

Stanford University

From the Selected Works of Eric David Chan

May, 2007

The FDA and the Future of the Brain-Computer Interface: Adapting FDA Device Law to the Challenges of Human-Machine Enhancement

Eric D Chan, *Stanford Law School*



Available at: https://works.bepress.com/eric_chan/1/

The FDA and the Future of the Brain-Computer Interface: Adapting FDA Device Law to the Challenges of Human-Machine Enhancement

Eric Chan^o
April 5, 2007

The neuroelectronic interface is an emerging technology that uses electrical signals to communicate directly with the human brain. It promises to make possible a new generation of user-worn prosthetic devices that can be controlled at the speed of thought, functioning as actual extensions of the human body. Prototypes already exist, though they are still in development – artificial retinas, which can provide replacement sight for the blind; sophisticated prosthetic limbs. Though current applications are geared towards replacing lost natural function, there is no reason that these brain-computer interface devices cannot also be used to enhance the capabilities of a healthy human body. Neuroelectronic devices may not only allow humans to run faster, jump higher, and see farther, but they might potentially impart new forms of sensory perception and control over the world that were previously unimaginable.

This paper explores the new safety risks and burgeoning legal and ethical implications of neuroelectronic enhancement devices under U.S. Food & Drug Administration law. It argues that the Premarket Approval regime administered by FDA's Center for Devices and Radiological Health is deficient in two respects when it comes to these futuristic devices. First, by focusing on device approval as the sole regulatory event, FDA fails to effectively ensure the safety and effectiveness in the long term—over the life of a user. Second, FDA's "procedural" regulatory regime does not consider the moral, ethical and social considerations—"substantive" concerns—that enhancement devices will implicate. Only regulation that accounts for these issues can raise public awareness and prevent the inevitable public backlash and moratorium on neuroelectronic development when something goes wrong.

This paper thus proposes two main modifications to existing FDA device law. FDA should create a new "Class IV" designation for neuroelectronic devices, implementing along the way a two-tiered approval process to better assess long-term risks of safety and effectiveness. In order to consider the broader questions of enhancement itself, a "Class IV-E" sub-designation should be established to review Class IV devices that have "significant potential" to enhance human abilities.

^o Student, Stanford Law School, Class of 2007. My thanks to Professor Hank Greely for his helpful guidance and suggestions. Any errors in this manuscript are my own.

TABLE OF CONTENTS

Introduction	4
I. Survey of Existing User Interfaces and Prosthetic Devices	7
A. Output Interfaces	7
1. Physical Contact.....	7
2. Myoelectric Interfaces	8
3. EEG-Based Interfaces	11
4. Direct Neuroelectronic Interfaces	12
B. Input Interfaces	14
1. Cochlear (Auditory) Implants	16
2. Visual Input Interfaces	16
3. Kevin Warwick’s Ultrasonic Sense	18
C. Blurring the Input/Output Distinction	19
D. Prosthetics that Enhance: the Next Logical Step	20
E. The Limitations of Brain-Computer Interfaces	22
1. Biocompatibility: Minimizing Damage and Long Term Signal Degradation.....	22
2. Brain Compatibility: Speaking the Language of the Brain.....	23
II. FDA Device Law	24
A. FDA Device Classes	25
1. Class I Devices	26
2. Class II Devices	26
3. Class III Devices	27
B. FDA Device Approvals	27
1. Pre-Market Notification: the 510(k)	27
2. Pre-Market Approval (PMA)	28
(i) Evidence Required	28
(ii) Device Approval Process	29
(iii) Post-Approval Reports	30
C. Restriction on PMA Approvals	31
D. Post-Approval Regulation	32
1. Quality System Regulation, Design Controls	32
2. Post-Market Surveillance & MDR Reporting	33
III. The Advantages and Shortcomings of Existing FDA Device Law	35
A. The New Safety & Efficiency Challenges of Neuroelectronic Devices	37
1. New Safety Issues	37
2. New Effectiveness Issues	38
3. Enhancement or Restoration: What Baseline for Risk?	39
B. Dealing with the Implications of Enhancement: A “Substantive” Complement to the FDA’s “Procedural” Approach	40
1. Why the FDA?	41
2. What Sorts of Substantive Concerns Arise?	42
(i) Naturalness	42
(ii) Propriety	42
(iii) Identity	43

(iv) Individual Choice	43
(v) Impact on Society	44
(vi) Problems with International Regulation	44
IV. A Proposed Solution	45
A. New Device Class IV: A Shift to Long-Term Regulation	46
B. Ensuring Safety and Effectiveness for Neuroelectronic User Devices	46
1. Gaining “Conditional” Approval: the First Step	48
2. From Conditional to Final Approval	48
3. Post-Approval Regulation	49
(i) Changes to Medical Device Reporting	49
(ii) Changes to Postmarket Surveillance	50
4. Regulation of Device Use Activities	50
C. Sub-Class IV-E: Examining “Substantive” Issues	50
Conclusion	54

INTRODUCTION

“The Engineer” has billions of intelligent nanobots in her blood, allowing her to morph her limbs into any conceivable machine. “Apollo” has super-strength and ocular implants that extend his visual range for hundreds of miles. And “The Midnighter” has a neural implant that analyzes a million different combat scenarios in a single second, making him the deadliest man alive. These fictional characters are members of “The Authority,” a pretty normal superhero team featured in a pretty popular comic book.¹ What’s unusual about them is how they got their powers. They were not endowed with special abilities at birth or through convenient freak accidents; instead, their advanced surgical implants and enhancements (some bestowed by aliens, others at the hands of evil geniuses) are what elevate them to “post-human” status.

While this fanciful account of a world of revolutionary enhancements is only science fiction, *The Authority* touches upon issues related to human enhancement that will actually arise in the foreseeable future. The technology poised to make it happen is the “neuroelectronic

¹ See WARREN ELLIS AND BRIAN HITCH, *THE AUTHORITY: RELENTLESS* (Wildstorm Productions 2000); see also WARREN ELLIS, BRIAN HITCH, MARK MILLAR, AND FRANK QUITELY, *THE AUTHORITY: UNDER NEW MANAGEMENT* (Wildstorm Productions 2000).

interface” (or brain-computer interface), which gives the brain direct input-output communication with any number of mechanical or electrical devices.

Certainly, attempts to enhance the human body using technology are nothing new.² But what sets neuroelectronics apart is their potential for seamless and permanent integration with the body. Unlike existing prosthetic devices, most of which are clumsy and indirect (think of the standard prosthetic arm used by an upper-limb amputee), neuroelectronic-based user devices will be controlled at the speed of thought and will function as actual extensions of the human body. Once the technological hurdles are overcome – and they are significant – the potential of neuroelectronics will be limited only by the plasticity of the brain and its ability to adapt to strange new body parts.

Scientists are already starting to develop prototype *medical* devices designed to restore natural body functions – prosthetic arms that can move on demand and be manipulated with precision; CCD sensors that directly stimulate the optic nerve to provide replacement sight.³ But there is no reason such user devices can not also be used to *enhance* the capabilities of the human body. Not only could such devices impart sharper senses and stronger body parts, but they might also be designed to give the user novel senses, such as infrared-spectrum vision, additional mechanical limbs, or say, mental control of an entire fleet of aircraft.

Because neuroelectronic interface devices have such potential to extend human capabilities, they have the potential to revolutionize our society and our world.⁴ But they also have the potential to create a future that bears uncomfortable resemblance to that of *The Authority* – a world in which post-humans use their vast superiority over normal humans to bully

² See History and Prosthetics, Northwestern University Prosthetics-Orthotics Center website, at <http://www.nupoc.northwestern.edu/prosHistory.shtml> (describing prostheses worn in battle during the Dark Ages).

³ See Section I.B. 2. *infra*.

⁴ Enhancement biotechnologies, such as drugs, hormones, or genetic therapies, can only enhance the biological capabilities of the human body, and thus carry less potential than that of brain-computer user devices.

world leaders and live like kings.⁵ Even if that is unlikely, a more realistic outcome might be that enhancements never get developed at all. Without competent and smart regulation from the very start, negative public reaction may conceivably lead to a moratorium or outright ban on neuroelectronics – like stem cell research, halted in its infancy. A laissez-faire approach does not seem like a very good option.

However, the current U.S. regulatory scheme is simply not up to the challenge. Existing Food and Drug Administration (FDA) regulations are geared entirely towards the approval of medical devices, not neuroelectronic interface devices that are designed to enhance human abilities and may last a lifetime. Such devices differ drastically from medical devices for two reasons. First, without the counterbalancing benefit of treating disability and disease, the threshold for acceptable risks to safety and effectiveness must be lower for user enhancement devices than for medical devices. But even more importantly, the specter of human enhancement implicates far-reaching issues of propriety, identity, autonomy, and impact on society not present in the medical context. Do we allow people to use these devices to modify or mutilate their bodies, “cheat” in sports or more easily break the law? How will enhancements affect a user’s interaction with others, and the larger social dynamic? Current FDA law gives us no guidance. It is unclear how FDA should regulate these issues, if at all.

This paper’s solution balances these concerns with the need to preserve innovation in this developing area of technology. It emphasizes, first, that FDA (rather than an entirely new entity, or another governmental body) is the proper regulatory agency to handle enhancing brain-computer interfaces. It then proposes the creation of an entirely new “Class IV” designation for

⁵ Mark Millar and Frank Quitely, “The Nativity,” in *The Authority: Under New Management*, supra note 1 (The Authority deposes a Southeast Asian dictator over the protests of a hapless president who resembles Bill Clinton).

all brain-computer interface devices that engage in direct input-output communication with the brain, whether or not they are intended for medical or enhancement use.

Class IV regulation would proceed in two parts. First, FDA would regulate the safety and effectiveness of Class IV user devices differently than it does for other devices. Lesser emphasis would be placed on the single device approval, and more emphasis placed on monitoring over the entire lifetime of the user device. Second, user *enhancement* devices would be placed in a special subcategory of Class IV: call it “Class IV-E.” Under Class IV-E review, any user devices with “significant potential” to enhance would face both heightened review of safety and effectiveness issues, and review by advisory groups called “Enhancement Panels.” Based on FDA’s current system of advisory panels, the Enhancement Panel system would gather experts from a wide variety of backgrounds (including medicine, industry, consumer groups, and ethical and religious perspectives), that could competently examine the “substantive” concerns related to enhancement and more broadly inform the FDA’s decisionmaking.

The paper is divided as follows. Part I is a comprehensive survey of existing medical devices that engage in input/output communication with the human brain. It concludes with an examination of the current limitations of brain-computer interfaces and speculates on the future of such devices. Part II then describes the current FDA regulatory landscape for medical devices. Part III will make the case for FDA regulation while pointing out the shortcomings of existing FDA law in regulating safety, effectiveness, and the substantive issues of enhancement. Finally, Part IV presents a proposal for a new FDA device classification, Class IV, and a strategy for successful regulation of enhancement.

I. Survey of Existing User Interfaces and Prosthetic Devices

A wide variety of interfaces have been developed to conduct input and output communication with the human brain. “Outputs” involve sending commands from a user’s brain, directly or indirectly, to prosthetic devices. In contrast, “inputs” represent the sending of new sensory information to the human brain. The implantable neuroelectronic interface is the most promising, and provides both input and output capabilities. However, it is also the most invasive method and raises the greatest safety concerns. Less invasive methods, such as devices that sense tiny, existing muscle movements, and electrodes placed on the skin of the limb or scalp, provide primarily output (and limited input) functionality.

A. Output Interfaces

Prosthetic “output” devices are more common than “input” devices and come in a greater variety. Up until recently, all interfaces have been “indirect” mechanisms, acting upon a user’s muscle contractions and not direct commands from the brain. Newer brain output interfaces include EEG’s, which sample whole-brain electrical activity, and direct neuroelectronic connections, which focus on the firing of just a handful of neurons.

1. Physical Contact

The most non-invasive method for controlling a prosthetic device involves translating a wearer’s physical movements into movements of the prosthetic. For instance, a very simple prosthetic arm for a below-elbow amputee might directly link the angle of the user’s elbow (which a below-elbow amputee can still control) to the “opened” or “closed” state of the

prosthetic hand (the “terminal device,” in prosthetics parlance).⁶ More complex variations are possible.⁷ Though clever, pure physical interfaces are limited, requiring that the amputee retain the ability for muscle movement in the amputated limb, such as the ability to raise and lower a shoulder. Many arm prostheses also require a body harness for support, are uncomfortable and unwieldy, and for these reasons go unused by their owners.⁸

2. Myoelectric Interfaces

More recent artificial limbs can detect and “amplify” minor muscle movements and the electrical impulses they generate. Rather than translating a user’s actual muscle movement, myoelectric prosthetic devices (the “myo” prefix stands for muscle) are active, powered devices that utilize electric motors and digital signal processors.⁹ They employ small electrodes to sense the electrical signals that race down muscle tissue, such as an amputee’s residual biceps and triceps, when the muscle contracts.¹⁰ A processor then interprets specific patterns of contraction as commands to move individual motors in the prosthetic device; the strength of the myoelectric

⁶ Dick H. Plettenburg, *Basic Requirements for Upper Extremity Prostheses: The WILMER Approach*, PROC. OF THE 20TH ANN. INT’L CONF. OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOC’Y 2276, 2277 (1998), available at <http://ieeexplore.ieee.org/iel4/6018/16089/00744691.pdf?arnumber=744691>.

⁷ One popular configuration allows an *above*-elbow amputee to control both the position of the prosthetic elbow position and the open/closed position of the prosthetic hand with the same set of shoulder movements. The Sarcos AdVantage Arm utilizes a system with two internal cables. A user first flexes his shoulder muscles (activating one cable) to raise or lower the elbow. The elbow position is then locked into place, and the user can then control the position of the terminal device “using his shoulder muscles via a second cable. There is a substantial learning curve. See Harold H. Sears, Ph.D., *Advances in Arm Prosthetics*, in *Motion*, May-June 1999, at http://www.amputee-coalition.org/inmotion/may_jun_99/armprosth.html. See also M.E. Cupo & S.J. Sheredos, *Clinical evaluation of a new, above-elbow, body-powered prosthetic arm: a final report*, *J. Rehabil. Res. Dev.*, Oct. 1998; 35(4):431-46 (abstract available at <http://www.pubmed.gov>).

