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COMMENTS

THE FOOD AND DRUG ADMINISTRATION AND THE FUTURE OF THE BRAIN-COMPUTER INTERFACE: ADAPTING FDA DEVICE LAW TO THE CHALLENGES OF HUMAN-MACHINE ENHANCEMENT

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I. 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 likely arise in the foreseeable future. The technology poised to make it happen is the "neuroelectronic inter-

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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).

face" (also known as a brain-computer interface, or "BCI"), which gives the brain direct input-output communication with any number of mechanical or electrical devices.[2]

Certainly, attempts to enhance the human body using technology are nothing new.[3] However, what sets neuroelectronics apart is the 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.[4]

Scientists are already starting to develop prototype *medical* devices designed to restore natural body functions, such as prosthetic arms that can move on demand and be manipulated with precision, and charge-coupled device (CCD) sensors that directly stimulate the optic nerve to provide replacement sight.[5] But there is no reason such user devices could 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.

Given that neuroelectronic interface devices have such potential to extend human capabilities, it follows that they also have the potential to revolutionize our society and our world.[6] 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 world leaders and live like kings.[7] Even if such

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2. *See infra* Parts II.A–C.

3. *See* Prosthetics Org UK, A History of Prosthetics and Amputation Surgery, http://prosthetics.org.uk/ (click on "History of Limbs" in left-hand menu) (describing prostheses worn in battle during the Dark Ages) (citing Patricia A. Padula, and Lawrence W. Friedmann, *Acquired Amputation and Prostheses Before the Sixteenth Century*, The Journal of Vascular Disease, 38 (2 Pt 1), 133-41 (Feb. 1987)) (last visited Jan. 2, 2008).

4. *See infra* Part II.B (discussing the limitations of neuroelectronic interfaces, including possible limits on the plasticity of the brain).

5. *See infra* Part II.B.2.

6. By definition, 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.

7. Mark Millar and Frank Quitely, *The Authority: Under New Management*, The Nativity (Wildstorm Productions 2000) (relating an episode in which The Authority deposes a Southeast Asian dictator over the protests of a hapless president who resembles Bill Clinton).

an outcome appears unlikely, a more realistic result might that enhancement technologies are never fully developed. Without competent and smart regulation from the very start, negative public reaction may conceivably lead to a moratorium or outright ban on neuroelectronics: halted, like stem cell research, in its infancy. A laissez-faire approach is not the solution.

However, the most probable candidate for regulating neuroelectronics is simply not up to the challenge of addressing devices that enhance human abilities. The existing three-tier Food and Drug Administration ("FDA") device regulations are geared entirely towards the approval of *medical* devices, which are restorative in nature.[8] In contrast, neuroelectronic devices can be designed to enhance human abilities, will typically be more invasive than medical devices due to their need to communicate directly with the brain; and may last a lifetime. Thus, this Comment suggests that the approval process for such devices should differ drastically from the process for medical devices in two fundamental ways. First, without the counterbalancing benefit of treating disability and disease, the threshold for acceptable risks to safety and effectiveness ought to be lower for user enhancement devices than for medical devices (i.e., more stringent scrutiny should be required).[9] More importantly, the regulation of human enhancement must account for the far-reaching issues of propriety, identity, autonomy, and impact on society not present in the context of pure medical uses. 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 provides no guidance as to if and how these issues should be regulated.

This Comment proposes a solution that balances these concerns with the need to preserve innovation in this developing area of technology. It first emphasizes that the FDA, rather than an entirely new entity or another governmental body, is the appropriate agency to regulate brain-enhancing computer interfaces. This Comment then proposes the creation of a new Class IV designation for *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.

Implementing a Class IV regulation would proceed in two parts. First, the FDA would regulate the safety and effectiveness of Class IV user devices differently than it does for other devices.[10] Specifically, due

8. FDA law categorizes medical devices into three classes, Class I, Class II, and Class III, based upon the amount of risk involved in their use. *See generally* 21 U.S.C. § 360c(a). Section II., *infra*, discusses the FDA regulatory scheme in detail.

9. *See infra* Part IV.A.3.

10. *See infra* Part V.

to the invasive and permanent nature of neuroelectronic devices, less emphasis would be placed on the initial event of device approval, and correspondingly more emphasis would be 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, dubbed "Class IV-E."[11] Under Class IV-E review, any devices with "significant potential" to enhance human abilities would face both heightened review of safety and effectiveness issues and review by advisory groups called 'Enhancement Panels.' Based on the FDA's current system of advisory panels, Enhancement Panels would gather experts from a wide variety of backgrounds, including medicine, industry, consumer groups, and ethical and religious perspectives, capable of comprehensive examination of the substantive concerns related to enhancement that would more broadly inform the FDA's decision-making.[12]

This Comment 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 describes the current FDA regulatory landscape for medical devices. Part III makes the case for FDA regulation while pointing out the shortcomings of existing FDA laws in regulating safety, effectiveness, and the substantive issues of enhancement. Finally, Part IV proposes a new FDA device classification, called Class IV; and a strategy, Class IV-E, for regulating enhancement.

II. 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, which holds the greatest potential for integration with the nervous system, can provide both input and output capabilities. However, it is also the most invasive method and raises the greatest safety concerns.[13] 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.[14]

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11. *See infra* Part V.C.

12. *See infra* Part V.C.

13. *See infra* Parts II.A.4, II.E.1, and IV.A.

14. *See infra* Part II.A.2 (surveying myoelectric interfaces); Part II.A.3 (describing EEG-based interfaces).

A. Output Interfaces

Prosthetic output devices are more common than input devices and are available in a greater variety. Up until recently, all interfaces were "indirect" mechanisms, acting upon a user's muscle contractions and not direct commands from the brain. Newer, more direct 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.[15]

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 allow her to open or close a prosthetic hand, or the "terminal device" in prosthetics parlance, by adjusting the angle of her elbow.[16] Similarly, a more complex version allows an above-elbow amputee lacking an elbow joint to control an artificial hand using shoulder muscle movements alone.[17] Though clever, purely physical interfaces require the amputee to retain the ability for muscle movement in the amputated limb, such as the ability to raise and lower a shoulder. Many arm prostheses go unused by their owners because they require a body harness for support, or because they are uncomfortable and unwieldy.[18]

2. *Myoelectric Interfaces*

More recent artificial limbs can detect and "amplify" minor muscle

15. *See infra* Parts II.A.3-4.

