Health Capital Topics
Volume 9
Issue 5
May 2016
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New Electroceutical Technologies May Revolutionize Medical Care

Over the past few years, there has been increasing interest and research in electroceuticals.[1] Electroceuticals are devices that target individual nerve fibers or specific brain circuits to treat an array of medical conditions.[2] The devices modulate the neural impulses that control many voluntary and involuntary movements of the human body, repair lost function, and reinstate a healthy balance.[3] Electroceuticals may treat major conditions such as hypertension, diabetes, obesity, heart failure, pulmonary disorders, and vascular disease.[4] Not only could these devices treat major conditions, they could do so in a safe, non-intrusive manner.[5] Currently, many electroceutical devices, such as pacemakers, defibrillators, and deep-brain stimulators, exist on the market and harness electrical impulses to treat various diseases.[6] However, currently available electroceutical devices do not target specific cells and are limited in their scope for expansion.[7] This *Health Capital Topics* article will discuss the increasing interest in the electroceuticals industry and the potential impact electroceuticals may have on healthcare delivery.

Many healthcare technology innovators believe that the electroceutical device market is ripe for expansion. While there are electroceutical devices currently available in today's market, experts at *GlaxoSmithKline* (GSK), the largest pharmaceutical company in the United Kingdom, say that these devices fail to take into account the complexities of the nervous system.[8] The nervous system plays a vital role in maintaining all aspects of physical and mental health.[9] Whenever there is an infection or injury, nerves trigger reflexive responses, or electrical impulses.[10] Electrical impulses are the language of the nervous system, in that essentially all organs and functions of the body are regulated through circuits made of neurons communicating through these electrical impulses.[11] These circuits are what are targeted by electroceuticals for therapeutic intervention.[12] There are already devices on the market today that harness electrical impulses to treat disease.[13] Some devices and treatments include: (1) pacemakers and defibrillators; (2) deep-brain stimulation that is used to improve the quality of life for those with Parkinson's disease and depression; (3) sacral nerve stimulation to help restore some bladder control in people with paraplegia; and, (4) vagus-nerve stimulation which has multiple clinical benefits in diseases ranging from epilepsy to rheumatoid arthritis.[14] Consumer devices, such as Thync, work by signaling nerves on the head and neck to act on the brain's adrenaline system to activate the body's "natural state of energy or calm."[15] However, neural tissue is compact, and therefore unrelated circuits often run close together.[16] Current devices activate or inhibit numerous cells across an area broadly, which results in imprecise clinical effects,[17] since neural circuits act through very precise electrical impulses.[18] In order to successfully treat disease, the device must precisely target a particular nerve; a sophisticated process that is deficiently mimicked by today's devices.[19] However, experts believe that the stepping stones are already in place to rise above these limitations and create devices that will be able to artificially modulate nerves to restore healthy patterns of signaling in neural circuits to treat disease.[20] Through multidisciplinary collaboration and public-private funding, electroceuticals could soon become a mainstay of medical treatment.[21]

In October of 2015, the *Defense Advanced Research Projects Agency* (DARPA) launched the first seven research projects of its *Electrical Prescriptions* (ElectRx) program.[22] The goal of this program is to reframe the approach of modern medicine and chronic illness by developing a closed-loop system that treats diseases by modulating the activity of peripheral nerves.[23] ElectRx consists of two *Technical Areas* (TAs), labeled TA1 and TA2.[24] TA1 deals with the *biological foundations for feedback-controlled neuromodulation*, while TA2 deals with *disruptive bio-interface technologies*.[25] This two-prong approach focuses on: (1) "*innovative studies of human physiology and demonstration of novel neuromodulation strategies in humans*"; and, (2) "*neural interface and biosensing technologies that offer advanced capability for long-term use,… and can be deployed without surgery*."[26] ElectRx hopes to be able to treat diseases, such as rheumatoid arthritis, chronic pain, inflammatory disease, and post-traumatic stress disorder, that may not be responsive to traditional treatments.[27] DARPA has made similar technological advancements through its Revolutionizing Prosthetics program, which allows people living with paralyzed or missing limbs to be able to manipulate objects by sending signals from their brain to robotic devices.[28]