⁸ See Plettenburg, *supra* note 6 at 2276.

⁹ See Bill Dupes, *The Body Electric: Recent Developments in Bionic Technology*, in *Motion*, May-June 2004, at 52; available at http://www.amputee-coalition.org/inmotion/may_jun_04/body_electric.html.

¹⁰ SearchMobileComputing.com, What is a Myoelectric Signal?, http://searchmobilecomputing.techtarget.com/sDefinition/0,,sid40_gci936219,00.html. A myoelectric sensor requires three electrodes to be placed against the skin: two to measure the voltage difference that occurs when the desired muscle contracts, and a third placed in a neutral area to measure background noise (which is then canceled out). *Id.*

output signals generated are proportional to the strength of the muscle contraction.¹¹

Dr. Todd Kuiken has adapted this concept for a number of upper-limb amputees who lack the shoulder, bicep, or triceps muscles necessary to operate conventional myoelectric arm prostheses.¹² Kuiken's innovative procedure reroutes nerve endings from the shoulder (nerve endings that, before amputation, used to control arm and hand movements), surgically grafting them onto bands of pectoral muscle in the chest.¹³ Once the transplanted nerve endings have grown into the pectoral muscle, a process that takes roughly six months, the amputee can contract those bands of chest muscle by simply "thinking" about moving the nonexistent muscles in his arm and hand.¹⁴ A conventional myoelectric prosthetic arm can then be fitted that picks up electrical signals from the newly innervated bands of chest muscle, rather than from the shoulder itself. Four amputees to have successfully undergone Kuiken's procedure to date, including Jesse Sullivan, a double amputee who lost his arms in an electrocution accident, and Claudia Mitchell, who lost an arm in a motorcycle accident¹⁵; the latest incarnation of Kuiken's arm includes six motors and three forms of arm rotation.¹⁶ Typically, the device is not permanent and can be taken on and off at will.

The applications of myoelectric interfaces are not limited to replacement limbs. The National Aeronautics and Space Administration (NASA) is developing a "subvocal speech

¹¹ Charles Murray, *Rewired, Amputee Lifts Arm with Mind*, ELECTRONIC ENGINEERING TIMES, Jan. 17, 2005, at 6 (arm manufacturer explaining that "[t]he challenge is to tell the arm which motors it should run, and in which direction and how fast").

¹² *Id.*

¹³ Rehabilitation Institute of Chicago, *Introducing Jesse Sullivan, the World's First Bionic Man*, <http://www.ric.org/bionic/>.

¹⁴ Press Release, Rehabilitation Institute of Chicago, *Patient Profile: Jesse Sullivan*, <http://www.ric.org/bionic/jesseprofile.pdf>; *see also* Murray, *supra* note 11.

¹⁵ Jim Ritter, *'Bionic woman' shows off arm: 1st female to have robotic surgery*, CHICAGO SUN TIMES, Sept. 14, 2006, at 6. The article notes that Kuiken's surgery failed with one patient whose nerves suffered too much damage from amputation to be rerouted. Also, understandably, the surgery is more difficult in women, as the surgeon must avoid damaging the breast. *Id.*

¹⁶ *Id.*; Kelly Kennedy, "Bionic Arm Brings Back Sense of Touch," Chicago Tribune, June 23, 2005, Nation/World section.

system” which picks up nerve signals in the throat via four button-sized sensors placed under the chin and on both sides of the Adam’s apple.¹⁷ Because the sensors pick up myoelectric signals, they can function even when no sounds or lip or facial movements are made – since the act of reading or silently talking to oneself sends speech signals to the tongue and vocal cords.¹⁸ Patterns of nerve signals are then interpreted as discrete words and sounds.¹⁹ NASA suggests this technology could be used to communicate with others or with a speech-activated machine in a variety of settings– in noisy or crowded environments, in military operations where silence would be useful, or as a tool for speech-handicapped persons.²⁰

Myoelectric output interfaces are one step closer to brain-controlled devices that can be integrated into the body. While their noninvasiveness is their greatest asset, they do share the same shortcoming as traditional, “passive” prosthetics: a requirement that good working muscle and nerve be present to operate the device. In this sense, Dr. Kuiken’s nerve rerouting procedure is just a clever workaround. A second drawback of myoelectric interfaces is their indirect method of operation – a myoelectric signal is one additional step removed from the brain, which may mean weaker signals.²¹ Kuiken, in particular, has found that muscular signals from the skin face strong interference from the environment, even overhead fluorescent lights.²²

¹⁷ “*NASA Develops System To Computerize Silent, Subvocal Speech*,” 3/19/2004 Aerospace & Defense. NASA is also developing “non-contact capacitative sensors” that would operate through clothing and without wires. Iddo Genuth, *Subvocal Speech – Speaking Without Saying a Word*, *The Future of Things*, Oct. 12, 2006, <http://www.tfot.info/content/view/80/58/> (interview with Chuck Jorgensen, NASA Chief Scientist for Neuroengineering).

¹⁸ Press Release, NASA, *NASA Develops System To Computerize Silent, ‘Subvocal Speech’* (Mar. 17, 2004), http://www.nasa.gov/home/hqnews/2004/mar/HQ_04093_subvocal_speech.html. Of course, as with all myoelectric devices, healthy nerve and muscle must be present, because some activation of the speech muscles is required.

¹⁹ NASA, *Subvocal Speech Demo*, Mar. 17, 2004, <http://www.nasa.gov/centers/ames/news/releases/2004/subvocal/subvocal.html>. In initial trials, the system recognized words (choosing from a small number of words, vowels and consonants) with an accuracy rate of 92%. NASA Press Release, *supra* note 18. In a 2006 interview, NASA’s Jorgensen noted a modest increase in vocabulary size (25 words, 38 vowels & consonants) with the use of only two sensors. Genuth, *supra* note 17.

²⁰ *Id.*; NASA Press Release, *supra* note 18.

²¹ Still, a myoelectric interface is currently the only feasible way to send commands to a user-worn device using peripheral nerve signals instead of signals directly from the brain. Apparently, the electrical impulses from the

3. EEG-Based Interfaces

Researchers have also had moderate success translating brain waves, when monitored by an electroencephalogram (EEG), into commands to computers or prosthetic devices. EEG is a non-invasive technique that relies on electrodes placed on many different areas of the scalp to sense activity at the surface of the brain.²³ With so many inputs, it does not sense individual neurons firing; instead, it helps visualize “brain waves” resulting from distinctive patterns of electrical activity.²⁴ For example, the Brain-Computer Interface Lab at the New York State Department of Health, led by John Wolpaw, has successfully trained patients wearing EEG’s to control the movement of a cursor across a two-dimensional computer screen.²⁵

This method of interfacing with computers is unusual because it requires users to precisely control the intensity of their brain waves, which is much more difficult than activating a specific part of their brains, such as the motor cortex. According to testers, a user must be a certain state of concentration or “zone,” and is often helped by focusing on a certain image, childhood memory, or other figment of imagination.²⁶ Wolpaw’s group has successfully trained 80% of its patients after 10 sessions to reliably manipulate the cursor across the screen. *Id.* It

peripheral nerves themselves are too weak to serve as the signal to any electrical device, and it is difficult maintain an electrical connection with nerves under the skin’s surface because the area beneath the skin, where the peripheral nerves end, is constantly changing. Murray, *supra* note 11. On the other hand, at least one private company, Victhom Technologies (formerly Neurostream Technologies), is going to try. Victhom’s “NeuroStep” is a “closed loop” medical device that will interface with both sensory and motor peripheral nerve signals. *See* Press Release, Victhom, Victhom Human Bionics Announces a Pre-IDE Meeting with the US FDA for its Neurostep, <http://www.victhom.com/news/2006-11-22-e.pdf>.

²² Murray, *supra* note 11.

²³ Definition of EEG, Medline Plus Medical Encyclopedia, National Library of Medicine, <http://www.nlm.nih.gov/medlineplus/ency/article/003931.htm>

²⁴ Public Broadcasting System, The Secret Life of the Brain, Scanning the Brain:EEG, available at <http://www.pbs.org/wnet/brain/scanning/eeg.html>

²⁵ Malcolm Ritter, “Computers Obeying Brain Signals,” USA TODAY, Apr. 4, 2005,

http://www.usatoday.com/tech/news/2005-04-03-brain-computer_x.htm. Wolpaw and others recently obtained a patent on similar technology utilizing ECoG, not EEG. *See* An ElectroCorticography-Based Brain Computer Interface (BCI) and Related Methods, U.S. Patent No. 7,120,486 (filed Dec. 12, 2003). The difference is that ECoG is more invasive: an electrode array is implanted on the surface of the brain, below the scalp and dura mater. *Id.*

²⁶ Ritter, *supra* note 25. Ritter’s article offers an entertaining first-hand account of how unpredictable and difficult it is to control the strength of his brain’s “beta” rhythm. The fact that complete concentration is required may be a disadvantage.

remains to be seen whether the accuracy and reliability of EEG-based control can be improved to match that of more invasive neuroelectronic interfaces.²⁷

4. Direct Neuroelectronic Interfaces

Unlike EEG interfaces, neuroelectronic (brain-computer) interfaces sense the direct firing of a small number of brain neurons and translate those into electronic signals. This is most commonly achieved by the direct surgical implantation of a microchip on the surface of the brain – a procedure that requires intrusive (and potentially risky) surgery below the surface of the skull. The biggest advantage of neuroelectronic interfaces over EEG’s is that patients do not need to learn to control their brain waves. Rather, because of the direct link between neurons and electrodes, just “thinking” about taking action can generate distinct neural signals that can be processed by a computer or chip.

The BrainGate chip, developed by Brown University Professor John Donoghue and his Cyberkinetics, Inc. startup company, is one of the first direct neuroelectronic interfaces for use in humans. It contains 96 microelectrodes that fit onto a surface the size of a baby aspirin, which can be implanted on a portion of the exposed surface of the brain.²⁸ These electrodes, each thinner than a hair, extend about a millimeter below the surface of the brain and are connected to a wire which runs to a small metal plate, or pedestal, attached to the skull. The signals from the metal plate are then amplified and sent to a computer for processing.²⁹ In trials, Donoghue has found that different commands (“move my hand left” vs. “move my hand right”) created distinct,

²⁷ At least two startups, NeuroSky and Cyberlearning, plan to bring EEG-based videogame console add-ons to market. Dean Takahashi, *Gamers May Soon Control the Action With their Thoughts*, MERCURY NEWS, Apr. 6, 2006. The CEO’s of both companies ultimately hope to enable gamers to become virtual Jedi, giving them the ability to “lift objects . . . and toss them at enemies in ways that resemble the action in the George Lucas films.” *Id.*

²⁸ *Id.*; Ian Sample, “Meet the Mind Readers: Paralysed People Can Now Control Artificial Limbs by Thought Alone,” THE GUARDIAN (UK), Mar. 31, 2005, at 4. See also Cyberkinetics Neurotechnology Systems, Medical Products,

<http://www.cyberkineticsinc.com/content/medicalproducts/braingate.jsptechnology/platformtechnology.jsp>.

²⁹ Sample, *supra* note 28. Quite literally, the patient is plugged into a computer, “The Matrix”-style.

detectable patterns of brain activity in the neurons measured by the microelectrodes.³⁰ The BrainGate is currently being tested in a pilot clinical trial under an Investigational Device Exemption (IDE) from FDA.³¹

Paraplegic patient John Nagle made the news when researchers implanted the BrainGate chip over a section of his brain's motor cortex dealing with hand and arm movements.³² Nagle showed an ability to perform a number of tasks with his mind: control a TV, move a mouse cursor on a screen, and command an artificial hand to open and close grip.³³ For instance, an experiment to see whether Nagle could move a cursor to hit a desired target on a computer screen, Nagle adapted to the system "within minutes" and was able to talk while performing the task;³⁴ he mastered it within four days.³⁵ However, Nagle was relatively slow: on average, it took him 2.5 seconds to guide the cursor to the target.³⁶

Brain-computer interfaces are even simple enough for a monkey to master. Miguel Nicolelis at the Duke Center for Neuroengineering has implanted a chip similar to the BrainGate in Aurora, a macaque monkey, and has successfully trained her to reach for objects using an

³⁰ *Id.* Encouragingly, the brain signals that normally control movement were still active in Nagle even though he had lost the use of his body four years prior. *Id.*

³¹ Cyberkinetics Neurotechnology Systems, Medical Products, http://www.cyberkineticsinc.com/content/clinicaltrials/braingate_trials.jsp. The system is being tested in three other people: one with a spinal cord injury, one with Lou Gehrig's disease, and a brain stem stroke survivor. See Andrew Pollack, *Paralyzed Man Uses Thoughts to Move a Cursor*, N.Y. TIMES, July 13, 2006, at A1.

³² Pollack, *supra* note 31. Nagle had the implant removed after just over a year. *Id.*

³³ Hochberg, L.R., Serruya, M.D, Friebs, G.M, Mukand, J.A., Saleh, M, Caplan, A.H., Branner, A., Chen, D., Penn, R.D., and Donoghue, J.P. (2006) *Neuronal ensemble control of prosthetic devices by a human with tetraplegia*. NATURE, 442, 164-171 (13 July 2006).

³⁴ Editorial, *Is This the Bionic Man?*, 442 NATURE 109, 109 (July 13, 2006), available at <http://www.nature.com/nature/journal/v442/n7099/full/442109a.html>.

³⁵ Pollack, *supra* note 32 (interview with Matt Nagle, noting accuracy of 73%-95% after four days).