16. 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.

17. *See* Harold H. Sears, Ph.D., *Advances in Arm Prosthetics*, 9 in Motion (May-June 1999), *available 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*, 35 J. Rehabil. Res. Dev., 431-46 (Oct. 1998) (abstract available at http://www.pubmed.gov). The Sarcos AdVAntage Arm utilizes a system with two internal cables that 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. *Id.* A user first flexes his shoulder muscles (activating one cable) to raise or lower the elbow. *Id.* 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. *Id.* There is a substantial learning curve, however. *Id.*

18. *See* Plettenburg, *supra* note 16, at 2276.

movements and the electrical impulses they generate.[19] Rather than translating a user's actual muscle movement, myoelectric prosthetic devices (the "myo" prefix stands for muscle) are powered devices that utilize electric motors and digital signal processors.[20] They employ small electrodes to sense electrical signals that race down muscle tissue, such as an amputee's residual biceps and triceps, when the muscle contracts.[21] A processor then interprets specific patterns of contraction as commands to move individual motors in the prosthetic device; the strength of the myoelectric output signals generated are proportional to the strength of the muscle contraction.[22]

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.[23] Kuiken's innovative procedure reroutes nerve endings from the shoulder that, before amputation, controlled arm and hand movements, and surgically grafts them onto bands of pectoral muscle in the chest.[24] 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.[25] 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.[26]

Four amputees 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 accident;[27] the latest incarnation of Kuiken's arm includes six mo-

19. *See* Bill Dupes, *The Body Electric: Recent Developments in Bionic Technology*, 14 in Motion, 52 (May-June 2004), *available at* http://www.amputee-coalition.org/inmotion/may_jun_04/body_electric.html.

20. *Id.*

21. SearchMobileComputing.com, What is a Myoelectric Signal?, http://searchmobilecomputing.techtarget.com/sDefinition/0,,sid40_gci936219,00.html (last visited September 24, 2007) (stating that 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)).

22. 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").

23. *Id.*

24. Rehabilitation Institute of Chicago, Introducing Jesse Sullivan, the World's First Bionic Man, http://www.ric.org/bionic/ (last visited September 24, 2007).

25. *Id.*; *see also* Murray, *supra* note 22.

26. Murray, *supra* note 22.

27. Jim Ritter, *'Bionic Woman' Shows off Arm: 1st Female to Have Robotic Surgery*, Chicago Sun Times, Sept. 14, 2006, at 6. Kuiken's surgery failed with one patient whose

tors and three forms of arm rotation.[28] Typically, the device is not permanent and can be taken on and off at will.[29]

The applications of myoelectric interfaces are not limited to replacement limbs. Notably, the National Aeronautics and Space Administration (NASA) is developing a "subvocal speech 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.[30] These "subvocal" sensors detect myoelectric signals and can function when no sounds or lip or facial movements are made because the act of reading or silently talking to oneself sends speech signals to the tongue and vocal cords.[31] Patterns of nerve signals are then interpreted as discrete words and sounds.[32] NASA suggests this technology may be used to communicate with others or with a speech-activated machine in a variety of settings, such as in noisy or crowded environments, in military operations where silence would be useful, or as a tool for speech-handicapped persons.[33]

Myoelectric output interfaces bring us one step closer to brain-controlled devices that can be integrated into the body. While their noninvasiveness is myoelectric devices' greatest asset, they share the same shortcomings as traditional, "passive" prosthetics because both require healthy functioning muscles and nerves in order to operate the device.[34] In this sense, Dr. Kuiken's nerve rerouting procedure is merely a clever workaround. A second drawback of the myoelectric interface is its indirect mode of operation. Because myoelectric signals are picked up from the skin, rather directly from the nervous system, they may be susceptible to environmental interference. Kuiken, for example, has found that muscular signals from skin receive strong interference from over-

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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.*

28. *Id.*; *see also* Kelly Kennedy, *Bionic Arm Brings Back Sense of Touch*, Chicago Tribune, June 23, 2005, Zone C, at 1.

29. Murray, *supra* note 23.

30. Iddo Genuth, *Subvocal Speech – Speaking Without Saying a Word*, The Future of Things, Oct. 12, 2006, http://www.tfot.info/content/view/80/58/ (last visited September 24, 2007) (interview with Chuck Jorgensen, NASA Chief Scientist for Neuroengineering).

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

32. NASA, Subvocal Speech Demo, http://www.nasa.gov/centers/ames/news/releases/2004/subvocal/subvocal.html (last visited Jan. 12, 2008). In initial trials, the system recognized words (choosing from a small number of words, vowels and consonants) with an accuracy rate of 92%. Press Release, *supra* note 31. Furthermore, in an 2006 interview, NASA's Jorgensen noted a modest increase in vocabulary size (25 words, 38 vowels & consonants) with the use of only two sensors. *See* Genuth, *supra* note 30.

33. *Id*; *see also* Press Release, *supra* note 31.

34. *See* Subvocal Speech Demo, *supra* note 31.

head fluorescent lights.[35] At present, however, detecting myoelectric signals is still more reliable than directly sensing signals from the peripheral nerves themselves, as the signals from those peripheral nerves may be too weak.[36]

3. *EEG-Based Interfaces*

Researchers have enjoyed moderate success translating brain waves into commands received by computers or prosthetic devices when using an electroencephalogram ("EEG") to monitor activity.[37] 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.[38] With so many inputs, an EEG cannot sense individual neurons firing; instead, it helps visualize "brain waves" resulting from distinctive patterns of electrical activity.[39] 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.[40] According to testers, in order to interface, a user must be within a certain state of concentration or "zone," and is often helped by focusing on a certain image, childhood memory, or other figment of imagination.[41]

At the Brain-Computer Interface Lab at the New York State Department of Health, Dr. John Wolpaw has successfully trained patients wearing EEG's to control the movement of a cursor across a two-dimensional computer screen.[42] Wolpaw's subjects are fitted with a device that resembles a blue shower cap covered with 64 white polka-dots electrodes,

35. Murray, *supra* note 22.

36. *Id.* (discussing problems with detecting peripheral nerve signals directly from the brain). Apparently, the electrical impulses from the 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. *Id.* On the other hand, at least one private company, Victhom Technologies, formerly Neurostream Technologies, is going to try. *See also* Press Release, Victhom, Victhom Human Bionics Announces a Pre-IDE Meeting with the US FDA for its Neurostep, (Nov. 22, 2006), *available at* http://www.victhom.com/news/2006-11-22-e.pdf (discussing Victhom's "NeuroStep," a "closed loop" medical device that will interface with both sensory and motor peripheral nerve signals).

