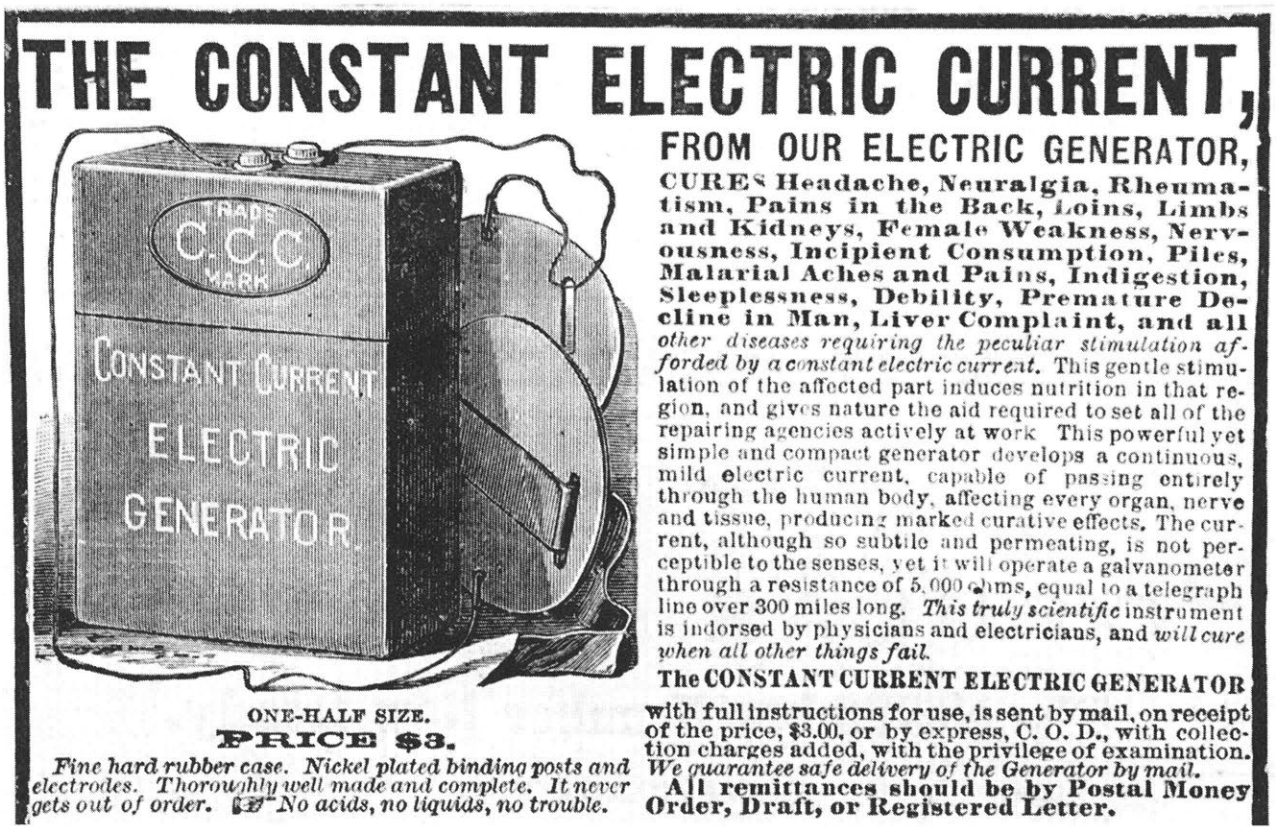


Figure 6.2. An advertisement for one of the few consumer medical batteries that used only direct current (1881, Frank Leslie's Newspaper). Courtesy of the Bakken.

Second, the medical battery, like tDCS, provided stimulation that was used about the head. Although the head was not the exclusive site of stimulation like it is in tDCS, it was considered part of the body, and in the late nineteenth and early twentieth century there were no

major distinctions between cranial and non-cranial use. Indeed, while today electrical treatment for mental disorders almost exclusively targets the brain, in the era of the medical battery, mental disorders were thought to be treatable by stimulation to various sites on the body.[11]

Third, and perhaps most importantly, the medical battery and tDCS devices are the only consumer electrotherapy products in the last century-and-a-half to have thrived both as consumer products and as legitimate medical and /research devices. By comparison, other stimulation devices have remained solely in the realm of the consumer (e.g., electric socks) or medical practitioner (e.g., electroconvulsive therapy, deep brain stimulation). While some electrostimulation devices—such as cranial electrotherapy stimulation (CES) devices—are prescribed by medical practitioners for treatment by patients at home, their use is relatively restricted, and there has not arisen a comparable consumer movement such as the one that has sprung up around tDCS.

This chapter reviews a number of features thought to be unique to the present day *home* use of brain stimulation, with a particular focus on analogies between tDCS and uses of the medical battery in the United States between 1870 and 1920. Indeed, viewed in the long durée, it seems that many of the features characterizing the contemporary home use of tDCS are a repetition of themes that occurred a century ago with regard to the medical battery. The first section of this chapter considers three commonalities: a do-it-yourself movement, anti-medical establishment themes, and conflicts between lay and professional usage. The second section of this chapter considers a number of features that appear to be unique to the present-day context: the dominant discourse about risk and safety, the division between cranial and non-cranial stimulation, and the use of stimulation for cognitive enhancement purposes.

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[11] Rowbottom and Susskind, *Electricity and Medicine*, 113-119.

Commonalities: tDCS and the medical battery

Do-it-yourself movement

The contemporary do-it-yourself (DIY) tDCS movement arose in late 2011, when lay individuals began building stimulation devices in the privacy of their own homes.[12] While some utilize tDCS in an attempt to "enhance" themselves (e.g., improve learning and memory), others use it to self-treat mood disorders such as depression and anxiety.[13] In recent years, a number of commercial manufacturers have entered the market, and there are now at least at a dozen neurostimulation devices available for purchase by the general public, ranging from "kits" that require assembly to out-of-the-box direct-to-consumer wearable devices, such as Thync, Halo, and Foc.us.[14] The range of devices has blurred the meaning of "do-it-yourself" tDCS: some use the term in reference to the hands-on construction of a stimulation device, while others use it more broadly to refer to the self-directed nature of the stimulation itself. Here, I adopt the former definition, using DIY to refer to the actual assembling of the device, and "home use" to refer to the general phenomenon of self-stimulation outside of academic or medical settings.

Though today self-treatment may seem somewhat anomalous, up until a hundred years ago, it was considered the norm; books like *Every Man His Own Doctor* (1736) and *The People's*

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[12] Anna Wexler, "The Practices of Do-It-Yourself Brain Stimulation: Implications for Ethical Considerations and Regulatory Proposals," *Journal of Medical Ethics* 42, no. 4 (April 1, 2016): 211–15, doi:10.1136/medethics-2015-102704.

[13] Anita Jwa, "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, no. 2 (July 13, 2015): 292–335, doi:10.1093/jlb/lsv017.

[14] Anna Wexler, "A Pragmatic Analysis of the Regulation of Consumer Transcranial Direct Current Stimulation (TDCS) Devices in the United States," *Journal of Law and the Biosciences* 2, no. 3 (February 1, 2016): 669–96, doi:10.1093/jlb/lsv039.

Common Sense Medical Adviser (1876) provided guidance on home medical care.[15] Although one could visit a physician to receive treatment, one could just as easily self-treat at home.[16] When the first electrotherapy devices emerged in the late 1700s—utilizing static (known at the time as "Franklinic") electricity—it was hoped that they would become a universal and cheap home treatment for a wide variety of maladies.[17] Even at this time, electricity appealed to those with an affinity for tinkering: according to one historian, there was a "do-it-yourself ethos" to medical electricity and it was "commonly regarded as one of the possible self-remedies for use at home."[18]

The do-it-yourself nature of electrical treatment continued into the nineteenth century, when on-demand electric current (both alternating and direct) could be used to provide electrotherapy. In the first half of the century, electrical stimulation devices were mostly hand-built by individual instrument makers, but by the end of the nineteenth century, new manufacturing processes allowed for the mass production of electrotherapy devices, which were sold both to medical practitioners and consumers.[19] Although medical catalogues sold a variety of expensive electrotherapy devices to physicians—such as "wall cabinet" batteries that contained multi-cell units, and chairs for providing electric stimulation—the entry-level option

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[15] Ray Vaughn Pierce, *The People's Common Sense Medical Adviser in Plain English, Or, Medicine Simplified* (Buffalo, N.Y.: World's Dispensary Printing-Office and Bindery, 1876), http://archive.org/details/peoplescommonsen00pierrich; and John Tennant, *Every Man His Own Doctor, or the Poor Planter's Physician* (Williamsburg, 1734).

[16] Paul Starr, *The Social Transformation Of American Medicine: The Rise Of A Sovereign Profession And The Making Of A Vast Industry*, Reprint edition (New York: Basic Books, 1982).

[17] Paola Bertucci, "Therapeutic Attractions: Early Applications of Electricity to the Art of Healing," in *Brain, Mind and Medicine: Essays in Eighteenth-Century Neuroscience*, ed. Harry Whitaker, C. U. M. Smith, and Stanley Finger (Springer US, 2007), 271–83.

[18] Paola Bertucci, "Revealing Sparks: John Wesley and the Religious Utility of Electrical Healing," *The British Journal for the History of Science* 39, no. 03 (September 2006): 341–62, doi:10.1017/S0007087406008363.

[19] Currier, *Guide to Electrotherapy Instruments,* 7.

was the medical battery, which was usually the cheapest stimulation device ($10-40) offered in late nineteenth and early twentieth century medical catalogues.[20] Many of the medical batteries marketed to consumers were identical to the low-end models sold to physicians.

In addition to purchasing ready-made batteries, at least some individuals built their own devices at home. Magazines like *Popular Mechanics* published instructions on how to construct a medical battery,[21] and ads for instructional books about electricity often appeared in the advertising section of magazines. Indeed, a number of these books—such as *Induction Coils and Coil-Making* (1894); *Electric Instrument Making for Amateurs* (1888), and *Induction Coils: How to Make, Use and Repair Them* (1901)—contained chapters on the construction of a medical battery.[22] Whereas today a home user might post an electronics question about tDCS to an Internet forum, at the turn of the twentieth century, an individual could write to the "Correspondence" section of a magazine, in hopes of having his or her medical-battery-related electrical question answered in print.[23]

While it is difficult to get a sense of the prevalence of the "do-it-yourself" medical battery, at least some of these home-constructed medical batteries survive today. Among the artifacts at the Bakken (a museum dedicated to the use of electricity in life and medicine) is a medical battery that was hand-built by the donor's grandfather sometime in the early twentieth

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[20] Waite & Bartlett Manufacturing Co. (New York), *Illustrated Price List of Electro-Medical and Electro-Surgical Instruments for Physicians and Surgeons : 1895 & 1896* (New York : Murray Printing Co., 1896), http://archive.org/details/illustratedprice00wait.

[21] "Amateur Mechanics," *Popular Mechanics* 11, no. 1 (1909): 36.

[22] Frederick Charles Allsop, *Induction Coils and Coil-Making; a Treatise on the Construction and Working of Shock, Medical and Spark Coils* (London & New York: E. & F N. Spon; Spon & Chamberlain, 1894); Selimo Romeo Bottone, *Electrical Instrument Making for Amateurs, a Practical Handbook* (London, Whittaker & co.; New York, D. Van Nostrand, 1888), http://archive.org/details/electricalinstru00bottrich; Norman Hugh Schneider, *Induction Coils: How to Make, Use, and Repair Them Including Ruhmkorff...*, 2nd ed. (Spon & Chamberlain, 1901), http://archive.org/details/inductioncoilsh00schngoog.