³⁶ *Id.* In contrast, it takes a healthy human equipped with a computer mouse in hand only one second to hit the same target. Interestingly, a solution to this performance problem was proposed by another team whose work in monkeys was published alongside Donoghue's. By implanting electrodes on a different part of the brain, the dorsal premotor cortex (which activates sooner than the motor cortex), Shenoy et al. was able to achieve a usable motor signal in a much shorter time frame. Gopal Santhanam, Stephen Ryu, Byron M. Yu, Afsheen Afshar, Krishna V. Shenoy (2006) *A High-Performance Brain-Computer Interface*, NATURE 442, 195-198 (13 July 2006).

external robotic arm controlled by the chip.³⁷ Unlike the BrainGate, which samples a fairly small number of neurons in a single cortical area, Nicolelis' research utilized a "neural ensemble" approach. His team sampled from a relatively large number of neurons in a variety of cortical areas associated with motor function and the sense of touch in order to predict several motor parameters for the robotic arm, such as hand position, velocity, and gripping force.³⁸

There are a number of major obstacles that must be overcome before neuroelectronic interfaces are usable. One concern is whether a limited sample size of neurons (the BrainGate chip only looks at 96 neurons) can pick up complex brain commands, because the brain typically activates a whole ensemble of cortical areas in motor function. (EEG researcher John Wolpaw likens the brain chip approach to trying to play a symphony by only using the violins, and not the whole orchestra.³⁹) In addition, these systems are still bulky prototypes, with wires running out of the brain; miniaturization and wireless data transmission will be necessary to make them practical, and to minimize the risk of infection that comes with having a hole for wires in the skull that exposes the brain. Finally, there is the serious issue of long-term biocompatibility of electrodes that penetrate the surface of the brain; this is discussed further in Section I.E. below.

B. Input Interfaces

In contrast to the progress being made with neuroelectronic "output" interfaces, brain-computer "input" interfaces (which can send sensory information to the brain) are still in their infancy. The reason lies in the level of understanding of the brain that scientists need to manipulate each kind of signal. In output interfaces, information flows from the brain to the

³⁷ Peter Evans, *A Monkey's Mind Over Matter: Aurora Makes Things Move with Thought Control*, DAILY TELEGRAPH (U.K.) Apr. 6, 2005, at 14.

³⁸ Carmena, J.M., Lebedev, M.A., Crist, R.E., O'Doherty, J.E., Santucci, D.M., Dimitrov, D.F., Patil, P.G., Henriquez, C.S., Nicolelis, M.A.L., *Learning to Control a Brain-Machine Interface for Reaching and Grasping by Primates*. PUBLIC LIBRARY OF SCIENCE BIOLOGY, 1: 193-208 (2003).

³⁹ Ritter, *supra* note 25. Of course, Wolpaw's EEG method is like listening to the whole orchestra hundreds of feet away and on the other side of a busy freeway.

machine, and the focus is on detecting a signal that the machine can use – the sample activity of a few dozen neurons, myoelectric activity, or brainwaves. In contrast, a true brain-computer input interface requires information to flow from the device to the brain; a neuroelectronic input device, whether it be an artificial eye or an altogether novel sense, must generate an electrical signal that the brain can understand.

Input signals to the brain don't have to be perfect copies of natural signals to be usable – they merely have to be similar enough to regular brain signals, and the brain's ability to adapt will do the rest.⁴⁰ But right now, science knows next to nothing about how electric impulses in the nerves and brain are translated into the discrete sensations of vision, hearing, touch, and proprioception that we experience in every day life.⁴¹ Unsurprisingly, crude attempts to stimulate points on the auditory or visual cortex with electricity result in the neural equivalent of static: perceived “phosphenes” (flashes of white light) in the case of visual cortex stimulation, or “hissing” noises in the case of the auditory cortex.⁴² The most promising approach, at least for input devices that correspond to an existing human sense such as sight or sound, appears to be stimulation of the peripheral nerves that lead to the brain rather than the central nervous system itself.⁴³ However, the direct stimulation approach is still quite popular.

⁴⁰ *Id.* at 126.

⁴¹ See Alison Abbott, *Neuroprosthetics: In Search of the Sixth Sense*, 442 NATURE 125 (2006). This is a problem distinct from understanding the ways in which auditory and visual information are processed and integrated by the nervous system and the brain. The visual system and visual cortex, for example, have been well-mapped, yet nobody knows how to stimulate the visual system to generate realistic spatiotemporal images on demand.

⁴² See *id.* at 127 (examining the difficulties involved in direct cortical stimulation); Definition of Phosphene, Wikipedia, <http://en.wikipedia.org/wiki/Phosphene>. Many researchers believe that the cortex of the brain is simply too complicated to stimulate with simple electrical impulses. Abbott, *supra* note 410. The article notes that 96% of cortical activity in the brain is “internal,” meaning different parts of the brain are communicating with each other, not the outside world; and much of this activity occurs at levels of abstraction higher than raw sensory input. *Id.*

⁴³ *Id.* Of course, this give us no guidance on how to get the brain to interpret foreign signals from radically new input sources that do *not* correlate to a human sense such as sight or sound.

1. Cochlear (Auditory) Implants

Cochlear implants, the most well-established and widely used kind of input interface, are designed for hearing-impaired individuals who have lost hearing in the inner ear, meaning conventional hearing aids (which merely amplify sound) are ineffective for them.⁴⁴ The typical cochlear implant consists of the following components: a user-worn microphone that picks up sound waves from the environment; a computer chip that selectively picks out and arranges some of these sounds; a transmitter which then converts the selected sounds into electrical impulses; and electrodes that carry these impulses and stimulate the auditory nerve.⁴⁵ At least one variation on the device sends its signal directly to the auditory brainstem instead of the auditory nerve.⁴⁶ Despite generating sounds that are perceived by the brain as “totally artificial,”⁴⁷ cochlear implants work reasonably well, even allowing some users to understand speech over the telephone, without external visual cues such as lip-reading.⁴⁸ However, results vary and the implants require significant customization and training for each individual user.⁴⁹

2. Visual Input Interfaces

⁴⁴ Artificial cochleas have been implanted in more than 50,000 people and have FDA Pre-Market Approval. John Horgan, “*The Myth of Mind Control*,” DISCOVER MAGAZINE, Oct. 2004 at 40, 40-47.

⁴⁵ See generally National Institute on Deafness and Other Communication Disorders (NIDCD) website, Cochlear Implants Page, <http://www.nidcd.nih.gov/health/hearing/coch.asp> (overview of cochlear implant technology). Another fairly lucid description of the technology can be found in MICHAEL CHOROST, REBUILT 6-8 (Houghton Mifflin 2005), an entertaining and emotionally powerful novel about the author’s experience with a cochlear implant.

⁴⁶ See Premarket Approval Database entry for Nucleus 24 Auditory Brainstem Implant (ABI) System, at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=3862>. This is a specialized application intended for use only in individuals in which both auditory nerves have been (or will be) destroyed by tumors (specifically, by neurofibromatosis type II). Food & Drug Administration, Premarket Approval Order for Nucleus 24 ABI system, <http://www.fda.gov/cdrh/pdf/p000015a.pdf>; see also AETNA, CLINICAL POLICY BULLETIN NO. 0013 (REVISED), COCHLEAR IMPLANTS AND AUDITORY BRAINSTEM IMPLANTS (July 7, 2006), <http://www.aetna.com/cpb/data/CPBA0013.html> (stating health care provider’s policy on when such implants become “medically necessary”).

⁴⁷ See Abbott, supra note 410, at 126. Michael Chorost, who lost his natural hearing as an adult, provides an excellent description of how a cochlear implant would sound to a normal person. See CHOROST, supra note 45. He describes the input from his artificial cochlea as “something which resemble[s] hearing” and “equivalent to hearing,” but far from what ordinary people experience. *Id.* at 79.

⁴⁸ http://en.wikipedia.org/wiki/Cochlear_implant.

⁴⁹ *Id.*

As one would expect, the progress of visual neuroelectronic interfaces for the blind lags far behind that of the cochlear implants. All of the interfaces currently in development rely on the phenomenon of phosphene vision— the fact that stimulating specific parts of the retina, optic nerve, or visual cortex results in the human sensation of rows of dots and streaks of light.⁵⁰ The typical artificial vision system receives and processes signals from a CCD camera, and then transmits the signals to electrodes that stimulate the visual system.⁵¹ The differences among the various approaches lie mainly in the placement of the electrodes: some researchers have placed them on the surface of the retina, others below the surface of the retina or in the optic nerve, and yet others on top of or inside the visual cortex itself.⁵²

For instance, William Dobbelle, a pioneer in the field of artificial vision since the late 1970s, favors electrode arrays that are encased in biocompatible plastic and implanted on the surface of the visual cortex.⁵³ (Canadian Jens Naumann, a patient who became blind over twenty years ago, became famous in 2002 when he drove a convertible Mustang slowly around a parking lot, using only the visual signals he received from Dobbelle’s visual system.⁵⁴) Professor Richard Normann at the University of Utah has developed a similar cortical implant in which microwire electrodes actually penetrate the surface of the brain, allowing safer and easier

⁵⁰ See Definition of Phosphene, supra note 42. Because phosphenes are perceived as spread out over the visual field, researchers can “map” specific phosphene responses in a given individual to provide more coherent (albeit “pixelated”) vision. Wikipedia, Brain-Computer Interface, http://en.wikipedia.org/wiki/Brain-computer_interface.

⁵¹ Richard Normann, University of Utah Center for Neural Interfaces, Sight Restoration for Individuals with Profound Blindness (2001), <http://www.bioen.utah.edu/cni/projects/blindness.htm>. See also Kwabena Boahen, *Neuromorphic Microchips*, SCIENTIFIC AMERICAN May 2005 at 56-63; Ian Johnston, *The Magic Eye that Could Help Blind to ‘See’ Again*, THE SCOTSMAN (Edinburgh, Scotland) April 5, 2005 at 17.

⁵² See Normann, supra note 51, for an overview of the pros and cons of these different approaches to electrode placement. It’s unclear which approach has the most promise, but it is possible that some approaches will work better with certain kinds of blindness (for example, a retinal or optic nerve implant may be useful for those with macular degeneration; if the optic nerve no longer functions, then a cortical implant will be the only option.)

⁵³ Steven Kotler, *Vision Quest*, WIRED, Oct. 9, 2002, <http://www.wired.com/wired/archive/10.09/vision.html>. Unlike Richard Normann’s microelectrode implant, Dobbelle’s implant does not puncture the surface of the cortex, which may make it more biocompatible in the long term.

⁵⁴ *Id.*; see also Canadian Broadcasting Channel, CBC News: Sunday, Out of the Dark – the Jens Naumann Story, <http://www.cbc.ca/sunday/sight/story.html> (web coverage of story originally broadcast Jan. 5, 2003).

stimulation of the visual cortex.⁵⁵ (If this sounds familiar, that's because Normann's electrode array implant was the progenitor for the BrainGate *output* interface, discussed in section I.A. 4. supra.)⁵⁶ In a different line of investigation, Professor Gislin Dagnelie of Johns Hopkins is experimenting with a chip implanted on the back of the retina that he hopes will stimulate not only flashes of light, but will also allow patients to differentiate between horizontal and vertical lines.⁵⁷

The usefulness of these systems may improve with the implementation of greater resolution sensors and larger arrays.⁵⁸ At some point, perhaps they will even allow blind individuals to attain “functional mobility” – the ability to discern enough detail in the visual field to get around in say, a crowded city.⁵⁹ Of course, as scientists learn more about sensory input to the brain, perhaps visual input interfaces will hopefully provide a form of perception more realistic than mere flashes of light.

3. Kevin Warwick's Ultrasonic Sense

Perhaps the most exciting possibilities presented by input brain-computer interfaces are not merely in replacing the deficient senses of sight and sound, but in opportunities to create entirely new forms of human perception. In at least one instance, the future has already arrived. Kevin Warwick, professor of Cybernetics at the University of Reading, England, claims to be the

⁵⁵ See Kotler, supra note 53. Normann's implant apparently uses only a thousandth of the current that Dobbelle's implant uses to stimulate the brain. *Id.* This may be important, as Kotler at one point actually observed Jens Naumann fall into a violent seizure due to overstimulation from Dobbelle's implant. *Id.*

⁵⁶ Medical Devices & Surgical Technology Week, *Spinal Cord Injury; \$6.7 Million Granted for Bionic War on Disabilities*, Jan. 23, 2005, at 286 (describing Normann's Utah Electrode Array).

⁵⁷ Victoria Fletcher, “Artificial Eye that Will Let the Blind See,” DAILY EXPRESS (UK), April 5, 2005.

⁵⁸ Not that many more “pixels” may be needed. By subjecting humans with healthy eyes to a pixelated visual field akin to what a blind individual with a visual implant sees, one study found that the ability to navigate an environment began to plateau after attaining a 25 x 25 array of phosphenes, with as few as 10x10 phosphenes providing helpful visual information. Cha, K., K. Horch, et al. (1992), *Simulation of a phosphene-based visual field: visual acuity in a pixelated vision system*. Ann. Biomed. Eng. 20(4): 439-49.

⁵⁹ Kotler, supra note 53.

first human to successfully receive extra-sensory input via a neuroelectronic interface.⁶⁰ As part of a project he billed as “Cyborg 2.0,” Warwick underwent surgery to implant a 100-electrode micro-array into the median nerve in his wrist; wires from the implant were threaded under his skin, exited further up the arm, and connected to a radio transmitter on his arm.⁶¹ Warwick then donned an ultrasonic sensor placed on a baseball cap that could communicate with his implant. Blindfolded, he was able to successfully find his way around the lab using only the feedback from the sensor: the ultrasound would send more frequent pulses of current to his medial nerve when he got closer to an obstacle in the room, then die off when he moved away.⁶²

This relatively simple proof-of-concept experiment bodes well for the future of novel input interfaces. The ultrasonic sense did not affect Warwick’s other, natural senses, such as the sense of proprioception in the arm containing the implant. Rather, in his words, “I was just given something extra.”⁶³

C. Blurring the Input/Output Distinction

The input-output distinction is far from absolute. Indeed, no successful prosthesis (such as an artificial, brain-controlled arm) can be exclusively an “output” device without some feedback to the user. In particular, we rely on our sense of proprioception (which tells us such information as the angle of the joint, force of grip, vibration, and temperature) to help us move our natural limbs – and such feedback will be just as crucial for the operation of brain-controlled prostheses. While Aurora the Monkey has learned to use her robot arm by simply watching it

⁶⁰ Kevin Warwick – Home Page, .