37. Malcolm Ritter, *Computers Obeying Brain Signals*, USA Today, Apr. 4, 2005, *available at* http://www.usatoday.com/tech/news/2005-04-03-brain-computer_x.htm.

38. Medline Plus Medical Encyclopedia, Definition of EEG, http://www.nlm.nih.gov/medlineplus/ency/article/003931.htm (last visited September 24, 2007).

39. Public Broadcasting System, The Secret Life of the Brain, Scanning the Brain: EEG, http://www.pbs.org/wnet/brain/scanning/eeg.html (last visited September 24, 2007).

40. *Id.*

41. *Id.* (offering an entertaining first-hand account of how unpredictable and difficult it is to control the strength of his brain's "beta" rhythm).

42. Ritter, *supra* note 37.

which sense electrical activity on the scalp.[43] Once equipped in this manner, an EEG user attempts to control the movement of a cursor on a screen by altering his or her "beta rhythm," a distinctive pattern of brain waves.[44] Wolpaw's group successfully trained 80% of its patients to reliably manipulate the cursor across the screen after 10 training sessions.[45] It remains to be seen whether the accuracy and reliability of EEG-based control can be improved to match that of more invasive neuroelectronic interfaces.[46] Even Dr. Wolpaw appears to be hedging his bets; he is also investigating a more invasive variant of EEG, termed "electrocorticography," or ECoG, that has yielded more promising results.[47]

4. *Direct Neuroelectronic Interfaces*

Unlike EEG interfaces, neuroelectronic, or brain-computer, interfaces sense the direct firing of a small number of brain neurons, translating them into electronic signals.[48] This is most commonly achieved by the surgical implantation of a microchip on the surface of the brain, which requires invasive and potentially life threatening surgery below the surface of the skull.[49] The biggest advantage of neuroelectronic interfaces over EEG's is that patients do not need to learn to control their brain waves.[50] 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 microchip.[51]

The BrainGate chip, developed by Brown University Professor John Donoghue and his Cyberkinetics, Inc. startup company, is one of the first

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43. *Id.*

44. *Id.* (describing a "beta rhythm" as an idling rhythm whose strength varies when an individual's brain thinks about moving).

45. Ian Sample, *Meet the Mind Readers: Paralysed People Can Now Control Artificial Limbs by Thought Alone*, The Guardian (UK), Mar. 31, 2005, at 4.

46. *See, e.g.*, Dean Takahashi, *Gamers May Soon Control the Action With their Thoughts*, Mercury News, Apr. 6, 2006 (stating that the CEO's of two startups, NeuroSky and Cyberlearning, hope to bring EEG-based videogame console add-ons to market that would 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").

47. *See* Sample, *supra* note 45; *see also* An Electrocorticography-Based Brain Computer Interface (BCI) and Related Methods, U.S. Patent No. 7,120,486 (filed Dec. 12, 2003) (issued Oct. 10, 2006) (describing ECoG as the technique of recording electrical activity by means of electrodes placed below the surface of the skull, but above or below the dura mater; listing Wolpaw as an inventor of the patent).

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

49. *See* Sample, *supra* note 45.

50. *See* Ritter, *supra* note 37.

51. *Id.*

direct neuroelectronic interfaces for implantation and use in humans.[52] 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.[53] 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.[54] The signals from the metal plate are then amplified and sent to a computer for processing.[55] In trials, Donoghue found different commands such as "move my hand left" vs. "move my hand right" created distinct and detectable patterns of brain activity in the neurons measured by the microelectrodes.[56] BrainGate is currently being tested in a pilot clinical trial under an Investigational Device Exemption ("IDE") from the FDA.[57]

Paraplegic patient John Nagle made news when researchers implanted the BrainGate chip over a section of his brain's motor cortex dealing with hand and arm movements.[58] Nagle showed an ability to perform a number of tasks with his mind, such as: control a TV, move a mouse cursor on a screen, and command an artificial hand to open and close grip.[59] For instance, during 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;[60] he mastered it within four days.[61] However, Nagle was relatively slow; on average, it took him 2.5 seconds to guide the cur-

52. *Id.*; *see also* Sample, *supra* note 45; Cyberkinetics Neurotechnology Systems, Medical Products, http://www.cyberkineticsinc.com/content/medicalproducts/index.jsp (last visited Jan. 12, 2008).

53. *See* Sample, *supra* note 45.

54. *See* Ritter, *supra* note37.

55. Sample, *supra* note 45 (noting that the patient is, quite literally, plugged into a computer, "The Matrix"-style).

56. *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.*

57. Cyberkinetics Neurotechnology Systems, Medical Products, http://www.cyberkineticsinc.com/content/clinicaltrials/braingate_trials.jsp (last visited Jan. 12, 2008). The system is also 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.

58. Pollack, *supra* note 57 (stating that Nagle had the implant removed after just over a year).

59. L.R. Hochberg, M.D. Serruya, G.M. Friehs, J.A. Mukand, M. Saleh, A.H. Caplan, A. Branner, D. Chen, R.D. Penn, and J.P. Donoghue, *Neuronal Ensemble Control of Prosthetic Devices by a Human with Tetraplegia*, 442 Nature, 164-171 (July 13, 2006).