Additionally, the *National Institutes of Health's* (NIH) Common Fund has started a $248 million program

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called *Stimulating Peripheral Activity to Relieve Conditions* (SPARC), which is a community resource that provides public and private research communities with the scientific foundation to advance neuromodulation therapies towards precise neural control, in order to treat diseases and conditions.[29] The SPARC program was initiated to support interdisciplinary teams of researchers to ultimately develop new minimally invasive neuromodulation therapies.[30] Similar to ElectRx, the SPARC program is divided into multiple components, including: (1) Functional and Anatomical Mapping of Innervation of Major Internal Organs; (2) Next Generation Tools and Technologies; (3) Use of Existing Market-Approved Technology for New Market Indications; and, (4) Data Coordination, Mapping, and Modeling Center.[31] These components focus on enhancing scientific knowledge, developing new technologies, and exploring the utility of existing devices to address new indications of disease.[32] SPARC currently has partnerships with seven medical device companies through its New Market Indications Initiative, which allows for the medical device company to explore the utility of existing devices and address potential new applications, such as sleep apnea and heart failure.[33] Through these partnerships, new clinical utilities of market-approved devices are expected in the near term.[34] Not only is SPARC developing new technologies, but the program is also utilizing current market-approved devices in hopes of achieving market approval more quickly.[35] GSK hopes to act as a catalyst for electroceutical development, as evidenced by previous efforts to incentivize innovation in this field, including: (1) launching a funding program in April of 2013; (2) organizing a global forum in December of 2013 for a broader set of research on electroceuticals; and, (3) offering a one million dollar innovation prize to overcome a key hurdle in the field.[36] If these programs are successful, dependence on traditional drugs could be reduced, and new treatments could be created that could be better tailored to the needs of individual patients.[37]

The potential benefits of electroceuticals make these new technologies an exciting development in the world of medicine. In addition to being able to treat diseases that previously were not treatable, electroceuticals may also reduce the need for medication compliance on the part of the patient.[38] Electroceuticals could provide new opportunities for patients to improve their quality of life with lower side effects.[39] One of the biggest challenges associated with electroceuticals will be educating payers about the financial benefits of electroceuticals, since there is often a larger, one-time upfront fee for implantables or similar devices, but there are commonly cost savings over the course of 10-15 years.[40] There may also be a need to educate a new generation of doctors about electroceuticals.[41] With the incredible complexity of the nervous system, some critics argue that proponents of electroceuticals fail to realize the challenges in reliably, durably, and non-disruptively addressing a larger number of individual neurons without impeding their functionality.[42] Today's electroceuticals fail to address these challenges by only being able to provide treatment temporarily; once the device is removed from the patient, the patient's symptoms instantly return.[43] Additionally, critics believe that there are too many unknowns regarding the nervous system and the risks involved are too high.[44]

Notably, advancements in electroceuticals may have a significant impact on healthcare costs, if these technologies become a mainstay of medical treatment. Researchers generally agree that advances in medical technology have contributed to rising healthcare costs.[45] However, whether a particular new technology will increase or decrease health expenditures depends on several factors, such as the new technology's impact on the cost of treating an individual patient, whether the new technology supplements or becomes a substitute for existing treatment, and whether the direct costs of the new technology effect the use or cost of other healthcare services such as hospital stays or physician office visits.[46] For example, a case study of a single new technology may show cost savings per use if the new innovation is replacing a more expensive service and device, while an analysis of system-wide healthcare costs may show cost increases if the new technology has greater healthcare utilization than its predecessor.[47]

With the influx of funding and research regarding the innovation of electroceuticals, the field of neuromodulation may be an important market to monitor within the healthcare technological environment.[48] The increase in the number of clinical trials, new products, and potential clinical applications for neuromodulation devices is a testament to the growing interest about electroceuticals among clinicians, investors, and patients.[49] For those patients who have no success with traditional medical treatment, electroceuticals may provide an alternative approach for treatment.[50] Coupling improved physiological understanding with new technological capabilities could allow clinicians to precisely manage many acute and chronic conditions.[51] While electroceutical technology is still in the early stages of research and development, this field could have a significant impact on healthcare delivery in the future by revolutionizing the treatment of many chronic and acute diseases.

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