⁶¹ A. Asohan, *Leading Humanity Forward*, The Star (Malay), Oct. 13, 2003. Apparently, Warwick experimented with a range of sensor frequencies and found that he was most receptive to ultrasound pulses. *Id.*

⁶² *Id.*; Grant Rollings, *As Will Smith Film Opens, Boffin Reveals Plan to Become Half Man, Half Robot*, THE SUN (UK) Aug. 2, 2004.

⁶³ Asohan, *supra* note 61.

move⁶⁴, future research and testing will likely demonstrate that for output prostheses, proper feedback to the user will be as important as actual device control.

Similarly, no “input” device would be complete without “output” control. Our senses of vision, hearing, smell, etc. are not entirely passive. We can move our eyeballs, cause our eyes to focus at varying distances, or cause our ears to “hone in” on one particular sound frequency among many. Thus, input devices will also require the ability to control the sensory input to some extent, via an output signal.

Finally, at least one sort of brain-computer interfaces cannot be classified as either input or output: those that will function as replacements for part of the brain itself. Scientists are developing “neural prostheses” that may one day be able to replace entire parts of the brain that are defective or damaged.⁶⁵ University of Southern California’s Ted Berger is a pioneer in this field, developing an artificial hippocampus for patients who have lost hippocampal brain cells to Alzheimer’s.⁶⁶ His goal is to replace damaged brain tissue with computer hardware that could perform the same functions.⁶⁷ If his vision is realized, it could pave the way for a whole class of computer chips that provide neither input nor output capabilities, but interact in an intimate way with the brain.

D. Prosthetics that Enhance: the Next Logical Step

Of course, there is no reason to stop with user devices that merely restore lost sensory or motor function. Once the technological barriers are overcome, no other practical reason will

⁶⁴ See generally Evans, supra note 37.

⁶⁵ James Cavuoto and Warren Grill, *Neural-Silicon Hybrids Point to New Era in Technology*, NEUROTECH BUSINESS REPORT, <http://www.neurotechreports.com/pages/hybrids.html>.

⁶⁶ *Id.*

⁶⁷ Bob Calverly, *Building the Bionic Brain*, USC TROJAN FAMILY MAGAZINE (Winter 2002), available at http://www.usc.edu/dept/pubrel/trojan_family/winter02/bionic_brain.html. Rather than try to understand the exact workings of the hippocampus, Berger’s approach is to mimic the spatial-temporal patterns of electrical inputs and outputs of the hippocampus – in essence, to treat it as a black box. *Id.* His team has already built a 100-neuron model chip, and they ultimately intend to implant a 10,000 neuron model in primate hippocampus. Cavuoto, supra note 65.

prevent the development of devices that not only “restore,” but also “enhance” human function. In most cases, brain-computer interfaces would even use the same technology as regular medical devices. The primary distinction, then, between a neuroelectronic device labeled as “enhancing” and one classified as medical and restorative would be the *purposes* for which it would be used.

In a plausible scenario, human-enhancing brain-computer interfaces will develop in three broad phases. In the first phase, medical devices that are considered replacements for normal human function will begin to surpass normal human capabilities. These devices will be implanted at first only in disabled medical patients due to real or perceived risks of surgery or post-surgical complications. Once artificial limbs and senses surpass the performance of ordinary ones, some healthy people will want (for their first time) to surgically replace their working body parts with neuroelectronic prostheses.⁶⁸ Athletes might upgrade to robotic legs and arms that never tire; militaries may want to equip their soldiers with the enhanced hearing and sharper eyesight that only sensory prostheses can provide.⁶⁹ Making these enhancements available to the non-disabled, of course, will bring lurking questions about the propriety and morality of enhancement technology to the fore.

Next will come devices with novel functions for which there is no natural human counterpart. Visual receptors may see into the ultraviolet or infrared spectra, provide high-power magnification, or give a user the ability to digitally “record” what she sees for later playback. Subvocal speech implants might allow special ops military forces to communicate silently among themselves in a manner eerily approaching telepathy. Artificial, additional “limbs” (not

⁶⁸ In the words of one writer for Wired Magazine: “In the future, the disabled may prove *more* abled; we may all want their prostheses.” Kotler, *supra* note 53.

⁶⁹ Military applications of neuroelectronic interfaces are already being anticipated. Miguel Nicolelis’ research with Aurora the monkey is funded in large part by DARPA (an agency within the U.S. Department of Defense). See Duke University, Press Release, DARPA To Support Development Of Human Brain-Machine Interfaces (Aug. 15, 2002), available at <http://dukenews.duke.edu/2002/08/darpacontract0802.html>.

necessarily resembling arms or legs) may provide humans with greater control over their environment. Perhaps Kevin Warwick's ultrasonic sense is only the first step towards a universe of possibilities.

The third and final phase of enhancement technologies will consist of some too fantastic to be imagined today in any real detail. Neuroelectronic interfaces could eventually encompass any system capable of input-output communication with the brain. For example, a human-machine interface could allow a human to sense and control a large and complex system, such as an entire factory or a tank. Humans could directly perceive computer inputs, communicating with machines on an entirely intuitive level – imagine “Googling with your mind.” The ultimate result may be neural-silicon hybrids in which the man is indistinguishable from the machine.

E. The Limitations of Brain-Computer Interfaces

Back to reality for a second: while current research is promising, the obstacles to brain-computer interfaces are already becoming apparent, and they are quite significant. The challenges to developing usable brain-computer interfaces fall into two main categories, which can be called biocompatibility and “brain-compatibility.”

1. Biocompatibility: Minimizing Damage and Long Term Signal Degradation

The human brain was not designed to interface with consumer electronics. A recent editorial in *NATURE* identifies the biggest obstacle currently facing the long-term use of neuroelectronic interfaces: the ability of electrode microarray implants to send or receive brain signals degrades over time.⁷⁰ The culprit seems to be the brain's adverse reaction to electrode

⁷⁰ Degradation seems to begin after several months. *See, e.g.*, Pollack, *supra* note 31; Nature, *supra* note 34; Shenoy, *supra* note 36. This assessment applies to uninsulated microwire electrodes that penetrate the surface of the brain, such as Donoghue's BrainGate, Nicolelis's arrays in monkeys, and Normann's Utah Electrode Array.

implants: a variety of persistent inflammation and scarring processes.⁷¹ Obviously, these processes must be more fully understood if brain-computer interfaces are to be any more than a passing novelty.⁷² (The solution may involve coating the electrodes with bio-active molecules that are slowly released into the surrounding brain tissue.)⁷³

2. Brain Compatibility: Speaking the Language of the Brain

Scientists will also need a better understanding of how the brain processes and encodes information in order to effectively design neural prostheses.⁷⁴ Blindly inputting electrical impulses to the brain (whether via direct cortical stimulation or peripheral nerves) is a naïve approach; we need a more sophisticated model of how the brain communicates and receives information. Until then, we are merely “sorcerers’ apprentices, chanting half-understood incantations and hoping for the best.”⁷⁵

⁷¹ Polikov, V.S., Tresco, P.A. & Reichert, W.M. *Response of Brain Tissue to Chronically Implanted Neuro Electrodes*. J. NEUROSCI. METHODS 148, 1-18 (2005). Damage to the brain tissue includes the initial physical trauma of implantation, which can sever capillaries and extracellular matrix as well as destroy glia and neurons; the ‘micromotion’ of the electrodes as they move around after they are implanted; and chronic inflammation. *Id.* Furthermore, brain tissue apparently responds to long term, or ‘chronic,’ electrode implantation by forming encapsulating scars around the electrodes. This process begins immediately after implantation and is well underway six to eight weeks in; it serves to isolate electrodes from the neurons they are designed to measure. *Id.* (detailing the process of glial scar formation induced by reactive astrocytes). (Interestingly, glial scarring occurs only in higher vertebrates and may be part of the same phenomenon that makes it difficult for the human brain and spinal cord to heal; an analogous phenomenon of soft tissue encapsulation occurs for chronically implanted foreign objects in the human body. *Id.*) In addition, the initial scarring response is supplemented by a secondary response involving the attraction of activated microglia to the implantation site, where they attempt to phagocytose, or ‘eat,’ the foreign electrode material. *Id.*

⁷² Reichert et al. call for systematic studies to develop models (such as laboratory brain cell culture models) of this poorly understood scarring phenomenon, known as “reactive gliosis.” *Id.* He also suggests that long-term implantation studies should use actively conducting electrodes as the implants. Live electrodes were not used in the majority of previous studies; it is unclear whether that matters.

⁷³ Surveying the literature, Reichert notes that attempts (by Nicolelis and others) to manipulate the shapes and materials of electrodes do not affect long-term glial scar formation, only the short term wound healing response – after 6-12 weeks, scarring was identical regardless of electrode geometry. *Id.* In contrast, efforts to coat the electrodes with bioactive molecules, such as cell adhesion molecules, polypeptides, wound-healing suppressants, and even little bits of nerve tissue (“PNS explants” – apparently one of the most promising possibilities) have been mixed, but this also need further research. *Id.*

⁷⁴ Horgan, *supra* note 44; Abbott, *supra* note 41. Of course, there may be no single secret “code” (like the “genetic code”) that is the key to understanding the brain.

⁷⁵ Chorost, *supra* note 45, at 179.

II. FDA Device Law

Currently, no U.S. regulatory body asserts control over neuroelectronic enhancements. However, the Food & Drug Administration's broad regulatory jurisdiction over medical devices makes it the prime candidate to do so. Section 201(h) of the Food Drug & Cosmetic (FD&C) defines "device" as "an instrument, apparatus, implement, machine, contrivance, implant" which is intended for either of the two uses that define drugs: use in "the diagnosis . . . treatment, or prevention of disease" or use "to affect the structure or any function of the body."⁷⁶ As will be explained in Section III.A. *infra*, the latter half of this definition is broad enough to encompass devices that enhance. As it is, the range of products currently categorized as devices is already quite broad.⁷⁷

Within the FDA, the Center for Devices and Radiological Health (CDRH) oversees the approval and manufacture of all medical devices marketed in the U.S. and sets the relevant regulatory standards.⁷⁸ As with new drug approvals, FDA can attach strings to its device approval orders, restricting access to sale or use. Unlike drug regulation, CDRH regulations also extend beyond the regulatory approval process to cover the "post-market" period – after the

⁷⁶ Food, Drug & Cosmetic Act §201(h) (codified at 21 U.S.C. § 321) [hereinafter FDCA]. The FDA has clearly not exercised the outer limits of this jurisdiction (the clothes we wear would arguably affect the body's "structure" or "function"). Greely, *infra* note 132. Devices are distinguished from drugs, which FDA also regulates, in that devices do not achieve their primary function through "chemical action" or by being metabolized by the body. *Id.* See also FDA Device Advice, Is this Product a Medical Device?, <http://www.fda.gov/cdrh/devadvice/312.html>. (Device Advice is a helpful, business-friendly site containing clear and practical explanations of FDA medical device regulations.)

⁷⁷ FDA-regulated devices include simple bedpans and tongue depressors as well as complex microchip-controlled pacemakers. *Id.* All in all, there are approximately 1,700 generic types of devices on the market today, further grouped into 16 medical specialties, or "panels." FDA Device Advice website, "Classify Your Medical Device", at <http://www.fda.gov/cdrh/devadvice/313.html>. See also 21 C.F.R. §§ 862-892. A "generic type of device" is defined as "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness." 21 C.F.R. § 860.3(i).

⁷⁸ The CDRH was created by the 1976 Medical Device Amendments to the Food Drug & Cosmetic (FD&C) Act to oversee the regulation of medical devices. See Medical Device Act Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (May 28, 1976).

devices have been sold and are actually being used. They can require, for instance, regular surveillance and accident reporting. Each of these stages of FDA regulation is discussed below.

Unlike FDA drug regulation, then, which centers around the NDA drug approval process, a good portion of FDA's regulation of devices occurs *after* approval. As will be argued later, continuing regulation is a key feature of FDA law that makes it especially appropriate for the fluid world of developments surrounding brain-computer interfaces.

A. FDA Device Classes

FDA's goal is to ensure that medical devices introduced to market are "safe" and "effective."⁷⁹ It classifies each device into one of three categories based on the amount of risk involved in use of the device, and the level of regulation FDA will require to ensure the device's safety and effectiveness. Devices classified as "Class I" pose the least risk and require the least regulation, while "Class III" devices are the most dangerous and deserve the highest scrutiny.⁸⁰ FDA relies upon the advice of "classification panels" composed of experts from relevant fields in making its classifying decisions.⁸¹

All new devices (those introduced after May 28, 1976) are presumptively classified in Class III.⁸² This presumption may be overcome if FDA finds the new device to be "substantially equivalent" to an existing Class I or Class II device,⁸³ or if the new device is clearly low in

⁷⁹ See generally FDCA §513(a) (codified at 21 U.S.C. § 360c(a)).

⁸⁰ *Id.* Each successive device class is also subject to the regulations for the classes below, such as general controls, special controls, and performance standards.

⁸¹ FDCA § 513(b) (codified at 21 U.S.C. § 360c(b)) (directing FDA to assemble classification panels to assist FDA in classifying devices in interstate commerce before May 28, 1976); see generally Industry Canada, Medical Devices, Chapter 3: U.S. Requirements, <http://strategis.ic.gc.ca/epic/internet/inmd-am.nsf/en/hi00039e.html>.