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

61. Pollack, *supra* note 57 (interviewing Matt Nagle and noting his accuracy of 73%-95% after four days).

sor to the target.[62] For comparison, it takes a healthy human equipped with a computer mouse in hand only one second to hit the same target.[63]

BCI's 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 external robotic arm controlled by the chip.[64] Unlike BrainGate, which samples a fairly small number of neurons in a single cortical area, Nicolelis' team sampled 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.[65]

Unfortunately, a number of major obstacles must be overcome before neuroelectronic interfaces become usable outside of clinical trials. One concern is whether a limited sample size of neurons can pick up complex brain commands. For example, the BrainGate chip only looks at 96 data points; yet the brain typically activates a whole ensemble of cortical areas in motor function.[66] EEG researcher John Wolpaw compares the limited sample size available with a brain chip with trying to conduct a symphony by only using the violins, rather than the whole orchestra.[67] A further drawback is size: these systems are still bulky prototypes, with wires running out of the brain.[68] Miniaturization and wireless data transmission will be necessary to make a neuroelectronic interface practical and to minimize the risk of infection that comes with having a hole

62. *Id.* As an interesting aside, a solution to this performance problem has been 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, *A High-Performance Brain-Computer Interface*, 442 Nature, 195-198 (July, 13 2006).

63. Pollack, *supra* note 57.

64. *See* Evans, *supra* note 48.

65. *See* J.M. Carmena, M.A. Lebedev, R.E. Crist, J.E. O'Doherty, D.M Santucci, D.F. Dimitrov, P.G. Patil, C.S. Henriquez, M.A.L. Nicolelis, *Learning to Control a Brain-Machine Interface for Reaching and Grasping by Primates*, 1 Public Library of Science Biology 193-208 (2003).

66. *See generally* D.M. Santucci, J.D. Kralik, M.A. Lebedev, M.A. Nicolelis, *Frontal and Parietal Cortical Ensembles Predict Single-Trial Muscle Activity During Reaching Movements in Primates*, 22(6) Euro. J. Neurosci. 1529-1540 (2005); M.A. Lebedev, J.M. Carmena, J.E. O'Doherty, M. Zacksenhouse, C.S. Henriquez, J.C. Principe, M.A. Nicolelis, *Cortical Ensemble Adaptation to Represent Velocity of an Artificial Actuator Controlled by a Brain-Machine Interface*. 25 J. Neurosci. 4681-4893 (2005).

67. Ritter, *supra* note 37. Of course, employing the same analogy, Wolpaw's EEG method is like listening to the whole orchestra hundreds of feet away and on the other side of a busy freeway.

68. *See* Evans, *supra* note 48.

in the skull exposing the brain in order for wires to operate the device.[69] 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 0

B. Input Interfaces

By definition, brain-computer *input* interfaces send information from a machine to the brain. Compared to neuroelectronic *output* interfaces, brain-computer *input* interfaces are even further back in their infancy. This is because input interfaces require a comparatively greater understanding of how the brain encodes information (often termed "the neural code") than do output interfaces – an understanding that scientists do not currently have.[70] Output interfaces focus on detecting a brain signal that a machine can use by sampling, for instance, the activity of a few dozen neurons or by sensing myoelectric or brainwave activity.[71] Thus, it is possible to detect and use such an "output" signal without understanding how it was generated by the brain. In contrast, input devices by definition *must* send information to the brain in a format that the brain can understand.[72] Yet scientists do not even understand the basics of the neural code, much less the process by which electric impulses are translated by the brain into the discrete sensations of vision, hearing, touch, and proprioception we experience in everyday life.[73]

Input signals to the brain, of course, do not need to be exact duplicates of actual brain signals; if they are similar enough to natural signals, the brain's ability to adapt will do the rest.[74] Without a deeper grasp of the neural code, however, efforts to date have been fairly crude. Attempts to stimulate particular points on the auditory or visual cortex with electrical current typically result in the neural equivalent of static: perceived "phosphenes" (flashes of white light) when the visual cortex is stimulated, or "hissing" noises in when the auditory cortex is stimu-

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69. *Id.*

70. *See* John Horgan, *The Myth of Mind Control*, Discover Magazine, Oct. 2004, at 40 (explaining that "the neural code is often likened to the machine code that underpins the operating system of a digital computer" and describing the neural code as one of the "great scientific mysteries" on par with the origin of the universe); *see also infra* Part II.E.2.

71. *See supra* Part II.A.

72. *See* Horgan, *supra* note 70, at 42-43.

73. *See* Alison Abbott, *Neuroprosthetics: In Search of the Sixth Sense*, 442 Nature 125 (2006) (noting 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 that much of this activity occurs at levels of abstraction higher than raw sensory input).

74. *Id.* at 126.

lated.[75] A more promising approach appears to be stimulation of the peripheral nerves that lead to the brain rather than the central nervous system itself.[76] However, direct cortical stimulation approach is still a popular avenue in research, and may be the only alternative for input devices that do not correspond to an existing human sense such as sight or sound.[77]

This section discusses three examples of input interfaces that have been developed to date: cochlear implants, visual input interfaces, and a novel ultrasonic sense developed by one adventurous researcher.

1. *Cochlear (Auditory) Implants*

Cochlear implants, the most well-established and widely used type 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.[78] 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.[79] At least one variation on the device sends signals directly to the auditory brainstem instead of the auditory nerve.[80] Despite generating sounds that

75. *See id.* at 127 (examining the difficulties involved in direct cortical stimulation); Phosphene, Merriam-Webster's Collegiate Dictionary 874 (10th ed. 1998) ("a luminous impression due to excitation of the retina"). Indeed, many researchers believe that the cortex of the brain is simply too complicated to stimulate with simple electrical impulses. Abbott, *supra* note73.

76. *Id.*

77. *Id.*

78. See Horgan, *supra* note 70, at 45-46 (stating that artificial cochleas have FDA Pre-Market Approval and have been implanted in more than 50,000 people).

79. *See generally* National Institute on Deafness and Other Communication Disorders ("NIDCD"), Cochlear Implants, http://www.nidcd.nih.gov/health/hearing/coch.asp (last visited September 24, 2007) (presenting an overview of cochlear implant technology); *see also* Michael Chorost, *Rebuilt*, 6-8 (Houghton Mifflin 2005) (entertaining and emotionally powerful novel about the author's experience with a cochlear implant).