[23] "Answers to Correspondents," *The Electrical World* 18 (1891): 280.

century.[24] While the dozens of other medical batteries in the Bakken's collection all have some indication of origin—a company label glued inside the lid, numbered plug-ins for electrodes, patent numbers on the battery or iron core—this artifact lacks any of the typical markings. A similar home-built medical battery was recently sold by an antique dealer on Ebay.com, reportedly built "from scratch" at the turn of the twentieth century by the seller's great-grandfather.[25] At least from a visual perspective, the century-old DIY medical batteries appear strikingly similar to some contemporary home-constructed and direct-to-consumer tDCS apparatuses (**Fig. 6.3**). Thus, the DIY tDCS movement that has arisen today is not necessarily novel, but rather the most recent iteration of a longstanding characteristic of electrical medicine.

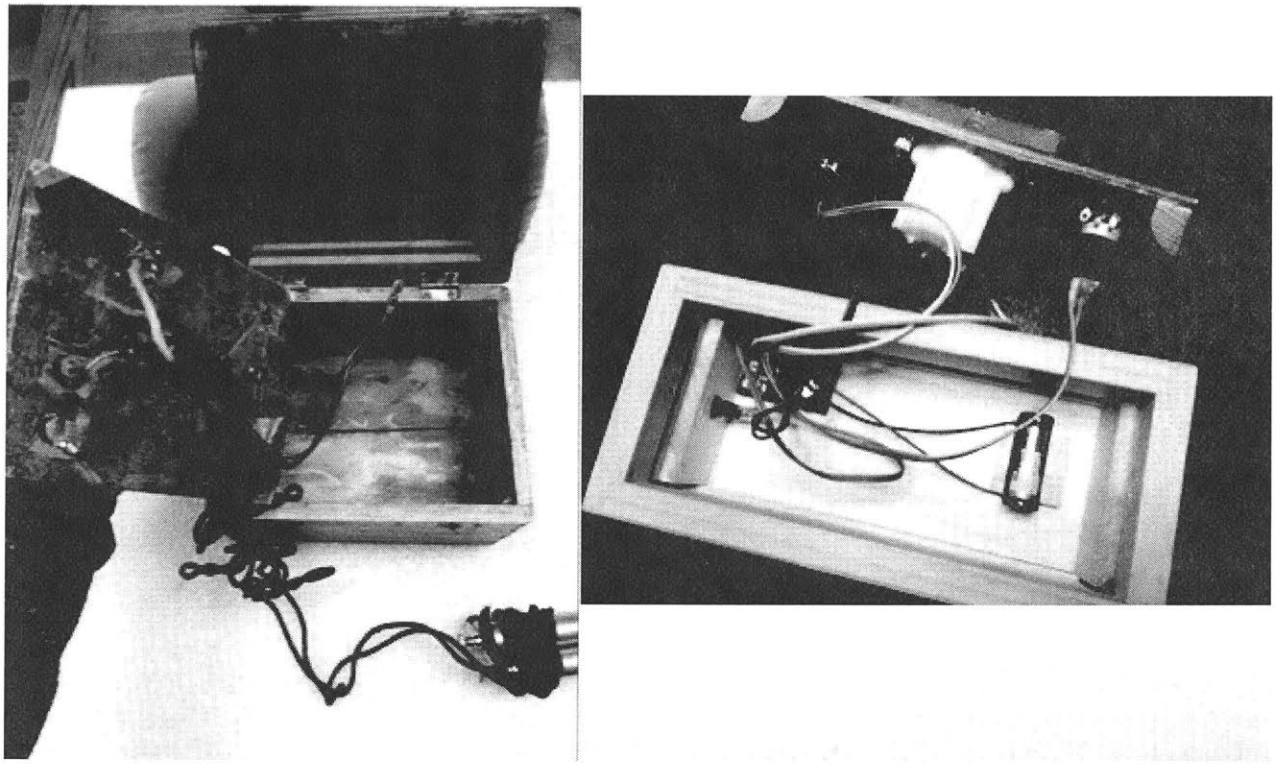


Figure 6.3. At left, a home-built medical battery circa 1900 (courtesy of the Bakken); at right, direct-to-consumer tDCS device from 2015 (courtesy of Super Specific Devices).

[24] "Stimulating coil" artifact (accession number 82.105), Bakken Artifact Collection.

[25] "Electric Shock Machine Victorian Era Scratch Built," accessed January 16, 2016, http://www.ebay.com/itm/ELECTRIC-SHOCK-MACHINE-VICTORIAN-ERA-SCRATCH-BUILT-WORKING-/111735045919.

Anti-establishment themes

Concomitant with "doing it yourself" is the notion of doing something *outside* of the mainstream establishment. Indeed, on Internet forums, home users have expressed hope that tDCS will become a universal treatment, one that will dispense with the need to see a physician or pay for expensive pharmaceuticals. Some users come to tDCS after experiencing frustration with modern medicine.[26] Furthermore, many of those who have currently incorporated tDCS into their current clinical practice are complementary and alternative medicine practitioners.[27] Thus, both among home users and in the clinic, tDCS carries a strong "alternative" association.

These same anti-establishment themes are evident with regard to the medical battery, especially among devices marketed to consumers, which were often advertised as a substitute for an expensive and inconvenient visit to a physician. For example, a pamphlet advertising Lindstrom's Electro-Medical Apparatus (**Fig. 6.4**) noted that it was like "a splendid doctor and drugstore combined," because it would "save you a great deal of money which would otherwise be spent for doctors and medicines." Indeed, the company encouraged readers to "Become your own doctor."[28]

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[26] See, e.g., https://www.reddit.com/r/tDCS/comments/1red4v/how_would_you_describe_your_experience_with_tdcs/; http://www.neurotalk.org/reflex-sympathetic-dystrophy-rsd-and-crps-/160980-update-remission-reach.html; and https://www.reddit.com/r/tDCS/comments/2i4dzh/my_experience_with_the_depression_montage/

[27] See, e.g., Edmonton Neurotherapy http://www.edmontonneurotherapy.com/brain_stimulation_therapies.html; Perth Brain Centre http://www.perthbraincentre.com.au/; Acacia Integrative Health Clinic http://www.acaciahealth.ca/clinic_services/.

[28] "Lindstrom's Electro-Medical Apparatus" (Electro Medical Co, Chicago, IL: ca 1895), 25-26. Bakken Library Collection.

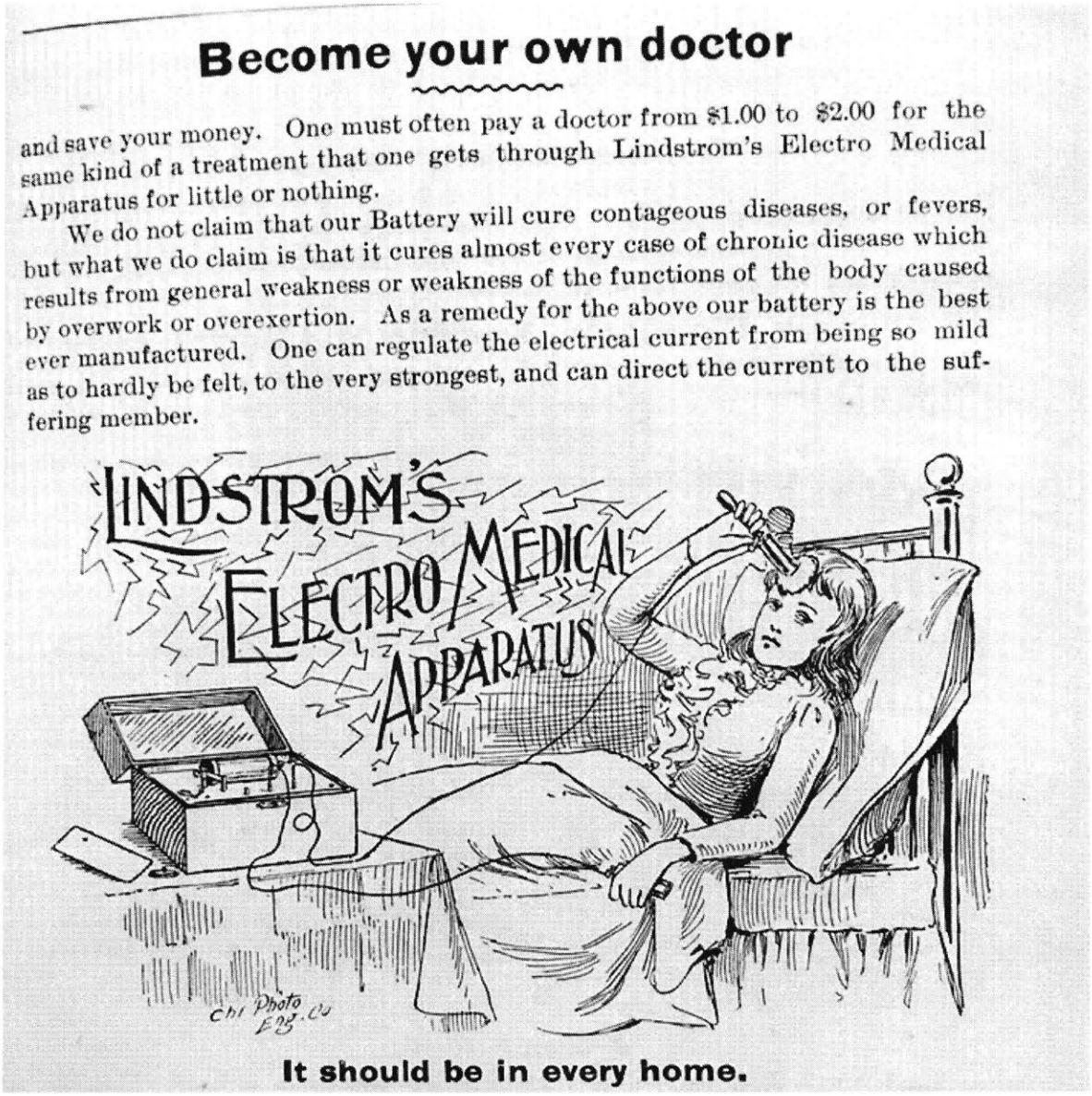


Figure 6.4. Lindstrom's Electro-Medical Apparatus (ca. 1895), courtesy of the Bakken.

Another company prefaced its medical battery offerings by noting that: "[m]any are unable to pay for the services of a physician, or even an electric specialist, to apply the current for the required length of time each day."[29] The negative attitude toward the medical

[29] "German Electric Belts and Appliances" (German Electrical Agency, New York, ca 1901), Bakken Library Collection.

establishment was sometimes even made explicit in the name of product itself: for example, the Manhattan Electrical Supply Company sold a medical battery known as the "Anti-Doc Medical Apparatus" (**Fig. 6.5**), which was marketed as provided "unfailing relief" for a variety of ailments.[30]



Figure 6.5. An ad for the "Anti-Doc" medical apparatus from the January 1907 issue of *Popular Mechanics*.