⁸² FDCA §513(f) (codified at 21 U.S.C. §360c(f)).

⁸³ 21 U.S.C. § 360c(f)(1)(A). This is also known as the 510(k) approval process, discussed below.

risk.⁸⁴ An existing device may also be reclassified downward upon the FDA’s initiative or upon the petition of the manufacturer.⁸⁵

1. Class I Devices

Class I devices are low-risk, low-complexity devices. FDA primarily regulates Class I devices through the use of “general controls” – very basic provisions governing adulteration and misbranding, device registration, records and reports, and good manufacturing practices.⁸⁶ Some examples of Class I devices are elastic bandages, examination gloves, and hand-held surgical instruments.⁸⁷ While Class I devices are nominally subject to the 510(k) Premarket Notification approval process (discussed below), FDA in practice exempts the vast majority of Class I devices from that requirement.

2. Class II Devices

Class II devices are defined as devices for which general controls are insufficient to ensure safety and effectiveness, but for which available methods exist providing such assurances.⁸⁸ So in addition to general controls, Class II devices are also subject to “special controls,” which may include special labeling requirements, mandatory performance standards,

⁸⁴ The FDA has streamlined classification for new, low-risk devices that are not based on a predicate device, via a process called “Evaluation of Automatic Class III Designation.” See FDA, NEW SECTION 513(F)(2) - EVALUATION OF AUTOMATIC CLASS III DESIGNATION (Feb. 19, 1988), available at <http://www.fda.gov/cdrh/modact/classiii.html>.

⁸⁵ 21 U.S.C. § 360c(f)(1)(B); see also 21 C.F.R. § 860.123 (requirements for petition for reclassification). *Contact Lens Mfrs. Assn. v. Food & Drug Admin. Dept. of Health and Human Services*, 766 F.2d 592 (D.C.Cir. 1985), demonstrates both kinds of reclassification initiatives. In the agency proceedings at issue in *Contact Lens*, the FDA determined that the manufacturers’ downward classification petition for certain a device (“RGP lenses”), while insufficient, merited further investigation. It then initiated its own reclassification investigation. *Id.* A successful downward reclassification petition must present “valid scientific evidence” that can assure that a device is safe and effective – sometimes meaning full clinical trials. 21 C.F.R. §860.7(c)(2). See also *Contact Lens*, 766 F.2d at 596-97 (describing FDA’s use of the “valid scientific evidence of safety and effectiveness” standard in reclassification proceedings.) In *Contact Lens*, FDA invited extended public notice and comment on the issue. *Id.*

⁸⁶ FDCA Act §513 (a)(1)(A) (codified at 21 U.S.C. §360c(a)(1)(A)); FDA Device Advice, General Controls for Medical Devices, <http://www.fda.gov/cdrh/devadvice/363.html>.

⁸⁷ FDA Device Advice, Device Classes, at <http://www.fda.gov/cdrh/devadvice/3132.html>.

⁸⁸ FDCA Act §513 (a)(1)(B) (codified at 21 U.S.C. §360c(a)(1)(B)); FDA Device Advice, Device Classes, *supra* note 87.

and postmarket surveillance. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.⁸⁹

3. Class III Devices

Lastly, Class III contains the most dangerous and complex devices, for which general controls and special controls alone cannot ensure safety and effectiveness. They include devices “represented to be for a use in supporting or sustaining human life” or that present a “potential unreasonable risk of illness or injury.”⁹⁰ For this reason, Class III devices are subject to FDA’s most stringent form of review, Premarket Approval (PMA). In addition, the general and special controls regulating the design, labeling, and post-market performance of Class I and II devices apply to Class III devices as well. Examples of Class III devices are replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.

B. FDA Device Approvals

The classification of a device will determine the burden of proof the FDA will require to demonstrate its safety and effectiveness for a given indication of use.⁹¹ Generally, this means a device must undergo one of two regulatory routes: the 510(k) process or the PMA process.

1. Pre-Market Notification: the 510(k)⁹²

The most common method of FDA device approval is the “traditional” 510(k) Premarket Notification.⁹³ A 510(k) application simply requires proof that a given device is “substantially

⁸⁹ FDA Device Advice, Device Classes, *supra* note 87.

⁹⁰ FDCA §513(a)(1)(C) (codified at 21 U.S.C. §360c(a)(1)(C)).

⁹¹ In addition, the date of introduction of the device (i.e., whether or not it was in commerce before the May 28, 1976 Medical Device Amendments went into effect) also affects the showing necessary to gain FDA approval; a device may be classified as “pre-amendment,” “post-amendment,” or “transitional” (this last category is for devices previously regulated as drugs). See *Ethicon, Inc., v. Food and Drug Admin.*, 762 F. Supp. 382, 384 (D.D.C. 1991). However, these distinctions are not likely to be relevant to neuroelectronic interface devices, which are by and large entirely new.

⁹² The name “510(k)” refers to the section of the original FD&C statute that governed pre-market notification; the statutory section has since changed (it is now §513(f)(1)(A), and is codified at 21 U.S.C. §360c(f)(1)(A).)

equivalent” to a device that has been previously classified and approved.⁹⁴ Under the substantial equivalence standard, a new device does not need to be identical to the predicate device; it just needs to have the same intended use and technological characteristics.⁹⁵ If it has different technological characteristics, or will be marketed for a different intended use, the changes must be shown not to raise new questions of safety or effectiveness.⁹⁶ In most cases, the 510(k) process can be completed quickly and is ideal for the routine approval of common, everyday medical devices.⁹⁷

2. Pre-Market Approval (PMA)

PMA is FDA’s most stringent form of premarket review, reserved for Class III devices. In contrast to the streamlined 510(k) process, FDA typically requires the submission of significant additional documentation in evaluating a PMA to ensure safety and effectiveness, and annual reports even after the PMA is granted.

(i) Evidence Required

Typically, a PMA will require clinical trials and other scientific data on the device’s safety and effectiveness.⁹⁸ FDA expects the evidence of a device’s effectiveness to include “well-controlled investigations, including [one] or more clinical investigations where appropriate,” conducted by qualified experts.⁹⁹ In addition to clinical investigations, FDA may

⁹³ Besides the “traditional” option, there are specialized variants on the 510(k) application. FDA, THE NEW 510(K) PARADIGM - ALTERNATE APPROACHES TO DEMONSTRATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS - FINAL GUIDANCE (Mar. 20, 1998), *available at* <http://www.fda.gov/cdrh/ode/parad510.html>. However, the “traditional” 510(k) has the broadest applicability and can be used at any time. FDA Device Advice, How to Prepare a Traditional 510(k), <http://www.fda.gov/cdrh/devadvice/3143.html>.

⁹⁴ 21 U.S.C. § 360c(f)(1)(A); See FDA Device Advice, “Premarket Notification [510(k)],” at <http://www.fda.gov/cdrh/devadvice/314.html>.

⁹⁵ *Ethicon*, 762 F. Supp. at 382 (discussing the substantial equivalence standard).

⁹⁶ 21 C.F.R. §807.87(g); FDA Device Advice website, Premarket Notification [510(k)], *supra* note 94. Clinical data is increasingly required for devices that have different technological characteristics than a claimed predicate device. LARS NOAH AND BARBARA NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY (2002) 246.

⁹⁷ NOAH, *supra* note 96.

⁹⁸ FDA Device Advice website, “Premarket Approvals”, at <http://www.fda.gov/cdrh/devadvice/pma/>.

⁹⁹ 21 U.S.C. § 360c(a)(C)(3).

also require significant non-clinical laboratory studies related to toxicology, immunology, biocompatibility, stress, wear, etc.¹⁰⁰ Since much of this data, especially clinical data, cannot be gathered until the device has been tested in humans, the FDA will commonly grant an Investigational Device Exception allowing a manufacturer to conduct clinical trials.¹⁰¹

(ii) Device Approval Process

Once all the requisite data on safety and effectiveness has been compiled, and clinical studies completed, staff experts at FDA's CDRH will evaluate the pre-market application and decide whether to grant approval. As with drugs, FDA will often bring in outside expertise to make device approval decisions that involve cutting-edge technology or controversial issues.¹⁰² FDA maintains a system of Advisory Committees to provide the agency with independent scientific and technical advice in specialized medical areas, such as antiviral drugs, anesthesiology or respiratory therapy devices.¹⁰³ These committees consist of representatives from industry and consumer groups as well as from traditional academia and medicine.¹⁰⁴ Though the final regulatory decision rests with FDA, great weight is placed on committee discussions and recommendations. Committees not only provide FDA with technical advice, but

¹⁰⁰ FDA Device Advice, Premarket Approvals, *supra* note 98.

¹⁰¹ Both the FDA and an appropriate Institutional Review Board (IRB) must approve the IDE application before any investigation can begin. 21 C.F.R. §812.42. However, independent FDA approval for an IDE is needed only when the device sought to be tested involves "significant risk." 21 C.F.R. §812.20. IRB approval (and FDA notification of that approval) is still required in all cases. FDCA §520(g)(3)(A)-(B) (codified at 21 U.S.C. §360j(g)(3)(A)-(B)). (An IRB is any group formally designated by a given institution to review biomedical research involving subjects. 21 C.F.R. §812.3.)

¹⁰² The decision to involve an Advisory Committee is a discretionary one. *See generally* Carlos Rados, *Advisory Committees: Critical to the FDA's Product Review Process*, FDA CONSUMER MAGAZINE, Jan-Feb 2004 issue, available at http://www.fda.gov/fdac/features/2004/104_adv.html; DIXIE FARLEY, GETTING OUTSIDE ADVICE FOR "CLOSE CALLS," JANUARY 1995 FDA SPECIAL CONSUMER REPORT, available at <http://www.fda.gov/fdac/special/newdrug/advice.html>.

¹⁰³ See <http://www.fda.gov/oc/advisory/default.htm> for an overview of all Advisory Committees, and <http://www.fda.gov/oc/advisory/acdevices.html> for a list of the 18 Committees on medical devices.

¹⁰⁴ *See* Rados, *supra* note 102. The reasoning is that a diverse committee membership can increase the quality and legitimacy of the decisionmaking. *Id.* Of course, even consumer advocates on the committee must be technically qualified to analyze data, risks and benefits. *Id.*

they may raise issues of safety or efficacy, or suggest additional studies.¹⁰⁵ Members can also raise relevant policy issues, and public comment is invited at committee meetings.¹⁰⁶

(iii) Post-Approval Reports

The manufacturer is required to submit periodic reports to FDA even after PMA approval, in the form of (1) annual reports that summarize any unpublished clinical or laboratory data, and any published literature, related to the device¹⁰⁷, and (2) “PMA supplements” whenever changes are made to the device that affect its safety or effectiveness.¹⁰⁸ Such changes may include new indications for use, labeling, technological characteristics, or manufacturing processes.¹⁰⁹

¹⁰⁵ See Rados, *supra* note 102.

¹⁰⁶ Carol Lewis, *Advisory Committees: FDA's Primary Stakeholders Have a Say*, FDA CONSUMER MAGAZINE, Sept.-Oct. 2000, available at http://www.fda.gov/fdac/features/2000/500_adv.html (discussing issues surrounding an advisory committee's approval of an AIDS drug.)

¹⁰⁷ 21 C.F.R. §814.84.

¹⁰⁸ *Id.* §814.39.

¹⁰⁹ *Id.*

C. Restrictions on PMA Approvals

In granting a PMA, FDA may impose restrictions on the sale and distribution of a device.¹¹⁰ It will do so where the device’s “potentiality for harmful effect or the collateral measures necessary to its use” make such restrictions necessary to guarantee safety and effectiveness.¹¹¹ Restrictions may include, for example, a command that a device be sold or operated only with the approval of a medical professional, making it effectively a “prescription” device (analogous to a prescription drug.)¹¹² They may also include a requirement for prominent labeling or post-approval surveillance or monitoring measures (discussed below).¹¹³

However, while FDA will grant approval only with respect to the manufacturer’s intended use of the device, the agency does not police “off-label” uses of a device (i.e. instances where the device is used for purposes other than the intended use.)¹¹⁴ This approach is highlighted by the FDA’s approach in the controversy over reprocessed single-use devices: the agency has allowed hospitals to reuse (after FDA-approved “reprocessing”) surgical tools even though those medical instruments were originally approved by the FDA for a single time use, followed by disposal.¹¹⁵ In this respect, FDA device regulation resembles its regulation of pharmaceutical drugs.

¹¹⁰ FDCA §515(d)(1)(B)(ii) (codified at 21 U.S.C. 360e(d)(1)(B)(ii)); FDA Device Advice Website, Postapproval Requirements, at <http://www.fda.gov/cdrh/devadvice/pma/postapproval.html>. The restrictions can be placed either in the PMA approval order itself, or by regulation subsequent to the order. *Id.*

¹¹¹ FDCA §520(e)(1) (codified at 21 U.S.C. § 360j(e)(1)).

¹¹² *Id.* §520(e)(1)(A).

¹¹³ 21 C.F.R. §§ 814.80, 814.82.

¹¹⁴ This may seem surprising, as the “indications for use” for a device can be quite elaborate. For example, the PMA approval order for one cochlear implant lays out detailed criteria and hearing test scores for determining when three separate groups of patients – adults, juveniles, and infants – should have access to the device. *See* FDA CDRH, Approval Order for Med-El COMBI 40+ Cochlear Implant System (Aug. 20, 2001), <http://www.fda.gov/cdrh/pdf/P000025.html> (click on Approval Order link). *See also* 21 C.F.R. §814.80 (prohibiting device from being “manufactured . . . labeled, distributed, or advertised” in violation of the conditions in the PMA order, but containing no prohibition on “use”).