80. *See* FDA, PMA Database, Nucleus 24 Auditory Brainstem Implant System, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=3862 (last visited September 24, 2007) (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* Oct. 20, 2000, *available at* http://www.fda.gov/cdrh/pdf/p000015a.pdf; *see also* Aetna, Cochlear Implants and Auditory Brainstem Implants, Clinical Policy Bulletin No. 0013 (Revised), July 7, 2006, *available at* http://www.aetna.com/cpb/data/CPBA0013.html (stating health care provider's policy on when such implants become "medically necessary").

are perceived by the brain as "totally artificial,"[81] cochlear implants work reasonably well, even allowing some users to understand speech over the telephone, without external visual cues such as lip-reading.[82] However, results vary and implants require significant customization and training for each individual user.[83]

2. *Visual Input Interfaces*

The progress of visual neuroelectronic interfaces for the blind lags far behind that of the cochlear implants. Unlike auditory input interfaces, they have not been commercialized, nor have they received FDA approval.[84] Furthermore, all of the interfaces currently in development rely on the primitive phenomenon of phosphene vision, which is the human sensation of rows of dots and streaks of light that result when specific parts of the retina, optic nerve, or visual cortex are stimulated.[85] 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.[86] The typical artificial vision system receives and processes signals from a CCD camera, then transmitting the signals to electrodes that stimulate the visual system.[87] The differences among the various approaches lie mainly in the

81. *See* Abbott, *supra* note 73, at 126; Chorost, *supra* note 79, at 79 (providing an excellent description of how a cochlear implant would sound to a normal person, from the perspective of an individual who lost his natural hearing as an adult: "something which resemble[s] hearing" and "equivalent to hearing," yet far from what ordinary people experience).

82. *See, e.g.*, Chorost, *supra* note 79, at 100-101 ("Voices on the phone still sounded like a tinny whisper against blank noise, but I could pick out most of the words I needed by a loose-limbed effort of will, like detecting human faces as they formed in the clouds.").

83. *See id.* at 177 (describing "a patient whom I'll call Beth, who had the same surgeon, the same implant, the same audiology, and the same software as I did, [ended up] with totally different results"). Chorost's book in general is an excellent account of one man's experiences in installing, adapting to, and upgrading his cochlear implant. *See generally id.*

84. *See* Horgan, *supra* note 70, at 45-46.

85. *See, e.g.*, U.S. Patent No. 6,658,299 at 1:14-18 (issued Dec. 2, 2003) ("A pulse or train of pulses directed to a given electrode connected to a unique location [within the human nervous system] results in the stimulated perception by the subject of a spot or cluster of light, called a phosphene, at its own particular location.").

86. *Id.*; *see also* N.R. Srivastava, P.R. Troyk, V.L. Towle, D. Curry, E. Schmidt, C. Kufta, G. Dagnelie, *Estimating Phosphene Maps for Psychophysical Experiments Used in Testing a Cortical Visual Prosthesis Device*, 3rd International IEEE/EMBS Conference on Neural Engineering, 130-133 (May 2-5, 2007), *abstract available at* http://ieeexplore.ieee.org/xpl/freeabs_all.jsp?tp=&arnumber=4227234&isnumber=4227185.

87. Richard Normann, *Sight Restoration for Individuals with Profound Blindness*, University of Utah Center for Neural Interfaces, http://www.bioen.utah.edu/cni/projects/blindness.htm (last visited Sept. 24, 2007); *See also* Kwabena Boahen, *Neuromorphic Microchips*, Scientific American, May 2005, at 56-63; *see also* Ian Johnston, *The Magic Eye*

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.[88] At this early stage of development, the comparative advantages of each particular approach are unclear.[89]

Nevertheless, advances have been made using a variety of approaches to visual implants. For instance, William Dobelle, a pioneer in the field of artificial vision since the late 1970s, favors electrode arrays encased in biocompatible plastic and implanted on the surface of the visual cortex.[90] Canadian Jens Naumann, a patient who has been blind for over twenty years, became famous in 2002 when he drove a convertible Mustang slowly around a parking lot by using only the visual signals he received from Dobelle's visual system.[91] In contrast, Professor Richard Normann at the University of Utah has developed a cortical implant that employs microwire electrodes that actually penetrate the surface of the brain, allowing safer and easier stimulation of the visual cortex.[92] If this sounds familiar, that's because Normann's Utah Electrode Array was the progenitor for the BrainGate *output* interface, discussed previously in section 0[93] In a different vein of investigation, Professor Gislin Dagnelie of Johns Hopkins is currently 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

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that Could Help Blind to 'See' Again, The Scotsman (Edinburgh, Scotland), Apr. 5, 2005, at 17.

88. Normann, *supra* note 87 (reviewing the pros and cons of the various approaches to electrode placement).

89. *Id.* However, some approaches may work better with certain kinds of blindness. *Id.* 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. *Id.*

90. Steven Kotler, *Vision Quest*, Wired, Oct. 9, 2002, http://www.wired.com/wired/archive/10.09/vision.html (last visited Sept. 24, 2007). Unlike Richard Normann's microelectrode implant, Dobelle's implant does not puncture the surface of the cortex, which may make it more biocompatible in the long term. *Id.* *See also* U.S. Patent No. 6,658,299, *supra* note 85 (patent on artificial vision system issued to William Dobelle).

91. *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 (last visited Jan. 12, 2008) (web coverage of story originally broadcast Jan. 5, 2003).

92. *See* Kotler, *supra* note 90 (noting that Normann's implant apparently uses only a thousandth of the current that Dobelle's implant uses to stimulate the brain). Using less electricity is likely a much safer approach, as Kotler actually observed Jens Naumann fall into a violent seizure caused by overstimulation from Dobelle's implant. *Id.*

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

vertical lines.[94]

The number of phosphenes stimulated by current artificial systems, or their "resolution," is fairly low.[95] Thus, the usefulness of these systems may improve with the implementation of greater resolution sensors and larger electrode arrays.[96] At some point, perhaps they will even allow blind individuals to attain the holy grail of "functional mobility," meaning the ability to discern enough detail in one's visual field to navigate without a cane or seeing-eye dog.[97] Furthermore, as scientists learn more about sensory input to the brain, perhaps visual input interfaces will provide a form of perception more akin to natural vision 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, that future has already arrived. Kevin Warwick, professor of Cybernetics at the University of Reading, England, claims to be the first human to successfully receive extra-sensory input via a neuroelectronic interface.[98] As part of a project he billed as "Cyborg 2.0," Warwick underwent surgery to implant an 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.[99] Warwick then donned an ultrasonic sensor placed on a baseball cap that communicated with his implant.[100] Blindfolded, he was able to successfully find his way around the lab using only feedback from the sensor because the ultrasound would send more frequent pulses of current to his medial nerve when he

94. Victoria Fletcher, *Artificial Eye that Will Let the Blind See*, Daily Express (UK), April 5, 2005.

95. *See, e.g.*, Normann, *supra* note 87 (noting that Normann's Utah Electrode Array is a 10 x 10 square grid, for a total of 100 pixels); Kotler, *supra* note 90 (stating that William Dobelle believes that a 32 x 32 grid containing 1,024 pixels should be sufficient).