[30] "Anti-Doc Medical Apparatus (as Advertised by the Manhattan Electrical Supply Co.)," *The Railroad Telegrapher* 24, no. 2 (1907): 2154.

Drawing professional boundaries

The home use of tDCS has been a source of much consternation for neuromodulation researchers, who fear that home users might "ruin it" for legitimate scientists, or that in the process of attempting to enhance or treat, individuals may actually end up harming themselves. In December 2015, the International Federation of Clinical Neurophysiologists (IFCN) became the first organization to issue a formal position paper against the home use of tDCS,[31] and individual researchers and ethicists have warned against the practice, both in the media and peer-reviewed journals.[32] Some researchers have attempted to close the door to the lay use of tDCS by arguing that direct-to-consumer products should be restricted or controlled through government regulation.[33] In addition, the Food and Drug Administration, the Institute of Medicine, and the American Academy of Arts and Sciences have all recently held meetings to address the home use of non-invasive brain stimulation.

Similar conflicts occurred in the late nineteenth century, when the medical battery and other electrotherapeutic devices were widely sold (and used by) consumers and "irregular" medical practitioners. In 1891 physicians formed the American Electrotherapeutic Association in

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[31] International Federation of Clinical Neurophysiology, "Position Paper: Transcranial Electric Stimulation in Do-It-Yourself Applications," December 13, 2015, http://www.ifcn.info/uploadfiles/documents/2015/Using_tES_devices_as_DIY_FINAL_13Dec15.pdf.

[32] Marom Bikson, Sven Bestmann, and Dylan Edwards, "Neuroscience: Transcranial Devices Are Not Playthings," *Nature* 501, no. 7466 (September 12, 2013): 167–167, doi:10.1038/501167b; and Melissa Hogenboom, "Warning over Electrical Brain Stimulation," *BBC News*, August 24, 2014, http://www.bbc.com/news/health-27343047.

[33] Olivia Carter and Jason Forte, "Medical Risks: Regulate Devices for Brain Stimulation," *Nature* 533, no. 7602 (May 12, 2016): 179–179, doi:10.1038/533179d; and Hannah Maslen et al., "The Regulation of Cognitive Enhancement Devices: Extending the Medical Model," *Journal of Law and the Biosciences* 1, no. 1 (March 1, 2014): 68–93, doi:10.1093/jlb/lst003.

an attempt to set themselves and their techniques apart from others on the market.[34] In addition, at least one New York-based electrotherapy clinic ceased training lay individuals, and instead restricted trainees to those who were medical school graduates.[35] To guard against the "fanatic and the charlatan," the newly formed *Journal of Electro-therapeutics* requested that readers periodically examine the list of contributors to ensure that "original articles… come from men whose names bear the weight of authority."[36] By demarcating professional borders, physicians were, in effect, attempting to limit what could be considered the "correct" usage of electrotherapy. Similar to tDCS, physicians and companies that manufactured high-end medical electrotherapy devices did not criticize the medical battery apparatus itself or the kind of therapy it provided, rather they criticized what they perceived to be illegitimate and improper uses of the device.[37]

Divergences: tDCS and the medical battery

Focus on use on the head

One major difference between the medical battery and tDCS is that today, there is little disciplinary overlap among researchers and clinicians who utilize brain versus body stimulation: the former tend to be comprised of neuroscientists, biomedical engineers, neurologists, and psychiatrists, whereas the latter are mostly physical therapists, biologists, and chiropractors.

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[34] Lisa Rosner, "The Professional Context of Electrotherapeutics," *Journal of the History of Medicine and Allied Sciences* 43, no. 1 (January 1, 1988): 64–82, doi:10.1093/jhmas/43.1.64.

[35] Margaret Cleaves, "The Record of Four Years (1895-1899) in an Exclusively Electro-Therapeutic Clinic," n.d., Bakken Manuscript Collection.

[36] William Harvey King, "Editorial," *Journal of Electrotherapeutics* 10 (1892): 16–17.

[37] "Illustrated Catalogue of McIntosh Combined Galvanic and Faradic Battery" (McIntosh Galvanic and Faradic Battery Co, 1881), 4; "Jerome Kidder Mfg Co, Illustrated and Descriptive Catalogue of Their Superior Medical Apparatus" (Jerome Kidder Mfg Co, ca 1890), title page; "Catalogue No. 28 of Victor Electro-Surgical Apparatus" (Victor Electric Co., 1905), 49. Bakken Library Collection.

Trans*cranial* stimulation is a subfield onto itself, distinct from trans*cutaneous* stimulation. Furthermore, contemporary electric stimulation devices that are FDA approved for use on the body often contain explicit contraindications for use about the head.[38] In the consumer realm, transcutaneous electrical nerve stimulation (TENS) devices to relieve muscle and joint pain are widely available for purchase in local drugstores (without a prescription), whereas the FDA has not approved any form of cranial stimulation device for over-the-counter use.

In the late nineteenth and early twentieth century, however, there were no significant distinctions between the cranial and non-cranial use of electricity. Electrical stimulation via the medical battery was applied to whatever body part—uterus, foot, bladder—happened to be ailing. One instructional pamphlet accompanying a consumer medical battery recommended that stomach inflammation be treated by placing the "positive" (anode) on the stomach and "negative" (cathode) on the back; hemorrhoids were treated by stimulation to the anal area, toothaches by stimulation to the teeth, and so on.[39] The head was not excluded as a site of stimulation: the same pamphlet recommended cranial stimulation for apoplexy (stroke), diseases of the brain, and sunstroke, among others. Although lower levels of current and shorter stimulation sessions were recommended when current was used on the head, the brain did not have the hallowed status that it does today.

It is interesting to note that although medical catalogues contained special electrode attachments for nearly every limb and orifice, it was extremely rare to find an electrode that was specifically indicated for use about the head. **Fig. 6.6** depicts the only designated head electrode

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[38] "Chattanooga Iontophoresis 2013" (DJO Global, 2013), http://international.chattgroup.com/products/chattanooga-iontotm (accessed June 7, 2016).

[39] Edward Trevert, *Electro-Therapeutic Hand Book : With Full Directions for Home Treatment of Nearly All Diseases That Can Be Cured or Relieved by the Application of Electricity* (New York ; Chicago : Manhattan Electrical Supply Co, ca. 190-), http://archive.org/details/electrotherapeut00trev.

for the medical profession that I found over the course my research;[40] the electrode does not appear in the prior catalogue from the company, nor does a similar product appear in any of the dozens of trade catalogue that I reviewed.

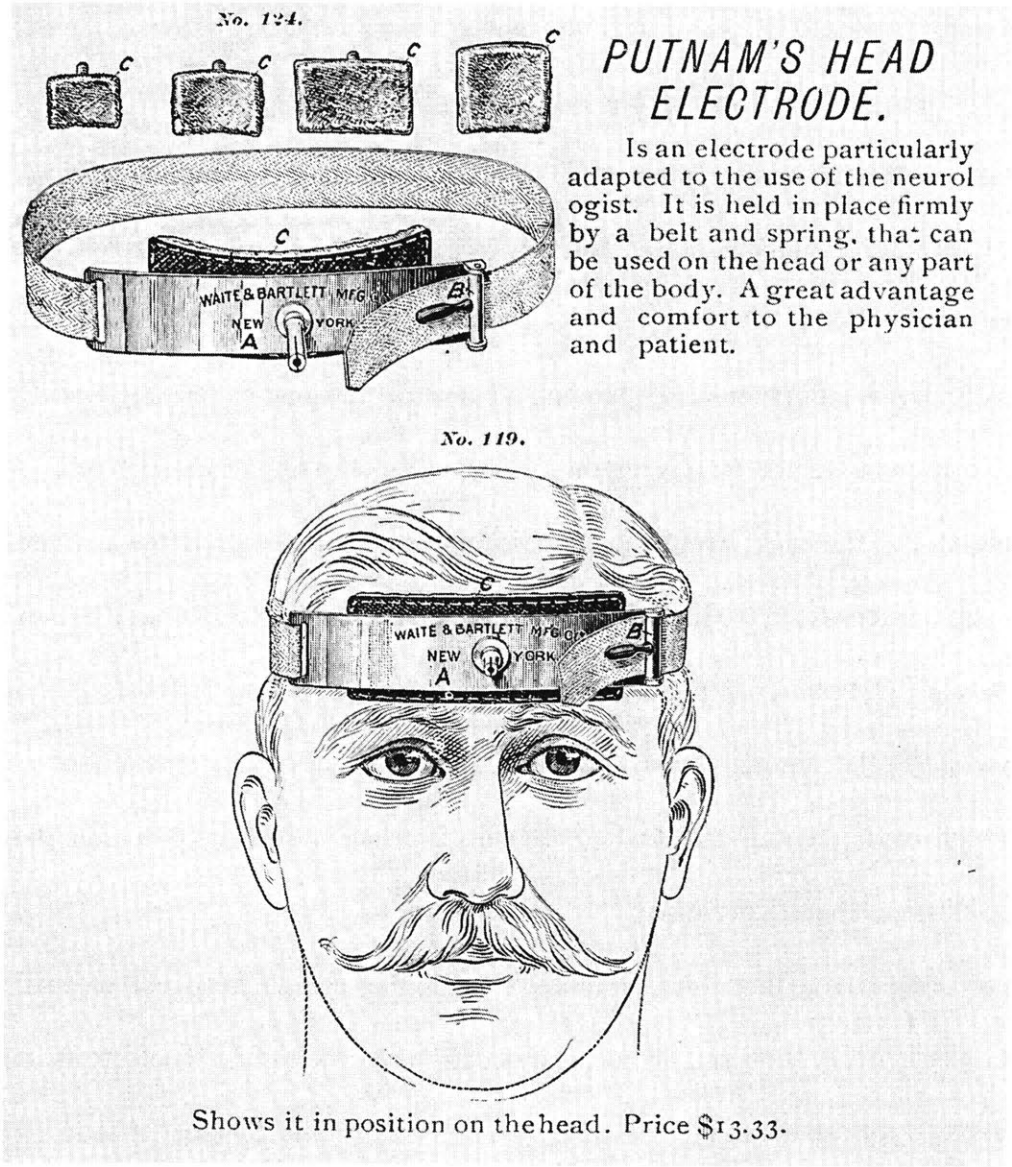


Figure 6.6. Putnam's Head Electrode, depicted in the Waite & Bartlett Mfg Co catalogue (1895-1896).

[40] Waite & Bartlett Manufacturing Co. (New York), *Illustrated Price List of Electro-Medical and Electro-Surgical Instruments for Physicians and Surgeons : 1895 & 1896* (New York : Murray Printing Co., 1896), http://archive.org/details/illustratedprice00wait.