¹¹⁵ *See* Janet Moore, *Medical Devices in Unexpected Places*, Star Tribune (Minn.) (Dec. 18, 2006), available at http://www.startribune.com/dynamic/mips_mobile_story.php?story=883483. FDA does, however, regulate rSUD

D. Post-Approval Regulation

Finally, FDA can require significant monitoring of device production and usage after approval. FDA's post-approval control includes two forms of regulation: oversight of the device development process, and surveillance & reporting requirements. While the former aims to minimize problems at the front end, the latter allow FDA to take the longer view, and respond to issues of safety and effectiveness that arise during long-term use.

1. Quality System Regulation, Design Controls

First, FDA requires that manufacturers of all medical devices (an exception is made for most Class I devices) implement a quality system for every step of the development process, including design, manufacture, packaging, and labeling. This Quality System (QS) regulation specifies general standards in areas such as employee training, equipment calibration, and process controls rather than specific measures for any given device.¹¹⁶

The interesting part of the QS regulation is the mandate for Design Controls. Like the QS regulation itself, the Design Controls are also constructed as a set of guiding principles, not a checklist. Their goal is to improve the "visibility" of the design process (both the initial design and any modifications), so problems can be recognized earlier and better responses can be

reprocessors. Medical Device User Fee and Modernization Act (MDUFMA) of 2002, Pub. L. No. 107-250; Ginette Y. Michaud, presentation at AdvaMed Conference, Arlington, VA, May 24-25, 2006, Reprocessing of Single Use Devices (PowerPoint available at www.fda.gov/cdrh/present/advamed-052405-michaud.ppt) (detailing the FDA regulatory scheme for reprocessed devices).

¹¹⁶ See generally 21 C.F.R. part 820.

made.¹¹⁷ Significantly, design controls extend to any software underlying a device, as it plays a key role in the operation of many devices and creates risks of device failure.¹¹⁸

Design Controls also incorporate innovative “Human Factors” considerations. This means the interface and design of devices should be as user-friendly as possible: manufacturers must account for “the interaction of human abilities, expectations, and limitations with work environments and system design.”¹¹⁹ These requirements may take on new meaning and importance as neuroelectronic devices more routinely interface with the human body.

2. Post-Market Surveillance & MDR Reporting

A second sort of post-approval regulation involves incident monitoring. Under the Medical Device Reporting (MDR) regulation, manufacturers, importers, and the medical facilities where the devices are used (“device user facilities”¹²⁰) must report regularly to FDA regarding deaths or serious injuries that involve the device.¹²¹ Manufacturers have the greatest reporting burden under this regulation.¹²² They, along with importers, must also report device

¹¹⁷ FDA CDRH, DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS (Mar. 11, 1997), *available at* <http://www.fda.gov/cdrh/comp/designgd.html> (providing guidance for the Design Control regulations, 21 C.F.R. §820.30). Design controls require manufacturers to explicitly consider “inputs” and “outputs” in a design and then to “verify” and “validate” the design choices that are made; these activities must be documented in the “device master record.” *Id.* (explaining concepts of design input, output, verification, and validation.) *See also* 21 C.F.R. §820.3 (definition of “device master record”).

¹¹⁸ FDA CDRH, GENERAL PRINCIPLES OF SOFTWARE VALIDATION; FINAL GUIDANCE FOR INDUSTRY AND FDA STAFF (Jan. 11, 2002), *available at* <http://www.fda.gov/cdrh/comp/guidance/938.html> (“FDA’s analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures.”)

¹¹⁹ FDA CDRH, Human Factors Program, <http://www.fda.gov/cdrh/humanfactors/whatis.html>. *See also* DICK SAWYER, FDA, DO IT BY DESIGN: AN INTRODUCTION TO HUMAN FACTORS IN MEDICAL DEVICES (Dec. 9, 1996), *available at* <http://www.fda.gov/cdrh/humfac/doi.html>.

¹²⁰ A “device user facility” is defined generally as “a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility.” 21 U.S.C. §360i(b)(6)(A), 21 C.F.R. §803.3.

¹²¹ FDCA §519(a)-(b) (codified at 21 U.S.C. §360i(a)-(b)). 21 C.F.R. §§ 803.1, 803.10; FDA CDRH, Medical Device Reporting – General Information, <http://www.fda.gov/cdrh/mdr/mdr-general.html>. Device user facilities are required to report only to the manufacturer for serious injury incidents, but must report to both to the FDA and the manufacturer for device-related deaths. *Id.* §803.30. User facilities must also submit annual report summarizing their incident reporting. *Id.* §803.33.

¹²² Manufacturers are responsible not only for “baseline reports” to the FDA, 21 C.F.R. §§ 803.50, 803.55, but follow-up reports on the incidents, 21 C.F.R. §803.56, and “5-day reports” when remedial action is necessary to

malfunctions that would be likely to contribute to death or serious injury.¹²³ Despite this rule, it is unclear when the MDR regulations require manufacturers to disclose device *flaws* to the FDA, doctors, or patients when those flaws have not yet resulted in malfunction.¹²⁴

Lastly, FDA may also require “postmarket surveillance” studies of any Class II or Class III medical device that might involve serious adverse health consequences, or is intended to be implanted in the human body for more than a year.¹²⁵ These studies require manufacturers to conduct large-scale studies to collect useful data about the performance of the device “as it is to be used in the general population for which it is intended”; the focus is on device failure, impact of failure on the patient, and morbidity and mortality.¹²⁶ For example, FDA has required both of the manufacturers of recently approved silicone breast implants to follow roughly 40,000 women for ten years after implantation to observe just these kinds of long-term side effects.¹²⁷ FDA can require surveillance of up to 36 months on its own discretion, or longer with the consent of the manufacturer (as with the breast implant studies).¹²⁸

Unfortunately, despite potentially broad postmarket regulatory powers in this area, FDA has not consistently or effectively regulated devices after approval. For example, FDA has characterized its postmarket surveillance authority as an “available, but widely misunderstood

prevent “an unreasonable risk of substantial harm to the public health.” 21 C.F.R. §803.53. (Foreign manufacturers must designate an agent to carry out the reporting requirements. *Id.* §803.58.)

¹²³ See 21 C.F.R. §§ 803.10, 803.40, 803.50.

¹²⁴ Barry Meier, *Implants with Flaws: Disclosure and Delay*, New York Times (Jun. 14, 2005), at C1 (calling attention to the lack of uniform standards about when to notify doctors, patients, or FDA about device flaws, which may or may not later result in serious injury or death.)

¹²⁵ FDCA §522 (codified at 21 U.S.C. §360l).

¹²⁶ See FDCA §519 (codified at 21 U.S.C. § 360i), and FDA Device Advice, Postmarket Surveillance Studies, <http://www.fda.gov/cdrh/devadvice/352.html>.

¹²⁷ FDA, Approval Order for Mentor MemoryGel Silicon Gel-Filled Breast Implants, <http://www.fda.gov/cdrh/pdf3/P030053.html> (click on “Approval Order”); FDA, Approval Order for Inamed Silicone-Filled Breast Implants, <http://www.fda.gov/cdrh/pdf2/P020056.html> (same).

¹²⁸ FDCA §522 (codified at 21 U.S.C. §360l).

and underutilized, tool.”¹²⁹ Similarly, reporting of adverse device incidents is sporadic, disorganized, and difficult to analyze because of an outdated computer system and infrequent enforcement.¹³⁰ This may change with FDA’s recent Postmarket Transformation Initiative.¹³¹

III. The Advantages and Shortcomings of Existing FDA Device Law

Asking FDA to regulate purely enhancing brain-computer interface devices is practical for two reasons. First, FDA’s jurisdiction is broad enough to cover enhancing devices, and the agency’s existing infrastructure and administrative expertise provide strong reasons not to create a regulatory scheme from scratch.¹³² Second, it is likely that FDA will be inclined to regulate enhancement devices anyway, if only for their *medical* implications: any delicate device installed in the body will have an impact on human health and function that raise issues of safety and effectiveness. (As discussed later, this is not the optimal solution.) Recent FDA decisions to regulate as devices two *cosmetic* products – decorative (color-changing) contact lenses¹³³ and

¹²⁹ FDA CDRH, REPORT OF THE POSTMARKET TRANSFORMATION LEADERSHIP TEAM: STRENGTHENING FDA’S POSTMARKET PROGRAM FOR MEDICAL DEVICES (Nov. 2006), *available at* <http://www.fda.gov/cdrh/postmarket/mdpi-report-1106.html>.

¹³⁰ FDA CDRH, Ensuring the Safety of Marketed Medical Devices: CDRH’s Medical Device Postmarket Safety Program –Synopsis and Recommendations (Jan. 2006), *available at* <http://www.fda.gov/cdrh/postmarket/mdpi-recommendations.html>.

¹³¹ FDA CDRH, Medical Device Postmarket Transformation Initiative, <http://www.fda.gov/cdrh/postmarket/mdpi.html>.

¹³² Food, Drug & Cosmetic Act §201(h) (codified at 21 U.S.C. § 321) (defining FDA jurisdiction over devices that affect “any structure or function” of the body.) Of course, the FDA clearly does not exercise the full extent of its jurisdiction over devices; for example, it is not in the business of regulating clothes. *See* Henry Greely, *The Social Effects of Advances in Neuroscience: Legal Problems, Legal Perspectives*, in *NEUROETHICS: DEFINING THE ISSUES IN THEORY, PRACTICE, POLICY* (Judy Illes ed., Oxford Univ. Press 2005) Section 3, at Section 3.1 [need page numbers] (noting that clothes can be said to “affect the structure or . . . function” of the human body).

¹³³ *See* Pub. L. No. 109-96 Nov. 9, 2005) (codified at 21 U.S.C. §360j(n)) (amending FD&C §520(n) to classify all contact lenses as “devices”); FDA CDRH, GUIDANCE FOR INDUSTRY, FDA STAFF, EYE CARE PROFESSIONALS, AND CONSUMERS - DECORATIVE, NON-CORRECTIVE CONTACT LENSES (NOV. 24, 2006), <http://www.fda.gov/cdrh/comp/guidance/1613.html> (FDA’s nonbinding recommendations). Interestingly, FDA originally decided to classify decorative lenses as cosmetics, not devices, but Congress had other ideas.

silicone gel breast implants¹³⁴ – lend support to the notion that the agency is interested in monitoring *any* class of devices that involve significant risk to the human body, not just “medical” devices.¹³⁵ Because neuroelectronic devices raise such novel and serious issues of safety and effectiveness, under existing FDA law they will likely be regulated as Class III devices and subjected to the PMA review process.¹³⁶

However, FDA would choose to regulate enhancement devices (or for that matter, any user device with significant enhancement potential) solely for their *medical* implications. There are two problems with that proposition. First, due to their invasiveness and permanent nature, brain-computer interfaces raise numerous new safety and effectiveness concerns that FDA would have to adapt to. Additionally, these concerns should be weighed more heavily when enhancement, not just medical health, is at issue. (The effect that enhancement should have on the baseline for risk is discussed in Part A below.) But second, and more importantly, FDA must recognize that neuroelectronics have implications related to their ability to *enhance*, as well. The specter of enhancement of the human body, by itself, raises a myriad substantive issues,

¹³⁴ See eMaxHealth, Silicone Gel-Filled Breast Implants Approved by FDA, Nov. 18, 2006, <http://www.emaxhealth.com/57/8311.html>.

¹³⁵ Both decorative contacts and silicone-based implants involve heightened safety risks (chronic, long term implantation of a foreign substance in one case, and close contact with the surface of the eye in the other) and have also been surrounded by public controversy. See, e.g., National Organization for Women, Press Release, FDA Approval of Dangerous Implants During Lame Duck Session Follows FDA Pattern of Favoring Money and Politics Over Science (Nov. 17, 2006), <http://www.now.org/press/11-06/11-17.html>. In some cases, the decision is not even the FDA’s. Prevent Blindness America, Press Release, Cosmetic Contact Lens Briefing Builds Support for Legislation (Oct. 8, 2005) http://www.preventblindness.org/news/releases/decorative_cl_briefing.html. It is unclear, however, how FDA also regulates the *effectiveness* of cosmetic devices.

¹³⁶ It is unlikely that general or special controls, alone, can ensure the safety & effectiveness of neuroelectronic devices – the hallmark of devices placed in Class III. Even the noninvasive myoelectric- or EEG-based input devices, which are less invasive, may be classified as Class III if FDA determines that their use presents a “potential unreasonable risk of illness or injury.” FD&C §513(a)(1)(C) (codified at 21 U.S.C. §360c(a)(1)(C)). Furthermore, the 510(k) route will not provide a “back door” for devices that significantly enhance abilities beyond normal, even if they are based upon a predicate device. Cf. Greely, *supra* note 132, at section 3.1. If the FDA finds that a cochlear implant that can “hear” ultrasound vibrations has new technological characteristics (and I think it would), it will require clinical data demonstrating the safety and effectiveness of the new features – similar to the standard of proof required for a PMA. It would not allow that device to gain approval as “substantially equivalent” to old cochlear implants. See section II.B. 1. *supra*.

including propriety, morality, and the societal impact of enhancing devices that FDA does not, and is currently unable to, address.

A. The New Safety and Efficiency Challenges of Neuroelectronic Devices

New safety and effectiveness issues arise with neuroelectronic devices because (1) they involve implanted components that will be in close contact with the brain or other parts of the nervous system; (2) they must function over the entire lifetime of the user; and (3) they have the potential for human enhancement, rather than just restoration of lost function. This section addresses these new risks with respect to both the baselines of medical use and enhancement, and argues that a lower tolerance for such risks should be imposed for pure enhancement devices.

1. New Safety Issues

The enhanced safety risks of neuroelectronics fall roughly into three categories: risks of adverse body reaction, risks of adverse brain feedback, and risks related to device failure.