96. 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. K. Cha, K. Horch, et al., *Simulation of a Phosphene-Based Visual Field: Visual Acuity in a Pixelized Vision System*, 20 Ann. Biomed. Eng. 439-49 (1992).

97. Kotler, *supra* note 90.

98. Kevin Warwick – Home Page, http://www.kevinwarwick.com (last visited Jan. 6, 2008).

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

100. *Id.*

got closer to an obstacle in the room, and die off when he moved away.[101]

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.[102] Rather, in his words, "I was just given something extra."[103]

C. Blurring the Input vs. 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 learned to use her robot arm by simply watching it move,[104] 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.[105] 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.[106] His goal is to replace damaged brain tissue with computer hardware that could

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

102. Asohan, *supra* note 99.

103. *Id.*

104. *See generally* Evans, *supra* note 48.

105. James Cavuoto and Warren Grill, *Neural-Silicon Hybrids Point to New Era in Technology*, NeuroTech Business Report, http://www.neurotechreports.com/pages/hybrids.html (last visited September 24, 2007).

106. *Id.*

perform the same functions.[107] 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, once the technological barriers are overcome, no other practical obstacle is likely to prevent the development of devices that not only restore, but also enhance human function. In most cases, brain-computer interfaces would use the same technology as regular medical devices. The primary distinction 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 individuals will want, for their first time, to surgically replace their working body parts with neuroelectronic prostheses.[108] 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.[109] Making these enhancements available to the non-disabled, of course, will bring lurking questions about the propriety and morality of enhancement technology to the forefront.

The second phase involves 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

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107. 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. *See also* Cavuoto, *supra* note 105.

108. Kotler, *supra* note 90 (quoting, in the words of one writer for Wired Magazine, "[i]n the future, the disabled may prove *more* abled; we may all want their prostheses") (emphasis added).

109. *See* Press Release, Duke University, DARPA To Support Development Of Human Brain-Machine Interfaces (Aug. 15, 2002), *available at* http://dukenews.duke.edu/2002/08/darpacontract0802.html) (suggesting that military applications of neuroelectronic interfaces are already being anticipated; noting that Miguel Nicolelis' monkey-based research is currently funded in large part by the Defense Advanced Research Projects Agency ("DARPA"), an agency within the U.S. Department of Defense).

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, which may not necessarily resemble 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 devices and concepts 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.[110] Humans could directly perceive computer inputs, communicating with machines on an entirely intuitive level – imagine Googling with your mind.[111] The ultimate result may be neural-silicon hybrids in which the man is indistinguishable from the machine.

E. The Limitations of Brain-Computer Interfaces

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 may be termed 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 such as Donoghue's BrainGate, Normann's Utah Electrode Array, and Nicolelis' devices in monkeys: the ability of these electrode microarray implants to send or receive brain signals degrades over time.[112] The culprit seems to be the brain's adverse reaction to the implants' uninsulated microwire

110. *See id.* (speculating that "'neurorobots' controlled by brain signals from human operators could be the ultimate applications of brain-machine interface technologies developed under a $26 million contract to Duke University sponsored by the DARPA").

111. *See* Rodney Brooks, *Toward a Brain-Internet Link*, Technology Review, Nov. 2003, *available at* http://www.technologyreview.com/Infotech/13349/ ("I'm starting to think that by 2020 we might actually have wireless Internet interfaces that ordinary people will feel comfortable having implanted in their heads . . . All the signs-early experimental successes . . . and military research thrusts-point in that direction.").

112. *See, e.g.*, Nature, *supra* note 60. *See also* Pollack, *supra* note 57 (indicating that degradation seems to begin after several months); Shenoy, *supra* note 62.

electrodes, which cause a complex variety of persistent inflammation and scarring processes when they puncture and penetrate the surface of the brain.[113] Damage to the brain tissue begins with the initial physical trauma of implantation, which can sever capillaries and extracellular matrix, and destroy neurons and supporting brain cells; subsequent 'micromotion' of the electrodes as they move around after implantation also plays a role in causing chronic inflammation.[114] Perhaps of even greater concern, brain tissue apparently forms encapsulating scars around the electrodes after a number of weeks, further weakening the effectiveness of the electrodes by isolating them from the neurons that they are designed to measure.[115] Scientists must fully understand both the short term and the long term processes in the brain that arise in response to implanted electrodes if brain-computer interfaces are to be any more than a passing novelty.[116]

Scientists are also actively looking for alternatives that minimize brain inflammation and scarring. For example, it seems that varying the shapes and materials used in manufacturing the electrodes affects the short-term inflammation response, but not longer term scar formation and encapsulation.[117] The solution may involve coating the electrodes with bio-active molecules that are slowly released into the surrounding brain tissue, but more research is necessary.[118]

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

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113. Vadim S. Polikov, Patrick A. Tresco, & William M. Reichert, *Response of Brain Tissue to Chronically Implanted Neuro Electrodes*, 2005 J. Neurosci. Methods 148, 1-18.

114. *Id.*

115. *Id.* (noting that the process of glial scar formation, known as "reactive gliosis," is induced by reactive astrocytes, begins immediately after implantation, and is well underway six to eight weeks later). Furthermore, 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.* Interestingly, an analogous phenomenon of soft tissue encapsulation occurs for chronically implanted foreign objects in the human body. *Id.*

116. *Id.* (calling for systematic studies to develop models, such as laboratory brain cell culture models, of this poorly understood scarring phenomenon, and suggesting the use of electrically active electrodes as the implants, which have not been used in previous studies).