Similarly, consumer products for use solely about the head were relatively rare, though the occasional "electric comb" or "scalp cap" was marketed for the relief of baldness.[41] Although one individual, George Francis Webb, received a patent in 1904 for a medical battery "hat" (**Fig. 6.7**) for unspecified purposes, it does not appear that the product was ever brought to market.[42]

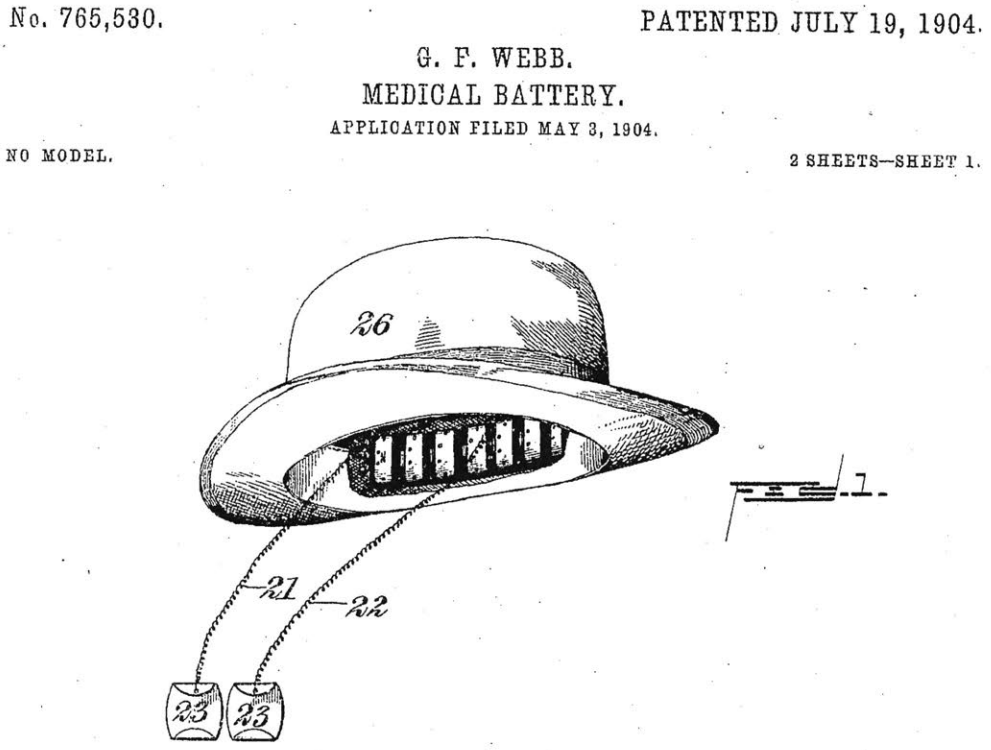


Figure 6.7. A medical battery mounted into a hat as depicted in a 1904 patent by George. F. Webb.

[41] "Riley's Electric Comb Battery" (Riley Electric Company, 1899); and The Naure Remedy Company, "Electro-Medical Scalp Cap.," 1911. Bakken Ephemera Collection.

[42] See Waits, *Medical Electricians*, and George Francis Webb, Medical Battery, US 765530 A, filed May 3, 1904, and issued July 19, 1904, https://www.google.com/patents/US765530.

Discourse of safety and risk

Today, notions of safety and risk comprise the dominant discourse surrounding the home use of brain stimulation. Indeed, the IFCN's formal position against the unsupervised home use of tDCS is based on concerns about the potential for self-harm. Such fears about the dangers of unsupervised stimulation, however, were largely absent a century ago. In fact, in the era of the medical battery, every reputable medical device manufacturer—that is, those that sold products exclusively for physicians—had a "family" or "household" battery that physicians could recommend for patients to use in their home. In many cases, the family battery was identical to models sold to physicians. That the family battery flourished for so many decades suggests that the unsupervised home use of electrical stimulation was, to a large extent, viewed as an acceptable practice by the majority of mainstream physicians.

There were, however, at least a few physicians who did not look favorably upon the unsupervised use of the medical battery: one textbook of electrical medicine cautioned that "No person should be given an apparatus with the instruction to treat himself, but the application of faradic current may, under certain circumstances, be left to a trained and trustworthy attendant."[43] In addition, Dr. William Hutchinson, a prominent physician, felt that the batteries misled families into believing that "electricity is of the nature of a non-intoxicating cocktail, to be taken at any and all times."[44] But the most vocal campaigner against family batteries was Dr. Samuel Monell, who in his 1910 book on electrotherapy, reserved harsh words for the device: "As well prescribe dried beans in a case of malaria as to 'try' a tawdry faradic battery when in need of genuine electrical treatment," he wrote. "A competent faradic apparatus costs from $50

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[43] George W. Jacoby, *A System of Physiologic Therapeutics: Electrotherapy*, ed. Solomon Solis Cohen (Philadelphia: P. Blakiston's Son & Co, 1901), 133.

[44] William F. Hutchinson, "What a Medical Practitioner Can Do With Electricity," *The Medical Times and Register* 23 (October 10, 1891): 283–85.

upwards."[45] In another work, Monell put his feelings about the medical battery more succinctly: "For in a true sense there can be no family battery; there can only be a proper use of electrical remedies when trained physicians administer them."[46]

Uses for Cognitive Enhancement

A final divergence between the medical battery and tDCS—and perhaps the most notable one—centers on the fact that while tDCS today is used at home both for treatment and cognitive enhancement, notions of electricity-related enhancement are nonexistent in the late nineteenth and early twentieth century. Indeed, the contemporary conceptualization of the brain as something that can be "hacked" in order to improve performance from a normal baseline state to an "optimized" one seems unique to the present-day context. Today, most direct-to-consumer tDCS products are marketed almost exclusively for brain optimization ("power your mind," "recharge your brain," "increase your attention span") and not treatment, likely in an attempt to avoid FDA regulation. By contrast, in the late nineteenth and early twentieth century medical batteries for consumers were marketed purely for treatment. Indeed, until the passage of the Federal Food Drug and Cosmetic Act in 1938, there were no federal regulations governing health claims made by manufacturers of medical devices, and medical battery companies could therefore freely tout the (supposed) therapeutic efficacy of their products.[47] For example, the index to an instructional pamphlet accompanying one consumer medical battery company lists

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[45] Samuel Howard Monell, *High Frequency Electric Currents in Medicine and Dentistry: Their Nature and Actions and Simplified Uses in External Treatments* (New York: W. R. Jenkins company, 1910), 131.

[46] Samuel Howard Monell, *Electricity in Health and Disease: A Treatise of Authentic Facts for General Readers* (New York: McGraw Publishing Company, 1907), 81.

[47] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. See also Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, *Food and Drug Law: Cases and Materials*, 4th ed. (St. Paul, MN: West Academic, 2014), 10-11.

75 different diseases that can be cured with electricity.[48] Similarly, physician reports on the use of the medical batteries focused solely on therapeutic treatments for a variety of diseases.

Is the notion of cognitive enhancement truly absent from the history of electrical medicine? Historian Stanley Finger has noted one early instance that may be the first recorded case of cognitive enhancement following electrical stimulation: in a 1783 letter to his friend Benjamin Franklin, Dutch physician Jan Ingenhousz described an overwhelming sense of mental clarity following an accidental electric shock.[49] Another historian, Paul Elliott, has written of a German physician who in 1803 reported that stimulation resulted in a boy becoming of "quicker mind"; however, the boy was reportedly of "deranged mind" prior to the treatment, and thus it is not clear whether the case was truly one of enhancement.[50]

In the 1920s and 1930s, after the medical battery had all but disappeared from the market, there were a number of home electrical stimulation products—of questionable efficacy—marketed directly to consumers to "rejuvenate" and "reinvigorate."[51] Although at first glance such wording seems to represents claims of enhancement, there was always an underlying implication that rejuvenation would target a sick or tired body, not a healthy one. Today, by contrast, brain enhancement carries the connotation of maximizing an extant ability (in a healthy individual) that has not been realized to its full potential. There was one product, however, that was briefly sold in the United States in 1927 and 1928 that was marketed for true cognitive

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[48] O.G. Tradewell, "Medical Electricity at Home" (Signal Electric Mfg Co, n.d.), Bakken Artifact Collection.

[49] Stanley Finger, *Doctor Franklin's Medicine* (Philadelphia: University of Pennsylvania Press, 2006), 111-114.

[50] Paul Elliott, "Electricity and the Brain: An Historical Evaluation," in *The Stimulated Brain: Cognitive Enhancement Using Non-Invasive Brain Stimulation*, ed. Roi Cohen Kadosh (San Diego: Academic Press, 2014), 3–33.

[51] de la Peña, Body Electric, 109; and James F. Stark, "'Recharge My Exhausted Batteries': Overbeck's Rejuvenator, Patenting, and Public Medical Consumers, 1924–37," *Medical History* 58, no. 4 (October 2014): 498–518.

enhancement purposes: the Konzentrator, a wearable metallic headband that was imported from Germany, and likely did not provide any current.[52] According to the advertising material, the Konzentrator "makes the brain receptive and the memory retentive"[53] and "enables you to focus power-thought upon your problems, much as a lens enables you to concentrate the sun's rays upon a focal point…"[54] In the photo accompanying the circular (**Fig. 6.8**), it is hard not to be reminded of the Thync device, a contemporary wearable electrical stimulation device that is marketed to provide either energizing or calm "vibes."[55]

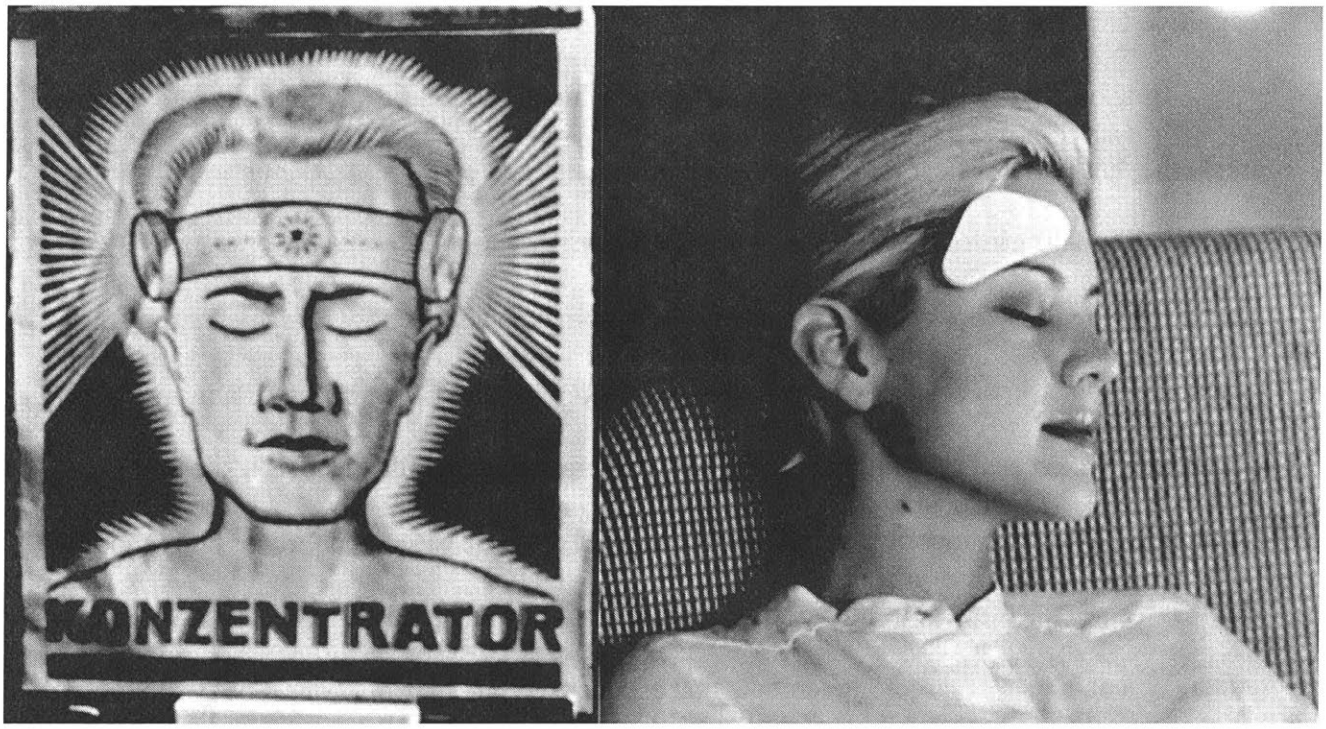


Figure 6.8. Left: advertisement for the Konzentrator, circa 1927-1928, courtesy of the American Medical Association. Right: Thync electrical stimulation device, 2015, courtesy of Thync, Inc.