First, there is always possibility of something going wrong when a foreign object is placed inside the brain. As discussed earlier in Section I.E. , pushing brain chip microelectrodes into the surface of the brain cortex provokes a complex, chronic brain inflammation response (that ultimately results in diminished chip function – an effectiveness issue.) There is also the risk of infection involved in invasive surgery, which may be heightened if the implant needs regular replacement and multiple surgeries. If the brain chips are coated with bioactive molecules or other components (currently the most promising solution to the inflammation problem), additional issues related to their safety must also be addressed.¹³⁷

¹³⁷ In that case, they may also have to be regulated as drug-device combinations. Both CDER (the FDA center that regulates drugs), CDRH (which regulates devices) may have jurisdiction over such a product. *See generally* Jeffrey Gibbs, State of the Union: Drug-Device Combinations, *MED. DEVICE & DIAGNOSTIC INDUS.*, Nov. 2006., available at <http://www.devicelink.com/mddi/archive/06/11/009.html> (excellent overview of the differing approval processes and timeframes for drugs and devices).

Second, the greatest care must be taken to ensure that signals that the brain *receives* from a given BCI device are within acceptable parameters. If device feedback is stronger or different than the brain is accustomed to receiving, there might be a possibility of damage or shock to the nervous system or brain. Hopefully, this class of risks will decline as more about the actual “language of the brain” becomes known. As a cautionary tale, however, consider the real seizure experienced by patient Jens Naumann, apparently caused by too much electrical stimulation during testing of the implant placed on the surface of his visual cortex by William Doherty.¹³⁸

A third set of safety concerns relates to device failure. Neuroelectronic devices will not typically be as critical or life-sustaining as pacemakers or defibrillators, so people will not necessarily die if they fail.¹³⁹ However, they *will* be implanted in healthier, younger, and more active people, and they will most likely be more complex. Thus, reliability in everyday life will be paramount. A user with a replacement robotic arm or retinal implants cannot afford for either to fail while she is driving on the freeway – whether it is because of a hardware or software malfunction or a problem with the connection between the device and the brain. In calculating the tolerances that can be allowed, the risks of failure anticipated by FDA must include hazards to *others* as well as to the user.

2. New Effectiveness Issues

Neuroelectronic devices present different challenges with regard to effectiveness. (As a threshold matter, it is unclear how effectiveness itself should be defined in relation to enhancement devices; this is addressed in subpart 3, below.) However it is defined, it’s clear that

¹³⁸ Kotler, *supra* notes 53, 55.

¹³⁹ With such devices, a failed or a short circuit can mean the difference between life and death, and recent, high-profile heart device recalls from Guidant and Medtronic have underscored this risk. See Barry Meier, *Citing Flaws, Maker Recalls Heart Devices*, N.Y. TIMES June 18, 2005, page A1. However, less emphasis seems to have been placed on the long-term function of pacemakers and defibrillator devices because they are typically are “passive” devices that are implanted in older people with poor health.

the “effectiveness” of brain-computer interface devices needs to be ensured over a greatly extended time frame – ideally, the life of the device user.

There is the constant risk that neuroelectronic function may diminish over time. Currently, inflammation and the accumulation of scar tissue in the brain severely diminish the long-term usefulness of implanted brain chips.¹⁴⁰ The implanted electrical components of a device may also degrade, batteries can die or components might shift so as to weaken the connection with the brain, especially in a physically active patient.¹⁴¹ The issue becomes even more important as young, able people begin to install enhancement devices that they will expect to last the rest of their natural lifetimes.

Effectiveness must also take into account the way different people adapt to the learning curve of their implanted devices. For example, different individuals experience varying degrees of success with current cochlear implants, with success often depending on their individual aptitudes with their device and their motivation to learn to use it.¹⁴² Individuals will always achieve varying levels of mastery, but if the device is so difficult to learn to use for some people that it is virtually useless, this should be factored into the effectiveness calculation.

3. Enhancement or Restoration: What Baseline for Risk?

Finally, it is important to note that freedom from risk is always a relative proposition, not an absolute one. Thus, the safety and effectiveness risks associated with neuroelectronic devices should be weighed differently depending on whether a device is being implanted and used for restorative or for enhancement purposes. It is easier to justify some or all of the safety risks examined above if the device is to be used to combat disability or disease, and harder to justify them when the device is just intended to replace an otherwise healthy body part.

¹⁴⁰ See Section I.E. I. *supra*.

¹⁴¹ Sample, *supra* note 28.

¹⁴² See CHOROST, *supra* note 45.

Similarly, the required level of “effectiveness” needs to be redefined in the context of enhancement. Device “effectiveness” in the context of a restorative, medical use is measured by how well it can rectify a disability or treat disease, but the same benchmark is not available for enhancement uses. A reasonable standard for effectiveness of an enhancement device might then be whether the new device provides more benefit than normal human function. But would we want healthy patients to install a replacement arm that is only marginally more “effective” than the regular arm they are cutting off, given all the pain, suffering and risks that they will have to endure?

Arguably, the general public will be smart enough to decide for themselves when it is worth it to replace a healthy, functioning body part with a bionic one – after all, it seems people already make a similar choice in deciding whether to undergo cosmetic surgery. (For quite a few years from now, the answer will probably be that body part replacement it will almost never be worth it.) Still, this shift in baseline in response to the shift from medical to enhancement use is an issue FDA should keep in mind.

B. Dealing with the Implications of Enhancement: A “Substantive” Complement to the FDA’s “Procedural” Approach

Current FDA device law acts as a “procedural” regime: basically, as long as a device is safe and effective, it can be put on the market. Underlying this approach is the assumption that medical devices are socially beneficial and need no further justification, as they provide invaluable services and capabilities to healthcare providers, to patients, and to society. In particular, user-centric medical devices such as artificial hearts, cochlear implants, and prosthetic arms grant ailing or disabled patients an important measure of autonomy. However, this premise needs to be re-evaluated in light of body-integrated devices that no longer “just” provide medical restoration for disability, but in fact surpass normal function.

User enhancement devices lead to a Pandora’s Box of such issues. How will other people treat those with neuroelectronic “upgrades”? Will they be discriminated against? What, if any, will be the psychological effects on the device user’s self-image and self-esteem? Will there be widespread jealousy and resentment, and will a gap arise between ‘haves’ and ‘have nots’? What effects would the widespread use of enhancement BCI’s have on society at large? For the most part, these questions arise independently of any safety and efficiency issues connected with the use of enhancement devices. They raise the bigger debate of whether these devices should be allowed on the market at all.

1. Why the FDA?

Granted that such issues will arise, *should* FDA examine issues that are not related to safety or effectiveness? One could argue that the FDA lacks the necessary institutional expertise to evaluate non-medical concerns that have nothing to do with the safety of a device or how it works. But it is important to keep several points in mind. First, these issues *will* come up, whether the FDA regulates them or not, and they will have to be addressed at some point. Second, FDA has far more institutional expertise than anyone else in evaluating the myriad aspects of devices that interface with the human body. And third, FDA already has the ability to regulate enhancement devices *for their own sake*, and not just for their medical implications.¹⁴³ In sum, FDA is in a far better position to address “substantive,” enhancement-related concerns than anyone else, and it can prepare for such regulation with much less “legislative” action than would be required to build a competent regulatory agency from scratch.

¹⁴³ Food, Drug & Cosmetic Act §201(h) (codified at 21 U.S.C. § 321) (defining FDA jurisdiction over devices that affect “the structure or any function of the body”).

2. What Sorts of Substantive Concerns Arise?

While the questions implicated by enhancement will not be fully fleshed out until brain-computer interfaces are more of a reality than they are today, the major categories of issues that must be dealt with by any regulatory scheme encompassing enhancement are already clear. This section highlights some of the main issues that might arise: “naturalness,” propriety, identity, individual choice. It also examines some of the potential impact of enhancement devices on society at large, and in the international arena.

(i) Naturalness

One powerful objection to man-machine surgical enhancement might be that it is not “natural.” As Professor Greely analyzes the issue, the “naturalness” objection can be traced to at least three sources – from a religious perspective (that man should not change what God has intended); from an evolutionary standpoint (that man should not change what natural selection or “nature” “intended”); or simply from a visceral, ill-defined repulsion towards such enhancements.¹⁴⁴ On the other hand, our society is fairly tolerant of other forms body alteration and even self-mutilation – tattoos, body art, and plastic surgery come to mind – and is even more tolerant of new kinds of technology. Which of these two tendencies will prevail as use of neuroelectronic devices become more widespread is unclear.

(ii) Propriety

On a more practical level, perhaps there is also an objection to allowing people to take such drastic, unjustified measures as cutting off a perfectly good pair of arms and replace them with robotic ones. However, given that very few people today cut off their own arms, it’s likely that people won’t amputate working body parts for neuroelectronic replacements unless the

¹⁴⁴ Henry T. Greely, *Regulating Human Biological Enhancements: Questionable Justifications and International Complications*, 4 Santa Clara J. Int’l L. 87, 93 (2006).

benefits significantly outweigh the drawbacks – which is not likely to be true for a while.

Because people can make their own cost-benefit calculations regarding their own body, the FDA shouldn't need to prevent people from “hurting” themselves in that manner by making that calculation for them.

(iii) Identity

Since neuroelectronic devices have the potential to integrate so seamlessly with the human body, it's also possible that they might affect the way we view ourselves as human beings.¹⁴⁵ There might, for example, be significant negative psychological effects associated with the installation and use of certain enhancement devices. Allowing people to have enhancements installed may require a certain level of mental health, for example, apart from any physical requirements.¹⁴⁶ If this turns out to be the case, then more rigorous controls on who can be given brain-computer devices may be needed. In any case, it is difficult at this point to speculate what effect enhancements will have on human identity, but it will not be negligible.

(iv) Individual Choice

Great care must be taken to preserve the element of choice as much as possible. In cases where a specific enhancement or implant would bestow an advantage, the specter of “involuntary” enhancement will always be present. For example, there may be situations where enhancement may literally be required of say, certain soldiers in the military. Alternatively,

¹⁴⁵ Prof. Greely argues that analytically, there is no valid analytical distinction between “tools,” i.e. external technological implements, and human technological enhancements that become part of the human body. *Id.* At 93-96. He is right that the main objection is to the means of enhancement rather than to the ends – but this observation doesn't make the objection go away. Most people would categorically treat an individual whose eyes had the ability of zoom magnification differently than they would a pair of binoculars.

¹⁴⁶ Also, as Michael Chorost discovered with cochlear implants, there is certainly a steep learning curve that not everyone can handle. Chorost relates the story of a woman who had a cochlear implant identical to his, yet dramatically failed to adapt to it over a period of time, becoming increasingly frustrated and depressed. CHOROST, *supra* note 45.

implied coercion may arise where even individuals who don't want to enhance themselves feel compelled to do so just to keep competitive.¹⁴⁷

(v) Impact on Society

It may turn out that the most significant concerns may arise from the impact of the proliferation of neuroelectronic implants on other people and society at large. To what extent would the widespread introduction of enhancement devices disrupt the functioning of society? Would there be discrimination or resentment from others in society from those who have installed a particularly valuable device? Would the abilities bestowed by enhancement devices provide people with an incentive to cheat or commit crime? While these concerns are indeed relevant, perhaps they should not be part of the regulatory calculation except in extreme circumstances.

(vi) Problems with International Regulation

The final category includes international issues, both direct and indirect. What immigration issues arise, especially if a given device is banned in one country (such as the U.S.) but allowed in others? Any regulatory scheme must also consider the indirect effects of regulation itself: overly-stringent FDA regulation (or a ban or moratorium) in the U.S. may simply incentivize device developers and those seeking to use neuroelectronic devices to shift their activities (whether it be development, testing, surgical installation, etc.) overseas.¹⁴⁸ A transnational device regulation scheme may be required for truly effective regulation of BCI

¹⁴⁷ See *id.* at 97-99 for a comprehensive overview of coercion issues.

¹⁴⁸ Interestingly enough, there has been at least one instance of what Greely terms an "enhancement tourist." *Id.* at 107. Apparently, Canadian Jens Naumann, the blind man who drove a car round a parking lot using Richard Dobbelle's artificial vision system, traveled to Portugal for the necessary brain implant surgery in order to avoid FDA rules. Kotler, *supra* note 53. (It's unclear why Dobbelle couldn't have applied for an FDA Investigational Device Exemption, although the article implies that he expected that he wouldn't have gotten FDA's permission.)

devices. Until then, FDA can only take into account the likely effects of its rules on enhancement devices on the behavior of individuals both here and abroad.¹⁴⁹

IV. A PROPOSED SOLUTION

As practical BCI-based devices inch closer to reality, it is important that the FDA act to put a regulatory framework into place that can handle both the heightened safety and effectiveness issues *and* the ethical, moral, and social issues of enhancement. During this process, the FDA should keep two overarching goals in mind. First, both neuroelectronics and enhancement are long-term propositions; FDA must shift the focus of device regulation away from a lone pre-market approval event, and towards heightened regulation over the life of the device (and the user). Second, regulation *can and should* foster and encourage device development. In this respect, regulation should continue to follow what FDA terms “the least burdensome approach” – an approach that minimizes regulatory interference when possible.¹⁵⁰

The following proposal puts forth two new device designations: “Class IV,” for the regulation of *all* neuroelectronic user devices, and a “Class IV-E” subdesignation for the subset of Class IV devices with “significant potential” for enhancement. Note that what follows is not a complete solution, especially to the speculative issues surrounding enhancement, but rather a default regulatory scheme that provides a framework to handle new problems as they arise.

¹⁴⁹ For more about FDA’s current transnational regulation pilot program, Harmonization By Doing, with Japan, see <http://www.fda.gov/cdrh/international/hbdpilot.html>.

¹⁵⁰ See FDA CDRH, THE LEAST BURDENSOME PROVISIONS OF THE FDA MODERNIZATION ACT OF 1997: CONCEPT AND PRINCIPLES; FINAL GUIDANCE FOR FDA AND INDUSTRY (Oct. 2002), *available at* <http://www.fda.gov/cdrh/ode/guidance/1332.html> (guidance for least burdensome approach required by law.)