117. *Id.* (stating that attempts by Nicolelis and others to manipulate the shapes and materials of electrodes affected the short term wound healing response, but after 6-12 weeks, scarring was identical regardless of electrode geometry.)

118. *Id.* (explaining that initial efforts to coat implanted electrodes with bioactive molecules, such as cell adhesion molecules, polypeptides, would-healing suppressants, and even little bits of nerve tissue, or "PNS explants," have had promising, but mixed results).

prostheses.[119] Blindly inputting electrical impulses to the brain, whether via direct cortical stimulation or peripheral nerves, is a naïve approach; a more sophisticated model of how the brain communicates, processes and receives information is needed. Yet science's understanding of the "neural code" is still evolving.[120] For example, while scientists once believed that the firing rate of neurons was the only scheme that the brain used for encoding information, modern studies suggest that more complicated patterns, such as groups of neurons firing in synchrony and feedback loops are involved.[121] In contrast to this rather reductionistic focus on individual neurons, Walter J. Freeman argues that the brain processes and conveys information via large-scale, chaotic electric and magnetic fields within the brain.[122] However, scientists' understanding of how the brain processes information is still very primitive, and no one theory has gained acceptance.[123]

As noted in the discussion of input devices, neuroelectronic devices will not need to emulate precisely the natural language of the brain; rather, they only need to be 'close enough' for the brain to adapt to them.[124] The success of cochlear implants, for example, demonstrates that the brain is flexible enough to adapt to foreign inputs produced by cochlear implants.[125] Similarly, Miguel Nicolelis has found in his research on output interfaces that neural pathways in the brains of monkeys actually rewire themselves so as to become more efficient in using their neuroelectronic implants.[126] Indeed, while Nicolelis believes that while the brain may ultimately not yield all its secrets, science will still "ferret out" enough of the brain's information-processing tricks to yield huge improvements in the usefulness of neuroelectronic interfaces.[127]

On the other hand, the brain may also have significant developmental limitations that may prove difficult to overcome. For example, it may

119. Horgan, *supra* note 70, at 43. *See also* Abbott, *supra* note 73 (suggesting that there may be no single secret "code" that is the key to understanding the brain, as there is with the single "genetic code" that dictates how sequences of DNA nucleotides are translated into amino acid sequences in proteins).

120. *See generally* Horgan, *supra* note 70.

121. Horgan, *supra* note 70, at 44.

122. *Id.*

123. *See generally* Horgan, *supra* note 70.

124. *See supra* Section I.B.

125. *See supra* Section I.B.1.

126. Nicolelis et al., *supra* note 65. The researchers sampled five different cortical areas to provide the output command for the robotic arm. *Id.* Before training, the monkeys sent a signal mostly from one cortical area, M1 (the primary motor cortex). By the end, however, the monkeys sent equally strong brain signals from four of the five motor areas sampled (M1, SMA, PMd, and S1) when they wanted to move the arm – a "functional cortical reorganization" resulting in more effective control over the robotic arm. *Id.*

127. Horgan, *supra* note 70, at 43.

be impossible to ever get a person who is born blind to "see" using an artificial retina, no matter how technologically advanced, because she has never developed the proper pathways in the visual cortex to interpret visual input.[128] Proper development of the visual cortex depends upon visual stimulation of the eye in a "critical period" shortly after birth.[129] These critical learning periods are the time of maximum neural plasticity, and, once they have passed, it is difficult, though perhaps not impossible, for the brain to catch up.[130] Ultimately, the effect of these developmental limitations will probably mean a matter of degrees: the earlier in life one receives a neuroelectronic device, the more proficiently that individual can learn to use it.[131]

III. FDA DEVICE LAW

The Food & Drug Administration's broad regulatory jurisdiction over medical devices make it the most natural candidate to exert regulatory authority over neuroelectronic enhancements. Section 201(h) of the Food Drug & Cosmetic Act ("FD&C") defines "device" as "an instrument, apparatus, implement, machine, contrivance, implant" which is intended for use either in "the diagnosis . . . treatment, or prevention of disease" or "to affect the structure or any function of the body" – the two uses by which drugs are defined.[132] As will be explained in below,[133] the latter half of this definition is broad enough to encompass devices that en-

128. *See generally* Jeffrey Cooper, *Development of Vision (Critical Periods)*, Optometrists Network, http://www.strabismus.org/critical_period_Hubel.html (last visited Jan. 12, 2008) (describing pioneering, Nobel Prize winning work by Hubel and Wiesel in the early 1960s that demonstrated that kittens in which one eye had been blindfolded after birth did not develop the portions of the visual cortex dedicated to processing images from that eye –known as "ocular dominance columns"– leaving them effectively monocular.); *see also* David Ottoson, Nobel Prize in Physiology or Medicine Presentation Speech (1981), *in* Nobel Lectures, Physiology or Medicine 1981-1990 (World Scientific Publishing 1993).

129. Cooper, *supra* note 128.

130. Ottoson, *supra* note 128 (noting that, in animals such as Hubel and Wiesel's sight-deprived cats, intense vision therapy after the end of the critical period did in fact result in improved, though not "normal," vision).

131. *See, e.g.*, Mitzi Baker, *Sooner is Better for Cochlear Implants, Study Shows*, Stanford Report, Dec. 7, 2005, *available at* http://news-service.stanford.edu/news/2005/december7/med-cochlear-120705.html (noting that "the earlier the implant is done, the better the chances for fully integrated speech perception in the brain," but cautioning that this ability to "fuse" the visual and auditory aspects of speech occurs only in children whose cochlear implants are installed before 30 months of age).

132. Food, Drug & Cosmetic Act, 21 U.S.C. § 321(h), (g)(1) (2007) [hereinafter FDCA]. The FDA has clearly not exercised the outer limits of this jurisdiction, as the clothes we wear would arguably affect the body's "structure" or "function". *See also* Greely, *infra* note 214 (explaining that 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); FDA Device Advice, Is this Product a Medical Device?, http://www.fda.gov/cdrh/devadvice/312.html (last visited Oct. 1, 2007) (Device Advice is a helpful,

hance. As it is, the range of products currently categorized as devices is already quite broad.[134]

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.[135] As with new drug approvals, the 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 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 in the sections that follow.