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[52] Hugo Gernsback, "Thought 'Konzentrator' Latest Swindle," *Science and Invention* 15, no. 11 (1928): 981.

[53] Ibid.

[54] JE Acker, "Method of Using the Konzentrator" (Psychotechnicum, 1927), Box 0213-21, American Medical Association Historical Health Fraud Archive.

[55] "Thync," accessed June 7, 2016, http://www.thync.com.

Conclusion

Many of the characteristics that seem unique to the contemporary controversy over tDCS were also present in the era of the medical battery (and sometimes earlier): a do-it-yourself movement, anti-establishment themes, and tension between professional and lay usage of the electrical stimulation device. There are some features, however, that set the contemporary home use of tDCS apart: among the most salient are the focus on the head (and brain) instead of body, researchers' objections to unsupervised home use on the grounds of safety and risk, and uses for cognitive enhancement purposes.

It should be emphasized that the differences highlighted here are not unique to electrical medicine, but rather reflect larger societal transformations. For example, the notion of safety (and of non-maleficence) has become a cornerstone of contemporary medical practice. Even outside the medical domain, scholars have observed that society is now characterized by an obsession with risk; according to one sociologist, risk assessment has become "a more or less ever-present exercise."[56] Furthermore, the contemporary focus on the head as a site of stimulation is tied to modern conceptions of neurology and disease, wherein the brain, not the body, is viewed as the seat of mental disorders. In addition, the present-day focus on cognitive enhancement is part of larger movements that are focused on "hacking" one's body—not just one's brain—to increase productivity.

Although the medical battery continued to be sold both to physicians and consumers through the 1910s, interest in the product had begun to wane around 1905. In many ways, the decline of the medical battery followed that of electrotherapeutics as a whole; during World War

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[56] Anthony Giddens, *Modernity and Self-Identity: Self and Society in the Late Modern Age.* (Stanford: Stanford University Press, 1991).

I (1914-1917) and after, medical schools began to drop electrotherapy from their curriculums, and journals and professional organizations once dedicated to the topic were collapsed under other organizations, particularly those related to physical therapy and radiology.[57] Historians have attributed the decline of electrotherapy in the US in the 1910s to a constellation of factors: a lack of clear mechanism of action, the absence of overwhelming positive effects, and shifting interest towards newer technologies, such as X-Rays, and the rise of psychology, which located mental disorders in the mind rather than the body.[58] In the consumer realm, the home use of electrical therapies was dramatically reduced—though never entirely disappeared—due in large part to crackdowns on "quackery" by organizations like the American Medical Association, as well as the institution in the early nineteenth century of regulation governing advertising claims made by manufacturers of medical devices.[59]

The history of electrical medicine, as explicated in much of the neuromodulation literature, tends to cite advancements that are in some way relevant to modern-day practice. In that sense, history has been conceptualized as a linear, progressive march towards the present state of scientific knowledge. It may be more informative, however, to cast a broader net, and recognize that the history of electrical medicine is a continuous, meandering path, replete with both missteps and triumphs. Though the history of electrical medicine often focuses on uses in professional medical and research domains, when examined from a broader social and cultural perspective, it is evident that electrical medicine has long been adopted by "tinkerers" and

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[57] Timothy W. Kneeland and Carol A. B. Warren, *Pushbutton Psychiatry: A Cultural History of Electric Shock Therapy in America* (Walnut Creek, CA: Left Coast Press, 2008), 38.

[58] Ibid.; Rowbottom and Susskind, Electricity and Medicine; Rosner, Professional Context of Electrotherapeutics; and John L. Greenway, "'Nervous Disease' and Electric Medicine," in *Pseudo-Science and Society in Nineteenth-Century America*, ed. Arthur Wrobel (Lexington, Ky: University Press of Kentucky, 1987).

[59] Eric W. Boyle, *Quack Medicine: A History of Combating Health Fraud in Twentieth-Century America* (ABC-CLIO, 2013).

consumers outside of sanctioned medical contexts. Viewed in this light, the rise of the home use of tDCS is not novel or even surprising, rather it is the latest wave in a series of ongoing attempts by lay individuals to utilize electricity for therapeutic purposes.

CHAPTER 7

Conclusion

In the introductory chapter to *Electric Bodies* (2001), a collection of essays that emerged from a workshop on the history of medical electricity, historians Paola Bertucci and Giuliano Pancaldi reflect on how the workshop participants "reacted with some surprise" to the similar themes that arose in each other's work: "It was as if, phoenix-like, the interaction of medicine and electricity in the long period under consideration had different lives, each one firmly rooted in the specific context in which it emerged, yet sharing features that continued to emerge again and again."[1]

In one sense, the story of tDCS fits neatly as an additional chapter in *Electric Bodies*: a "new" electrical medical technology arises, generating hope that an easy, cheap, and effective medical cure has finally been discovered. In both the media and scholarly articles, the new technology is portrayed as novel and innovative; links to "failed" or stigmatized electrotherapeutic technologies of the past are obscured and concealed (knowingly or unknowingly). There is a quick build-up of hype, resulting in a sharp increase in studies utilizing the technique, as shown in **Fig. 1.3**. Though the end of the tDCS story has not yet been written—the "hype" phase is still in full swing—by turning to the history of medical electricity, we can

[1] Paola Bertucci and Giuliano Pancaldi, eds., *Electric Bodies: Episodes in the History of Medical Electricity* (Bologna: Università di Bologna, 2001), 14.

surmise that it will not be smooth sailing: as historian Iwan Rhys Morus notes, medical electricity does not have an "easily-told story of emergence, consolidation and celebration."[2]

Indeed, hints at potential struggles over consolidation have been evident at neurostimulation conferences, where occasionally a presenter—usually from outside the core group of those who research electrical brain stimulation—will emphasize that tDCS has no known mechanism of action. In other words, although scientists have collected observations across studies—for example, after administering tDCS, more patients experience some relief from depression than those who do not—there is no plausible explanation for how such effects may be occurring.[3] Originally it was thought that the weak levels of current administered in tDCS stimulation lower the neuronal firing threshold, essentially making it "easier" for neurons to fire, but this explanation has largely been abandoned as it cannot explain certain variations, such as those observed across different levels of current and different lengths of stimulation sessions.[4]

There are also numerous open questions in the field: does tDCS need to be administered before or during a task for there to be an observed effect on cognition? Does a subject need to be actively practicing a cognitive task while being administered stimulation in order for an effect to be observed? Are the effects of tDCS replicable across small sample size studies, and if not, why? Could tDCS potentially be effective not because it is stimulating a specific brain region,

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[2] Ibid., 11.

[3] See discussion in Simon J. Pelletier and Francesca Cicchetti, "Cellular and Molecular Mechanisms of Action of Transcranial Direct Current Stimulation: Evidence from In Vitro and In Vivo Models," *International Journal of Neuropsychopharmacology* 18, no. 2 (2015).

[4] See ibid for discussion. To be more precise, previous studies observed that anodal stimulation—that is, where the current flowing in—increased cortical excitability (i.e., making it easier for neurons to fire) and cathodal stimulation decreased neuronal excitability, causing the opposite effect. But as discussed in Pelletier and Cichetti (2015; ibid) and other sources, this explanation has not explained the variations observed across many studies.

but rather because it may be targeting regions known to be related to the placebo effect—perhaps "amplifying" the placebo effect?[5] Is electrical current actually reaching the brain at all, or is it perhaps being transferred across the skull and affecting cranial nerves, thereby increasing "arousal" (i.e., attention) to a given task? Although a clear mechanism of action is not always needed for a given therapy to achieve closure—for example, deep brain stimulation is now considered to be an effective treatment for Parkinson's disease, despite the lack of known mechanism of action—having one certainly helps.

In *Electric Bodies,* Bertucci and Pancaldi note that the most salient similarity across historical time periods is that since the mid-eighteenth century, "practitioners of medical electricity had to fight hard to carve out and hold on to a niche for themselves, in the absence of a recognized field of expertise within the medical profession, and lacking the support of an accepted disciplinary or sub-disciplinary field established within the natural sciences."[6] Indeed, the essays in *Electric Bodies* show how electrical medicine has been engaged in a continuous struggle for credibility, with practitioners striving for acceptance from general medical professionals and fighting off "incursions" from irregular medical practitioners.

The story about tDCS that I have told in this dissertation, however, is not one of struggling for broader professional acceptance or fending off encroachment from irregular practitioners. In fact, tDCS has achieved a certain measure of professional legitimacy: research utilizing the technique is being conducted at top research universities around the world, U.S. federal funding bodies award grants for tDCS research, and studies utilizing tDCS are published in "mainstream" neuroscience journals. Though tDCS is indeed used by some alternative

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[5] H. M. Schambra et al., "It's All in Your Head: Reinforcing the Placebo Response With tDCS," *Brain Stimulation: Basic, Translational, and Clinical Research in Neuromodulation* 7, no. 4 (July 1, 2014): 623–24.

[6] Bertucci and Pancaldi, *Electric Bodies*, 14.

practitioners—this is a subject of my ongoing research—nearly all "professional" tDCS researchers I have spoken to are unaware of these alternative uses, and such uses are therefore not a subject of debate or controversy.

Rather, what this dissertation has focused on—and where it diverges from the historical episodes in *Electric Bodies*—is the "incursion" by *lay individuals*, both as described in the practices of the home use of tDCS (in Chapters 2 and 3), the marketing of stimulation devices for home use (Chapter 4), the home use of the medical battery in the U.S. in the late nineteenth and early twentieth century (Chapter 5), and a comparison of historical home uses of electricity for therapeutic purposes to present-day uses of tDCS (Chapter 6). While previous work, therefore, has focused on two main struggles of electrical medicine practitioners—on the one hand, their attempts to gain acceptance from broader professional medical societies, and on the other, their efforts to distinguish "legitimate" electrical medicine from that practiced by alternative or irregular medical practitioners—this dissertation has centered on the challenges presented to electrical medicine by lay users: a dispersed, informal set of individuals that have no formal relationship with one another.