A. New Device Class IV: A Shift to Long-Term Regulation

FDA should establish a “Class IV” category for any device that is (a) designed to send or receive commands “directly”¹⁵¹ to the brain or nervous system, (b) engages in *both* input and output communication with the brain, and (c) involves chronically implanted components. This definition purposely does not make reference to a specific form of connection between brain and device. Thus, it may encompass a diverse array of brain-computer interface user devices, direct and indirect – neuroelectronics, but also devices that interface with peripheral nerves, and perhaps even myoelectric, EEG-based, or future interfaces to the extent that they have components that are permanently implanted in the body.¹⁵²

Devices classified into Class IV would be treated just like Class III devices, but would face heightened scrutiny on two fronts. First, all Class IV devices would face heightened regulation of safety and effectiveness over the life of the device and the user, described in Part B below. Second, Class IV devices with “significant potential” to enhance normal human abilities would be further sub-classified as “Class IV-E” devices. Devices in this subclass IV-E would be subject to ongoing, nonbinding scrutiny by new FDA Advisory Committees, called “Enhancement Panels,” that can examine the substantive issues surrounding each class of enhancement devices.

B. Ensuring Safety and Effectiveness for Neuroelectronic User Devices

Today’s FDA device regulatory scheme, in which the Pre-Market Approval event is the single significant event, seems to have been modeled on the FDA experience in regulating pharmaceutical drugs. However, a scheme based on a single approval event does not make the

¹⁵¹ The term “directly” is designed to exclude means of control that are mediated by the human body, such as turning a steering wheel or manipulating a joystick.

¹⁵² This would arguably exclude today’s EEG and myoelectric (Kuiken and NASA model) devices, because they are non-invasive and can be removed. This reflects the recognition that permanent, invasive devices present the greatest ability to communicate with the brain, and present the greatest risks to safety and effectiveness.

same sense for permanent, invasive neuroelectronic devices as it does for pharmaceuticals, which are designed for immediate uptake and metabolization by the body. Too little is known about how BCI devices will interact with the human body over time for FDA to finalize approval and requirements at the front end. Only by painstaking trial and error, and experience, will device developers figure out what works and what doesn't. Unlike drug designs, device designs are always being tweaked and modified as developers learn from their past mistakes.¹⁵³ This reality should be incorporated into the regulatory process.

This paper proposes regulation of FDA Class IV devices with three separate phases: initial studies under an Investigational Device Exemption, followed by a "conditional" approval; larger observational, semi-commercial studies, followed by a full approval; and post-market regulation. Less restrictive requirements at the front end (in particular, neither conditional approval nor full approval status will require full-blown *clinical* trials, merely observational trials and other forms of data) will be balanced by more stringent enforcement of FDA's post market authorities on the back end.¹⁵⁴ By easing the product into market, and enforcing post-market regulatory measures such as surveillance and reporting indefinitely, FDA can discover risks to safety and effectiveness as they occur and deal with them effectively.

This section will describe what each of the three regulatory phases will look like under the proposed Class IV, ending with a further proposal for post-market restrictions on *use*, an area into which FDA has not normally ventured.

¹⁵³ One industry observer attributes an ex-FDA official as stating that "If you're not developing a [device] continuously, you're going to go out of business." Gibbs, *supra* note ____.

¹⁵⁴ FDA before has suggested this approach. See LEAST BURDENSOME FINAL GUIDANCE, *supra* note 150 ("Reliance on postmarket controls . . . should be considered as a mechanism to reduce the premarket burden for 510(k)s and PMAs, while still ensuring the safety and effectiveness of the device"). FDA is also currently pushing the concept of the "Total Product Life Cycle" (TPLC) in order to strengthen and standardize postmarket device regulation, and coordinate it with premarket regulation, so the approach proposed here dovetails with the direction in which the FDA is already moving. See FDA CDRH, REPORT OF THE POSTMARKET TRANSFORMATION LEADERSHIP TEAM: STRENGTHENING FDA'S POSTMARKET PROGRAM FOR MEDICAL DEVICES (Nov. 2006), <http://www.fda.gov/cdrh/postmarket/mdpi-report-1106.html>.

1. Gaining “Conditional” Approval: the First Step

The burden of proof required to gain Class IV “conditional device approval” should be far less than that for a PMA, so as to adjust to the realities of neuroelectronic user device development. FDA should increasingly look to other kinds of evidence of safety and effectiveness at the start. For example, because the greater risks posed by neuroelectronics might require a device to be much further along in development before it is tested on humans, there may also include a bigger role for animal testing, and perhaps for computer simulation and modeling, which might help predict what areas of stress, wear, injury, or discomfort might arise from the permanent implantation of a given device.¹⁵⁵ Under an Investigational Device Exemption, FDA should allow the device developer to install and develop prototypes in a small number of human subjects, with the results carefully monitored. Conditional approval should be granted only if these results appear to be safe and effective.

Finally, Class IV “conditional approval” should also require that the design manufacturer implement a Design Controls protocol (in order to increase the visibility of the design process, including documentation of all tweaks and changes), and Human Factors considerations of usability. As neuroelectronic devices will unquestionably involve the complex interaction of hardware, software, and nervous system, which will continually be changing, implementing these requirements sooner, rather than later, will save trouble down the road.

2. From Conditional Approval to Final Approval

After the groundwork of “conditional approval” has been laid, FDA should then allow a number of small observational studies, perhaps of a few dozen individuals, conducted under the

¹⁵⁵ See FDA, INNOVATION OR STAGNATION: CHALLENGE AND THE OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS, (March 2004), <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html> (recommending such improved “predictive” capabilities as a way to expose flaws in safety and effectiveness before accidents actually happen).

authority of the “conditional approval” process. Availability of the device (which at this point should be a fully working prototype) will still be restricted, but may be semi-commercialized – people may “buy” it and pay for it to be surgically installed. Individuals, however, must sign up with full knowledge of the risks. (Devices intended primarily for medical applications, of course, should be allowed wider availability than devices for pure enhancement.)

In the “conditional approval” stage, the device manufacturer must follow the patients who have installed the enhancing device, compiling data into an observational study that will last roughly three to five years. During this period, fairly substantial (but not drastic) changes to the device’s software and technical specifications may still be permitted. This observational data will form the basis for a full approval. While the FDA has followed a similar approach on an ad hoc basis, such as in its recent breast implant approvals,¹⁵⁶ it is important to make cautious marketing and long-term study a formal part of the review process.

3. Post-Approval Regulation

Once final approval is granted, the FDA must continue to monitor and regulate devices vigorously, making use of its existing postmarket surveillance and MDR reporting authorities. Though FDA has not used these two powers to the full extent that they are capable of being used, they do have the potential to form the basis for solid, post-approval device regulation. However, several “tweaks” that may help improve the effectiveness of post-market regulation are outlined as follows.

(i) Changes to Medical Device Reporting

First, MDR requirements are currently limited to the reporting of serious malfunctions or incidents resulting in injury or death. However, they are currently ambiguous as to the reporting of potential *flaws* that have not resulted in injury or death. Instead, full disclosure by the

¹⁵⁶ See the discussion of post-market surveillance in Section II.D. 2. *supra*.

manufacturer should be required as soon as it becomes aware of a potentially dangerous flaw. Another weakness of MDR reporting requirements is that they apply only to “device user facilities,” such as hospitals, but not the actual device users themselves. Since neuroelectronics and other enhancing user devices will be designed for use *outside* hospitals, FDA might establish a registration or licensing system for the users of Class IV devices, requiring them to report serious incidents to their doctor or the manufacturer.

(ii) Changes to Postmarket Surveillance

FDA can currently order a surveillance period longer than three years only if the manufacturer consents. A longer discretionary period (5-10 years), and even a mandatory surveillance period of some length may be helpful.

(iii) Regulation of Device *Use* Activities

Finally, while the general rule is that FDA does not regulate off-label, post-sale use of a device, perhaps this rule should change in certain circumstances in order to bolster FDA’s postmarket powers. In particular, FDA should prohibit the *resale* and *reuse* of a used brain-computer interface (i.e., where a user decides to surgically remove a device from his body and tries to sell it.)¹⁵⁷ FDA might also consider regulating the surgical procedures by which brain-computer interface devices are implanted.

C. Sub-Class IV-E: Examining of “Substantive” Issues

Not all neuroelectronic user devices, especially the first ones to be developed, will enhance human abilities.¹⁵⁸ The final piece of this proposal is the establishment of Sub-Class IV-E, which will encompass only those Class IV devices with “significant potential” to enhance human abilities. Devices in Class IV-E will be treated differently in two ways. First, they will be

¹⁵⁷ FDA already regulates re-use of reprocessed single-use devices (rSUDs) by hospitals by requiring reprocessing companies to provide validation data on cleaning, sterilization & functionality. Michaud, *supra* note 115.

¹⁵⁸ A case in point is cochlear implants. *See* CHOROST, *supra* note 45.

subject to higher scrutiny of safety and effectiveness risks, since enhancement carries with it a different baseline for risk.¹⁵⁹ Second, they will undergo examination of the secondary, “substantive” issues associated with human enhancement.

Defining Sub-Class IV-E in terms of “significant potential” to enhance sidesteps the thorny problem of off-label use. As mentioned earlier, it is very difficult to regulate or even define those uses to which a device may be put (which is why FDA doesn’t regulate use). A relatively bright-line rule can solve that problem: either a device can bestow abilities that are clearly beyond normal, or it cannot. Specifically, the term “significant” should ensure that only truly enhancing devices will be included, and not borderline cases or medical devices that can restore “normal” function.

So how *should* FDA regulate issues of naturalness, propriety, identity, impact on society, and so forth? Obviously, an independent review of those issues every time a manufacturer seeks approval of a new enhancement device would be cumbersome and inappropriate. Rather, this paper suggests that FDA should employ a tool it already has at its disposal: its system of Advisory Committees, composed of technically proficient medical, consumer, and industry representatives, which already provide advice in the evaluation of new technologies and “close calls.”¹⁶⁰

Following this structure, FDA should create “Enhancement Panels,” modeled on the Advisory Committees, covering different areas of human enhancement – visual, auditory, prosthetic limbs, etc. Their membership should consist of not only the constituencies mentioned above, but relevant voices from bioethical and religious perspectives, as well, akin to the

¹⁵⁹ Precisely because of the off-label problem, FDA should always evaluate a potentially enhancing device for safety and effectiveness not only against its stated indications for medical use (if any), but against general indications for enhancement use.

¹⁶⁰ See supra Section II.B. 2. (ii).

representation on the President’s Council on Bioethics. Like ordinary advisory committees, these Enhancement Panels would engage in substantive discussion of issues related to the devices to which they are assigned, and they would hold no direct decision-making power. However, like ordinary advisory committees, their advice would hold great weight.

Much in the same way that FDA’s Design Control regulations aim to increase the visibility of the device design process, the ultimate goal of enhancement panels will be to increase the visibility of these lurking, enhancement-related issues. Proceedings would be open to the public, and the panels would solicit public input. Enhancement panels, then, can serve to raise awareness of both the ethical and social issues the new technologies that implicate them. A structured examination of those issues in a public forum would enhance the legitimacy of whatever decisions the FDA ultimately decides to take.

This “advisory” approach recognizes that FDA’s other options are crude and limited. Flat-out rejection or a ban of a whole class of enhancement devices is a drastic action. This is especially true since enhancement issues are not directly the fault of a device’s manufacturer the way that safety or effectiveness issues might be. However, if FDA needs to take such action for a class of enhancement devices, its decision will at least be well-informed.

CONCLUSION

Brain-computer interfaces in general, and neuroelectronic user devices in particular, are still in their infancy. Vast challenges remain in making these devices both commercially and technologically feasible. In particular, it remains to be seen whether neuroelectronic interfaces can overcome the current challenges of biocompatibility and long-term signal degradation, or

whether other less invasive technologies such as EEGs and myoelectric interfaces can drastically increase in performance. Only time will tell if these technologies fulfill their potential, and only time will tell how and if they will impact our lives and our world.

In the meantime, however, pre-emptive regulation by the FDA, the agency with the regulatory system most suited to handle these new devices, would be a prudent course of action. Encouragingly, most of FDA's existing regulatory tools can be adapted for this task. Though legislative intervention might be needed to implement some of the details of the proposed Class IV and Class IV-E designations, many of the adjustments that would ensure safety and effectiveness, such as more rigorous enforcement of FDA's postmarket authorities (as well as the enhancement panel approach) may be initiated by the agency alone.

To summarize, a competent "default" regime such as the one proposed here would serve multiple functions. First, it would respond to the heightened, long-term safety & effectiveness risks presented by neuroelectronic devices in general, and user enhancement devices in particular. Second, it could help assure the public at large that "something" is being done about these new, challenging technologies. But perhaps more important than the "damage control" role that such a regime might play is the role in which a FDA regime would play in raising awareness about neuroelectronic user devices and guiding their development. It will have the ability to foster a substantive discussion of the problems associated with enhancement, while simultaneously allowing the underlying technologies time to develop. If, after a thorough discussion, FDA and its advisory committees believe that a certain kind of device should be banned, or a moratorium imposed, then it will be a decision well considered. It will be a better decision than the one that Congress might make in the wake of a highly publicized device

failure.¹⁶¹ The alternative to action – incomplete, inadequate regulation of enhancement user devices by FDA under the old approval-focused standards for medical devices – will simply not be acceptable.

Of course, regulation cannot solve all problems. If the fantasy world of *The Authority* starts to resemble our own, and if enhancements allow people to rob banks, fly across the world, or read other people's minds, the problem becomes larger than just the Food & Drug Administration. But for at least a long time, that will remain just science fiction. The more pressing problem, and the more manageable one, will be what human-integrated technology will mean for our lives, and for our world, in the coming decades. We may not be able to see into the future, but we can at least plan ahead.

¹⁶¹ Of course, an equally bad alternative to the scenario which leads ultimately a legislative moratorium on development is one in which there is no outcry at all. Without a public body such as FDA providing awareness and guidance of *all* the issues, not only the physical risks but the moral and philosophical ones, society may simply unthinkingly accept enhancement technologies without a full discussion of their value.