As I discuss in this dissertation, the home or "do-it-yourself" use of tDCS is not the first instance of lay users interacting with knowledge produced by professional researchers; scholars have previously documented how lay individuals, mostly comprised of patient groups (e.g., those related to AIDS, muscular dystrophy, post-traumatic stress disorder, and sudden infant death syndrome)[7] have in many cases gained sufficient credibility to influence the direction of medical

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[7] Steven Epstein, "The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials," *Science, Technology & Human Values* 20, no. 4 (October 1, 1995): 408–37; and Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (Berkeley, Calif.: University of California Press, 1996); M. Callon and V. Rabeharisoa, "Research 'in the Wild' and the Shaping of New Social Identities," *Technology in*

research or affect a political outcome. Related scholarship has examined how lay individuals and professional researchers differ in their "ways of knowing."[8]

In this dissertation, I argued that the home use of tDCS differs in a number ways from previous examples of lay interaction with scientific knowledge. First, I showed how home users of tDCS were different from the "patient activists" that have been previously been described, as their main aim is self-improvement, not influencing the direction of medical research or achieving a political outcome. Home users have also not successfully formed alliances with professional researchers. On the contrary, professional researchers view home users as a kind of threat to their reputation, and have attempted to set their practices apart by referring to the lay use of tDCS as "unorthodox" and by calling for regulation to control the availability of consumer tDCS devices. Though home users may in fact be "experts of experience," at this point professional tDCS researchers have not recognized this kind of expertise amongst home users.

Previous studies on the interaction between lay individuals and professional scientists have shown how lay individuals can challenge "normal science," by highlighting inconsistencies within the research literature. I demonstrated how this was case with regard to the home use of tDCS: where lay individuals feel that there are "gaps" in the scientific literature, or where they feel that established stimulation parameters are arbitrary, they experiment and extrapolate. For example, rather than sticking to one twenty-minute session every few days, home users stimulate their brains with longer and more frequent sessions.

Society, Studies in Science, Technology, and Society (STS) North and South, 25, no. 2 (April 2003): 193–204; Wilbur J. Scott, "PTSD in DSM-III: A Case in the Politics of Diagnosis and Disease," *Social Problems* 37, no. 3 (August 1, 1990): 294–310, doi:10.2307/800744; Michael P. Johnson and Karl Hufbauer, "Sudden Infant Death Syndrome as a Medical Research Problem Since 1945," *Social Problems* 30, no. 1 (October 1, 1982): 65–81).

[8] Phil Brown, "Popular Epidemiology and Toxic Waste Contamination: Lay and Professional Ways of Knowing," *Journal of Health and Social Behavior* 33, no. 3 (1992): 267.

In the last four years, the home use of noninvasive brain stimulation has become a major topic of discussion in the bioethics literature; ethicists have expressed concerns related to safety, distributive justice, autonomy and authenticity. Yet as Voarino et al. (2017) point out in their comprehensive review of the bioethical literature, each of these concerns rest on underlying factual assumptions—mainly regarding prevalence, efficacy and safety—for which there has been little empirical evidence.[9] Therefore, the comprehensive survey my collaborator and I conducted as part of this dissertation aimed to better understand if the concerns outlined in bioethics literature are supported by existing evidence.

We provided the first estimate of number of tDCS devices sold, and found no evidence that the home use of tDCS was increasing or may achieve widespread social uptake. We showed that home users who utilize tDCS for treatment rate it as significantly more effective than those who use it for enhancement/restoration, even though the discussion of enhancement has comprised the main focus of debates in the bioethics literature. We identified two primary safety concerns—skin burns and the unknown effects of the chronic use of tDCS—that should be the target of future ethical and policy discussions. Thus, it seems that while some issues identified in the bioethics literature—such as threats to autonomy due to potential coerced used of tDCS, and issues of authenticity—are less relevant and highly speculative, others, such as concerns about potential harm to home users and issues related to distributive justice, are empirically supported.

Among the most notable findings in the study was that approximately one-third of all those who had purchased and used a tDCS device on themselves did so to treat depression; yet, the border between what users considered treatment and enhancement was slippery. The study

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[9] Nathalie Voarino, Veljko Dubljević, and Eric Racine, "tDCS for Memory Enhancement: Analysis of the Speculative Aspects of Ethical Issues," *Frontiers in Human Neuroscience* 10 (2017), doi:10.3389/fnhum.2016.00678.

also presented the first examination of those who quit tDCS, showing that the most common reason for stopping tDCS was lack of efficacy. We also found that the tDCS subreddit—which had been the focus of previous studies of tDCS—should not be taken to be representative of home users of tDCS, as nearly half of respondents to the survey had never once visited the forum. Furthermore, we showed that a small percentage of individuals use tDCS on others, and provided an initial description of their usage practices: namely, that the majority use tDCS on family members, most commonly children or spouses, for treatment purposes.

This dissertation also provided a pragmatic, empirically grounded analysis of a hotly debated topic—the regulation of consumer tDCS devices. Although scientists and ethicists had proposed that there was a need for additional regulation to cover consumer tDCS devices, I argued that much of the existing literature neglected to consider current legal frameworks and factors such as the practical feasibility of implementation (i.e., the procedures, costs, and length of time required to modify regulation), the precise targets of regulation (exactly which devices additional regulation would affect, and how); and possible social implications (such as the possibility that home users might go further "underground" in response to a regulatory push). I argued that modifying a regulatory framework to questionably encompass a small sliver of devices that have yet to cause any serious adverse effects was both impractical and unrealistic. Rather than their being a "regulatory gap," I showed that there are in fact multiple, distinct pathways by which consumer tDCS can be regulated in the United States.

My research also presented a broader historical context for the home use of noninvasive brain stimulation. I examined the history of a portable shock-producing electrotherapeutic device known as the medical battery (1870-1920), which was used to provide electrical treatments in the home and clinic for nearly five decades and was thought to cure a wide variety of ailments.

Though companies marketed medical batteries primarily to either consumers or physicians, I demonstrated that the lines between what was considered a consumer product and a medical device were often muddled.

Most striking was the existence of the "family battery," a product that was sold by every major electromedical instrument manufacturer, yet aimed at non-physicians for the purposes of self-administering electrical stimulation. Although mentions of patients self-administering electricity are almost entirely absent from medical textbooks and journals, existing evidence—both from the long life of the family battery as well as from criticism that emerged from a handful of physicians—suggests that many physicians were indeed recommending that their patients self-administer electricity at home, whether via the family or consumer battery. While there were some physicians who were vocal against the use of electricity by lay individuals—as they felt it undermined the image of electrotherapy as a skilled procedure—evidence suggests that many were probably recommending the home use of medical electricity to their patients. Thus, I demonstrated how the professional ideals of electrotherapeutics were not always aligned with physicians' actual practices.

In addition, I showed how many of the characteristics that seem unique to the contemporary controversy over tDCS were also present in the era of the medical battery (and sometimes earlier): a do-it-yourself movement, anti-establishment themes, and tension between professional and lay usage of the electrical stimulation device. I argued, however, that there are some features that set the contemporary home use of tDCS apart: among the most notable are the focus on the head (and brain) instead of body, researchers' objections to unsupervised home use on the grounds of safety and risk, and uses for cognitive enhancement purposes.

I emphasized that the differences highlighted were not necessarily unique to electrical medicine, but rather reflected broader societal transformations. For example, the notion of safety (and of non-maleficence) has become a mainstay of medical practice. Scholars have written about how society is now characterized by an obsession with risk; according to Anthony Giddens, risk assessment has become "a more or less ever-present exercise."[10] Moreover, the present-day focus on the head as a site of stimulation is tied to modern notions of neurology and disease, wherein the brain, not the body, is viewed as the center of mental disorders. Furthermore, the focus on cognitive enhancement is part of larger movements that are focused on "hacking" one's body—not just one's brain—to increase productivity.

The history of electrical medicine, as discussed in much of the neuromodulation literature, is often conceptualized as a forward march towards the present "correct" state of scientific knowledge. Historians, however, have recognized that the history of electrical medicine is a continuous, meandering path, replete with both missteps and triumphs, and characterized by ongoing struggles for credibility and acceptance. This dissertation has highlighted one particular challenge—the lay or "DIY" use of electricity. While the lay use of electricity has not been the focus of historical work of electrical medicine, a closer look reveals that it has long been adopted by "tinkerers" and consumers outside of sanctioned medical contexts. I concluded by noting that when viewed in the long durée, the home use of tDCS is not novel or even surprising; rather it is the latest wave in a series of ongoing attempts by lay individuals to utilize electricity for therapeutic purposes.

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[10] Anthony Giddens, *Modernity and Self-Identity: Self and Society in the Late Modern Age.* (Stanford: Stanford University Press, 1991).

In the very first Table (**1.1**) of this dissertation, I showed how there were two groups using the same technology in different ways. Throughout this work, I have demonstrated that while home users rely heavily on the output of scientists, the information transfer has been unidirectional. That is, home users have drawn heavily upon the work of scientists, but scientists have not acknowledged that home users might have any expertise of value, and to the contrary, they have mostly warned against the home use of tDCS.

Yet, in July 2016, a group of scientists communicated directly with home users for the first time, in an open letter published in the *Annals of Neurology*.[11] The letter, which was authored by four neuroscientists and signed by 39 other researchers, outlined what is known and unknown about the safety of noninvasive brain stimulation, and asks users to give careful consideration to the risks. Though the letter is, on its surface, about safety, in a more significant way, it is a recognition that home users are here to stay, at least for now. It is a tacit acknowledgement of the two groups' uneasy co-existence; while the letter does not condone, it does not condemn. It sticks to the facts—outlining what studies have shown—and is admirably restrained, eschewing paternalistic tones in favor of measured ones. The letter also represents the first time that scientists have directly addressed the DIY movement; though it is not quite an olive branch, it is a commendable step forward, one that demonstrates a keen social awareness.

The letter—and the conflict over tDCS technology more generally—are occasion to reflect on the attempts by DIY and citizen science movements to democratize (and sometimes commercialize) techniques and information previously sequestered in the "ivory tower" of academia. These movements partially stem from growing societal frustration with the institutions of modern medicine, including the exorbitant price of pharmaceuticals and the glacial pace at

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[11] Rachel Wurzman et al., "An Open Letter Concerning Do-It-Yourself Users of Transcranial Direct Current Stimulation," *Annals of Neurology* 80, no. 1 (2016): 1–4.

which new therapies trickle down to patients. The self-administration of tDCS, as well as the sharing of restricted journal articles in real-time, is an inherently political act against the scientific community's tendency to restrict knowledge and devices to a privileged few: without an institutional affiliation, the price of a journal article is prohibitively expensive.

The open letter represents an important step in the scientific community coming to terms with the existence of parallel movements and the democratization of scientific knowledge. Such DIY and "lay" movements will likely only grow with advances in information and communication technology, and it is important to recognize their staying power. Rather than steadfastly warning of the dangers of such endeavors, harm-reduction strategies and open engagement approaches may ultimately prove more effective.

Appendix

A. Text of recruitment and reminder emails for consumer tDCS device survey

B. Consumer tDCS survey instrument

Appendix A

Text of recruitment and reminder emails for consumer tDCS device survey

1. Recruitment email

Subject: MIT Survey on Consumer tDCS Devices

Interest in brain stimulation technology is rapidly increasing, and MIT researchers are interested in learning more about how people use this technology at home. They are currently conducting the largest survey to-date on how people use—or don't use—consumer tDCS devices. We have chosen to partner with them in this research project. **They are interested in responses from *all* of our customers: regular users, occasional users, former users, and even those who never tried the device at all.**

Click here to complete the survey, which should take approximately 15 minutes. Note that this link is specific to those who have purchased one of our devices.

The survey will be open for 30 days (until July 15, 2016) but we encourage you to complete it at your earliest convenience. Your responses will help provide important data on the home use of brain stimulation technology.

Thank you!

2. Reminder email

Subject: MIT Survey on Consumer tDCS Devices

Reminder email: Just a reminder that the MIT Survey on Consumer tDCS Devices expires next week (July 14)! This is the largest survey to-date on how people use—or don't use—consumer tDCS devices. **The researchers are interested in responses from all of our customers: regular users, occasional users, former users, and even those who never tried the device at all.**

Click here to take the survey, which should take approximately 15 minutes. Note that this link is specific to those who have purchased one of our devices.

Your responses will help provide important data on the home use of brain stimulation technology.

Thank you!

Appendix B

Consumer tDCS Survey Instrument

You have been invited to participate in this study because you have purchased a transcranial direct current stimulation (tDCS) device.

Purpose of the Study: This study is being conducted by researchers at the Massachusetts Institute of Technology (MIT) to better understand the usage patterns of consumers who purchase tDCS devices.

Procedures: You will be asked to complete a brief questionnaire related to the purchase and use of your tDCS device. The questionnaire will take approximately 15 minutes or less.

Participation: Participation in this research study is completely voluntary. You may decline further participation at any time.

Compensation: There is no compensation for participating. However, it is hoped that through your participation, researchers will learn more about how individuals utilize tDCS devices.

Risks: There are no known risks associated with this study.

Confidentiality: All data obtained from participants will be kept confidential and will only be reported in an aggregate format (by reporting only combined results and never reporting individual ones). The results of this study may be published in scientific journals and presented at scientific conferences. In addition, the results of this study may be shared with consumer tDCS device manufacturers in an anonymized format.

Questions about the Research : If you have questions regarding this study, you may contact Anna Wexler (annaw@mit.edu) at any time. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143b, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253-6787.

I have read and understood the above consent form and choose to participate in this study.

- ○ Yes
- ○ No

1. Which of the following have you owned? Please select all that apply.

- ❑ ActivaDose II (Iontophoresis device)
- ❑ Apex type A
- ❑ BioCurrent Kit (2013)
- ❑ Brain Driver
- ❑ Brain Stimulator
- ❑ Caputron direct current source
- ❑ Chattanooga Ionto (Iontophoresis device)
- ❑ Cognitive Kit (2014-present)
- ❑ Foc.us v1
- ❑ Foc.us v2
- ❑ Foc.us GoFlow
- ❑ HaloSport
- ❑ MindAlive tDCS device
- ❑ NeuroConn DC Stimulator
- ❑ Neurofield tDCS/tACS
- ❑ Neurozapper
- ❑ PriorMind
- ❑ Soterix 1x1 tDCS
- ❑ SuperSpecific Devices tDCS unit
- ❑ tDCS Home Device Kit (2012-2013)
- ❑ tDCS-Kit (http://www.tdcs-kit.com
- ❑ tDCS-Ultra
- ❑ Thync
- ❑ TransCranial Technologies Stimulator (http://www.trans-cranial.com/tct/)
- ❑ Zwik QuickBrain
- ❑ home-built device
- ❑ other _____

2. Approximately how much did you pay for your device(s) in US dollars, including shipping and any accessories that you needed?

[*device(s) selected on Question 1*] .... [*numerical input]*

3. When did you purchase (or make) [*device(s) selected on Question 1*]?

[*device(s) selected on Question 1*] …. [*month/year input]*

4. Where did you purchase [*device(s) selected on Question 1*]?

- ❍ Directly from the company
- ❍ From a medical professional
- ❍ Caputron
- ❍ Ebay
- ❍ Amazon
- ❍ Other

5. What do you like most about [*device(s) selected on Question 1*]?

[text entry]

6. What do you dislike most about [*device(s) selected on Question 1*]?

[text entry]

7. Where did you first hear about tDCS? Please be as specific possible and include names of any newspapers, articles, and/or websites.

[text entry]

8. We are now going to ask you some general questions about your experiences with tDCS. Which of the following best describes your thoughts when purchasing or making a tDCS device?

- ❍ I intended to use tDCS primarily on myself.
- ❍ I intended to use tDCS primarily on others.

➔ If "primarily on myself" in selected, participants are skipped to Question 36.
➔ Those who select on "primarily on others" continue below.

9. Why did you want to use tDCS? Please be as specific as possible.

[text entry]

10. How many times have you administered tDCS to others?

- ○ Never
- ○ At least once

➔ If "never" is selected:

10A. Why did you never administer tDCS to others?

[text entry]

10B. Is there any reason why you would start administering tDCS to others?

[text entry]

➔ Then skip to Question 53.

11. To whom have you administered tDCS? Please select all that apply.

- ☐ friends
- ☐ family
- ☐ research subjects
- ☐ patients/clients
- ☐ other: _____

➔ If "family" is selected:

11A. Which family member(s) have you administered tDCS to?

- ☐ Child
- ☐ Parent
- ☐ Sibling (3)
- ☐ Spouse/partner
- ☐ Grandparent
- ☐ Grandchild (13)
- ☐ Aunt/uncle (14)
- ☐ Niece/nephew (15)
- ☐ Cousin (16)
- ☐ Other relative (17)

➔ If "patients/clients" is selected:

11B. You have indicated that you have administered tDCS to patients/clients. What is your medical/therapeutic background?

[text entry]

12. For what purpose did you administer tDCS to [*individual(s) selected in question 13*]?

[text entry]

13. Have you administered tDCS to others to treat a medical/psychological disease or condition?

- ○ Yes
- ○ No

➔ If "Yes" is selected:
13A. For which medical/psychological disease(s) and/or condition(s) have you administered tDCS?

- ❑ ADD/ADHD
- ❑ Addiction
- ❑ Anxiety
- ❑ Autism
- ❑ Bipolar disorder
- ❑ Chronic Pain
- ❑ Dementia
- ❑ Depression
- ❑ Epilepsy
- ❑ Migraine
- ❑ Schizophrenia
- ❑ Tinnitus
- ❑ Other _____

14. Have you administered tDCS to others to restore diminished abilities (for example, to counteract the effects of aging)?

- ○ Yes
- ○ No

➔ If "Yes" is selected:

14A. Which abilities did you target in these cases?

[text entry]

15. Have you administered tDCS to others to improve abilities in an otherwise healthy individual?

- ○ Yes
- ○ No

➔ If "Yes" is selected:

15A. Which abilities did you target in these cases?

[text entry]

16. To approximately how many people have you administered tDCS?

[numerical input]

17. How many sessions of tDCS, on average, have you administered to each person? Please enter a number.

[numerical input]

18. How did you learn which stimulation parameters to use?

[text entry]

19. We're now going to ask you a few question about your preferred stimulation parameters. Which montages have you utilized on others?

[text entry]

20. What level of current do you typically use on others (in milliamps)? Please enter a number.

[numerical input]

21. What is the typical length of stimulation session (in minutes)? Please enter a number.

[numerical input]

22. Did you attempt to measure or quantify the effects that tDCS had on those to whom you administered stimulation?

- ❍ Yes
- ❍ No

23. Do you feel that tDCS worked for its intended purpose?

- ❍ Definitely yes
- ❍ Probably yes
- ❍ Not sure
- ❍ Probably not
- ❍ Definitely Not

24. Please explain your answer.

[text entry]

25. Did tDCS cause any unwanted side effects on those you administered it to? Please explain.

[text entry]

26. When did you start administering tDCS to others?

[month/year input]

27. How often do you currently administer tDCS to others?

- ❍ frequently (more than three sessions per week)
- ❍ several times a month
- ❍ in fits and spurts
- ❍ I no longer use tDCS

➔ If "I no longer use tDCS" is selected:
27A. Please describe how frequently you used tDCS in the past. (For example, "I initially used tDCS daily for 3 months, then used it several times a month for the next 8 months.")

[text entry]

27B. Why did you stop using tDCS on others?

[text entry]

27C. Is there any reason why you would start using tDCS again? Please specify if so.

[text entry]

➔ Then skip to Question 30.

28. You indicated that you use tDCS [*frequency selected in Question 27*]. Has your frequency of use changed since you began using tDCS?

- ❍ Yes
- ❍ No

29. Please describe how frequently you used tDCS in the past. (For example, "I initially used tDCS daily for 3 months, then used it several times a month for the next 8 months.")

[text entry]

30. Have you administered any of the following to other individuals? Please select all that apply.

- ❑ Audio visual entrainment (AVE) therapy
- ❑ Binaural beats
- ❑ Biofeedback (excluding neurofeedback)
- ❑ Cranial electrotherapy stimulation (CES)
- ❑ Electroconvulsive therapy (ECT)
- ❑ Neurofeedback
- ❑ Prescriptions for pharmaceuticals
- ❑ Pulsed electromagnetic field therapy (PEMF)
- ❑ Transcranial alternating current (tACS)
- ❑ Transcranial magnetic stimulation (TMS)
- ❑ Transcranial random noise stimulation (tRNS)
- ❑ Transcutaneous electrical nerve stimulation (TENS)
- ❑ Transcutaneous vagus nerve stimulation (tVNS)
- ❑ Other _____

31. The previous questions asked about how you've used tDCS on other individuals. We are now going to ask you a set of questions about how you have used tDCS on yourself, if applicable.

Have you ever used tDCS on yourself?

- ❍ Yes
- ❍ No

➔ If "no" is selected, skip to Question X.

32. Approximately how many times have you administered sessions of tDCS to yourself? Please enter a number.

[numerical entry]

33. Why did you want to use tDCS on yourself? Please be as specific as possible.

[text entry]

34. How often do you currently use tDCS?

- ❍ frequently (more than three sessions per week)
- ❍ several times a month
- ❍ in fits and spurts
- ❍ I no longer use tDCS

➔ If "I no longer use tDCS" is selected:

34A. How would you characterize your former use of tDCS on yourself? In particular, we are interested in how long you used tDCS at different frequencies. (For example, "I initially used tDCS several times a week for 3 months, then stopped using it.")

[text entry]

34B. Why did you stop self-administering tDCS?

[text entry]

34C. Is there any reason why you would start self-administering tDCS again? Please specify if so.

[text entry]

➔ Then skip to Question 53.

35. You indicated that you self-administer tDCS [*frequency selected in Question 34].* Have your usage patterns changed since you began using tDCS?

- ❍ Yes
- ❍ No

➔ If "Yes" is selected:

35A. Please describe how frequently you used tDCS on yourself in the past. (For example, "I initially used tDCS daily for 3 months, then used it several times a month for the next 8 months.")

[text entry]

➔ Then skip to Question 53.

36. Why did you purchase a tDCS device? Please be as specific as possible.

[text entry]

37. How many times have you administered tDCS to yourself?

- ○ Never
- ○ At least once

➔ If "Never" is selected:

37A. Why did you never use tDCS?

[text entry]

37B. Is there any reason why you would start using it?

[text entry]

➔ Then, skip to Question 53.

38. Have you self-administered tDCS to treat a medical/psychological disease or condition?

- ○ Yes
- ○ No

➔ If "Yes" is selected:

38A. For which medical/psychological disease(s) or condition(s) have you self-administered tDCS?

- ☐ ADD/ADHD
- ☐ Addiction
- ☐ Anxiety
- ☐ Autism
- ☐ Bipolar disorder
- ☐ Chronic Pain
- ☐ Dementia
- ☐ Depression
- ☐ Epilepsy
- ☐ Migraine
- ☐ Schizophrenia
- ☐ Tinnitus
- ☐ Other _____

39. Have you self-administered tDCS to restore diminished abilities (for example, to counteract the effects of aging)?

- ❍ Yes
- ❍ No

➔ If "Yes" is selected:

39A. Which abilities did you attempt to restore?

[text entry]

40. Have you self-administered tDCS to improve "normal" abilities?

- ❍ Yes
- ❍ No

➔ If "Yes" is selected:

40A. Which abilities did you attempt to improve?

[text entry]

41. Approximately how many times have you administered tDCS to yourself? Please enter a number.

[numerical entry]

42. How did you learn which stimulation parameters to use?

[text entry]

43. We're now going to ask you a few question about your preferred stimulation parameters. Which montages have you utilized (if applicable)?

[text entry]

44. What level of current do you typically use (in milliamps)? Please enter a number.

[numerical entry]

45. What is the typical length of stimulation session (in minutes)? Please enter a number.

[numerical entry]

46. Did you attempt to measure or quantify the effects that tDCS had on you? If yes, please describe how you did so.

[text entry]

47. Did you experience any unwanted side effects from tDCS? If yes, please describe.

[text entry]

48. To what extent did you feel that your use of tDCS was successful?

- ❍ Totally unsuccessful
- ❍ Somewhat unsuccessful
- ❍ Not Sure
- ❍ Somewhat successful
- ❍ Totally successful

49. Please explain your answer.

[text entry]

50. When did you start using tDCS?

[month/year input]

51. How often do you currently use tDCS?

- ❍ frequently (more than three sessions per week)
- ❍ several times a month
- ❍ in fits and spurts
- ❍ I no longer use tDCS

➔ If "I no longer use tDCS" is selected:

51A. Why did you stop using tDCS?
[text entry]

51B. Please describe how frequently you used tDCS in the past. (For example, "I initially used tDCS several times a week for 3 months, then stopped using it.")

[text entry]

51C. Is there any reason why you would start using tDCS again? Please specify if so.

[text entry]

➔ Then skip to Question 53.

52. You indicated that you use tDCS [*frequency selected in Question 51*]. Has your frequency of use changed since you began using tDCS?

- ❍ Yes
- ❍ No

➔ If "Yes" is selected:
52A. Please describe how frequently you used tDCS in the past. (For example, "I initially used tDCS daily for 3 months, then used it several times a month for the next 8 months.")

[text entry]

53. Have you used any of the following on yourself at home? Please select all that apply:

- ❑ Audio visual entrainment (AVE) therapy
- ❑ Binaural beats
- ❑ Brain-training games (e.g., Lumosity or CogniFit)
- ❑ Cranial electrotherapy stimulation (CES)
- ❑ Consumer electroencephalography (EEG) device (e.g., Emotiv Insight or Muse)
- ❑ Dietary supplements or non-prescription drugs to improve cognition
- ❑ Prescription drugs to improve cognition
- ❑ Self-tracking tools to help optimize some aspect of my life (e.g., sleep or productivity)
- ❑ Self-tracking tools to help cope with a disease/condition
- ❑ Transcranial alternating current (tACS)
- ❑ Transcranial random noise stimulation (tRNS)
- ❑ Transcutaneous electrical nerve stimulation (TENS)
- ❑ Transcutaneous vagus nerve stimulation (tVNS)
- ❑ Other _____

54. Has a therapist or medical practitioner administered any of the following to you? Please select all that apply.

- ❑ Audio visual entrainment (AVE) therapy
- ❑ Binaural beats
- ❑ Biofeedback (excluding neurofeedback)
- ❑ Cranial electrotherapy stimulation (CES)
- ❑ Electroconvulsive therapy (ECT)
- ❑ Neurofeedback
- ❑ Prescriptions for pharmaceuticals
- ❑ Pulsed electromagnetic field therapy (PEMF)
- ❑ Transcranial alternating current (tACS)
- ❑ Transcranial magnetic stimulation (TMS)
- ❑ Transcranial random noise stimulation (tRNS)
- ❑ Transcutaneous electrical nerve stimulation (TENS)
- ❑ Transcutaneous vagus nerve stimulation (tVNS)
- ❑ Other _____

55. Are you familiar with the tDCS Subreddit (www.reddit.com/r/tDCS)?

- ❍ No, I have not heard of it
- ❍ Yes, I have heard of it, but never visited
- ❍ Yes, I have visited (or currently visit) the website on occasion
- ❍ Yes, I have visited (or currently visit) the website frequently

➔ If any of the three "Yes" options are selected:
55A. How often do you post to the tDCS Subreddit (now or in the past)?

- ❍ Never
- ❍ Rarely
- ❍ Occasionally
- ❍ A moderate amount
- ❍ A great deal

56. Please rate the extent to which you agree or disagree with the following statements.

	Strongly agree (1)	Somewhat agree (2)	Neither agree nor disagree (3)	Somewhat disagree (4)	Strongly disagree (5)
People don't use their brains to their fullest potential.	❍	❍	❍	❍	❍
Mainstream medicine is often out of touch with the needs of patients.	❍	❍	❍	❍	❍
The brain is an organ that can be "hacked" to improve performance.	❍	❍	❍	❍	❍
tDCS is a relatively safe technique.	❍	❍	❍	❍	❍
People only use a small percentage of their brains.	❍	❍	❍	❍	❍
I value alternative medicine practices.	❍	❍	❍	❍	❍
tDCS should remain available to the public.	❍	❍	❍	❍	❍
I expected to get more from tDCS than I actually did.	❍	❍	❍	❍	❍
tDCS should not be used on children.	❍	❍	❍	❍	❍
I identify with the DIY tDCS movement.	❍	❍	❍	❍	❍

57. Please rate the extent to which you agree or disagree with the following statements.

	Strongly agree (1)	Somewhat agree (2)	Neither agree nor disagree (3)	Somewhat disagree (4)	Strongly disagree (5)
tDCS should not be used without supervision/guidance from a trained professional.	❍	❍	❍	❍	❍
I learned most of what I know about tDCS from my colleagues.	❍	❍	❍	❍	❍
The media blows the issue of do-it-yourself tDCS out of proportion.	❍	❍	❍	❍	❍
Direct-to-consumer tDCS devices are merely novelty items.	❍	❍	❍	❍	❍
Government regulations should control the technical features (e.g., current output) of direct-to-consumer devices.	❍	❍	❍	❍	❍
The risks of using tDCS at home outweigh the benefits.	❍	❍	❍	❍	❍
Left-brained people are more rational and scientific, whereas right-brained people are more creative and artistic.	❍	❍	❍	❍	❍
Drugs and alcohol kill brain cells.	❍	❍	❍	❍	❍
We use our brain 24 hours a day.	❍	❍	❍	❍	❍
Brain activity can be studied through the oxygen	❍	❍	❍	❍	❍

consumption of specific brain areas.					

58. How often do you read articles about science?

- ❍ Never
- ❍ Rarely
- ❍ Occasionally
- ❍ Frequently
- ❍ Very Frequently

59. Compared to other people you know, how would you describe yourself?

- ❍ I am generally the first to try a new technology product.
- ❍ I am generally among the first to try a new technology product.
- ❍ I am generally in the middle when it comes to trying a new technology product.
- ❍ I am generally among the last to try a new technology product.
- ❍ I am generally the last to try a new technology product.

60. We are now going to ask you a few questions about your thoughts on the prevalence of the home use of tDCS, that is, uses of tDCS outside of the research laboratory and medical/therapeutic settings. There are no correct responses – please estimate to the best of your ability. In your country, what is the percentage of individuals who use tDCS at home (for any purpose)?

[text entry]

61. What percentage of individuals in your country would benefit from such use?

[text entry]

62, Thinking globally, how many people would you estimate use tDCS at home (for any purpose)?

- ❍ tens
- ❍ hundreds
- ❍ thousands
- ❍ tens of thousands
- ❍ hundreds of thousands
- ❍ millions or more

63. You're almost done! We just have some final demographic questions.Which best describes your gender?

- ❍ Male
- ❍ Female
- ❍ Prefer not to answer

64. What year were you born?

[dropdown box year selection]

65. Using this list of categories from the U.S. General Social Survey, select what you consider your race to be. You can select more than one.

- ❑ White
- ❑ Black or African-American
- ❑ American Indian or Alaska Native
- ❑ Asian Indian
- ❑ Chinese
- ❑ Filipino
- ❑ Hispanic
- ❑ Japanese
- ❑ Korean
- ❑ Vietnamese
- ❑ Other Asian
- ❑ Native Hawaiian
- ❑ Guamanian or Chamorro
- ❑ Samoan
- ❑ Other Pacific Islander
- ❑ Some Other Race
- ❑ Prefer not to answer

66. Which best describes your marital status?

- ❍ Never married
- ❍ Married
- ❍ Living with a partner
- ❍ Separated
- ❍ Divorced
- ❍ Widowed

67. Do you currently have children?

- ❍ Yes
- ❍ No

➔ If "Yes" is selected:

67A. How many children do you have?

- ❍ 1
- ❍ 2
- ❍ 3
- ❍ 4
- ❍ 5
- ❍ 6
- ❍ 7+

68. In which country do you currently reside?

[dropdown box selection]

➔ If "United States" is selected:

68A. In which state do you currently reside?

[dropdown box selection]

69. Do you live in a rural, suburban, or urban location?

- ❍ Rural
- ❍ Suburban
- ❍ Urban

70. What is the highest level of education you have completed?

- ❍ Some high school
- ❍ High school diploma or equivalent
- ❍ Some university or college
- ❍ College or university degree
- ❍ Master's degree
- ❍ Doctor or professional degree

71. What is your employment status?

- ❍ Employed full time
- ❍ Employed part time
- ❍ Unemployed looking for work
- ❍ Unemployed not looking for work
- ❍ Retired
- ❍ Student
- ❍ Disabled

72. What is your occupation?

[text entry]

73. What is your combined annual household income (in US dollars)?

- ❍ Less than $15,000
- ❍ $15,000-24,999
- ❍ $25,000-34,999
- ❍ $35,000-49,999
- ❍ $50,000-74,999
- ❍ $75,000-99,999
- ❍ $100,000-149,999
- ❍ $150,000-199,999
- ❍ $200,000-250,000
- ❍ More than $250,000

74. In general, do you consider yourself liberal or conservative?

- ❍ Very liberal
- ❍ Liberal
- ❍ Somewhat liberal
- ❍ Moderate
- ❍ Somewhat conservative
- ❍ Conservative
- ❍ Very conservative

75. ➔ Displays if "United States" is selected as country of residence in Question 68:
Generally speaking, do you usually think of yourself as a:

- ❍ Republican
- ❍ Democrat
- ❍ Independent
- ❍ No Preference
- ❍ Other
- ❍ Don't Know

➔ If either "No Preference," "Other," or "Don't Know" are selected:
75A. As of today, do you lean more to the Republican Party or more to the Democratic Party?

- ❍ Republican Party
- ❍ Democratic Party

76. How often do you attend religious services?

- ❍ Never
- ❍ Seldom
- ❍ A few times a year
- ❍ Once or twice a month
- ❍ Once a week
- ❍ More than once a week

77. Thank you so much for participating! If you have any additional comments or thoughts, please input them here.

[text entry]

78. Do you want to be informed when the results of this study are published?

- ❍ Yes
- ❍ No

79. Are you willing to be contacted by the researchers for a brief follow-up interview?

- ❍ Yes
- ❍ No

➔ If "Yes" is selected for Question 78 or 79: "No Preference," "Other," or "Don't Know" are selected:

80. Please enter your email address:

[text entry]

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