Unlike FDA drug regulation, which centers around the drug approval process[136], a good portion of FDA's regulation of devices occurs *after* approval.[137] 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

The FDA's goal is to ensure that medical devices introduced to market are "safe" and "effective."[138] 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 the 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 dan-

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business-friendly site containing clear and practical explanations of FDA medical device regulations.).

133. *See infra* Part IV.A.

134. FDA Device Advice, Classify Your Medical Device, http://www.fda.gov/cdrh/devadvice/313.html (last visited Oct. 1, 2007) (clarifying that FDA-regulated devices include simple bedpans and tongue depressors as well as complex microchip-controlled pacemakers). All in all, there are approximately 1,700 generic types of devices on the market today, further grouped into 16 medical specialties, or "panels". *Id. See also* 21 C.F.R. § 860.3(i) (defining a "generic type of device" 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").

135. *See* Medical Device Act Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (May 28, 1976) (stating that the CDRH was created by the 1976 Medical Device Amendments to the FDCA to oversee the regulation of medical devices).

136. *See* FDCA, 21 U.S.C. § 355 (2006) (detailing approval requirements for New Drug Applications ("NDAs").

137. *See infra* Parts III.B.2 and III.C-D (providing overview of post-approval regulations for devices such as postmarket surveillance and medical device reporting ("MDR").

138. *See generally* FDCA §513(a), 21 U.S.C. § 360c(a) (2006).

gerous and deserve the highest scrutiny.[139] The FDA relies upon the advice of classification panels comprised of experts from relevant fields in making its classifying decisions.[140]

All new devices, which are those introduced after May 28, 1976, are presumptively classified in Class III.[141] This presumption may be overcome if the FDA finds the new device to be "substantially equivalent" to an existing Class I or Class II device,[142] or if the new device is clearly low in risk.[143] An existing device may also be reclassified downward upon the FDA's initiative or upon the petition of the manufacturer.[144]

1. *Class I Devices*

Class I devices are low-risk, low-complexity devices. The 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.[145] Some examples of Class I devices are elastic bandages, examination gloves, and hand-held surgical instruments.[146] While Class I devices are nominally subject to the 510(k) Premarket Notification approval process,

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

140. FDCA § 513(b), 21 U.S.C. § 360c(b) (2006) (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 (last visited Oct. 1, 2007).

141. FDCA §513(f), 21 U.S.C. §360c(f) (2006).

142. 21 U.S.C. § 360c(f)(1)(A) (2006). This is also known as the 510(k) approval process, discussed below.

143. *See* FDA, New Section 513(f)(2) – Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff, Feb. 19, 1988, *available at* http://www.fda.gov/cdrh/modact/classiii.html (explaining that the FDA has streamlined classification for new, low-risk devices not based on a predicate device via a process called "Evaluation of Automatic Class III Designation").

144. 21 U.S.C. § 360c(f)(1)(B) (2006); *See also* Contact Lens Mfrs. Assn. v. Food & Drug Admin. Dept. of Health and Human Servs., 766 F.2d 592 (D.C. Cir. 1985) (demonstrating the use of both kinds of reclassification initiatives in the same factual situation: when the FDA found the manufacturer's downward classification petition to be insufficient, it initiated its own reclassification investigation). Interestingly, the FDA also invited extended public notice and comment on the reclassification investigation in *Contact Lens. Id.* at 596. *See generally* 21 C.F.R. § 860.123 (stating the requirements for petition for reclassification and establishing the use of the FDA's "valid scientific evidence of safety and effectiveness" standard in reclassification proceedings); 21 C.F.R. §860.7(c)(2) (stating the "valid scientific evidence" standard).

145. FDCA §513 (a)(1)(A), 21 U.S.C. §360c(a)(1)(A) (2006); *see also* FDA Device Advice, General Controls for Medical Devices, http://www.fda.gov/cdrh/devadvice/363.html (last visited Oct. 1, 2007).

146. FDA Device Advice, Device Classes, http://www.fda.gov/cdrh/devadvice/3132.html (last visited Oct. 1, 2007).

the 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.[147] So in addition to general controls, Class II devices are also subject to "special controls," which may include special labeling requirements, mandatory performance standards, and postmarket surveillance.[148] Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.[149]

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."[150] For this reason, Class III devices are subject to the 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.[151] Generally, this means a device must undergo one of two regulatory routes: the 510(k) process or the PMA process.

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147. FDCA §513 (a)(1)(B), 21 U.S.C. §360c(a)(1)(B) (2006); *See also* Device Classes, *supra* note 146.

148. FDCA §513 (a)(1)(B), 21 U.S.C. §360c(a)(1)(B) (2006) (listing, among other special controls, "the promulgation of performance standards, postmarket surveillance, patient registries, development and issemination of guidelines").

149. Device Classes, *supra* note 146.

150. FDCA §513 (a)(1)(C), 21 U.S.C. §360c(a)(1)(C) (2006).

151. *See* FDCA §513 (f)(1)(A), 21 U.S.C. § 360c(f)(1)(A) (2006) (stating 510(k) standard); 21 U.S.C. §360c(a)(C) (2006) (noting that Class III devices are subject to the PMA process of 21 U.S.C. §360e).

1. *Pre-Market Notification: The 510(k)*[152]

The most common method of FDA device approval is the "traditional" 510(k) Premarket Notification.[153] A 510(k) application simply requires proof that a given device is "substantially equivalent" to a device that has been previously classified and approved.[154] 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.[155] 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.[156] In most cases, the 510(k) process can be completed quickly and is ideal for the routine approval of common, everyday medical devices.[157]

2. *Pre-Market Approval*

Pre-Market Approval ("PMA") is FDA's most stringent form of premarket review, reserved for Class III devices. In contrast to the streamlined 510(k) process, the 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.

a. Evidence Required

Typically, a PMA will require clinical trials and other scientific data on the device's safety and effectiveness.[158] The FDA expects evidence of

152. 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 codified at 21 U.S.C. §360c(f)(1)(A) (2006).

153. *See* 21 U.S.C. §360c(f)(1)(A) (2006). 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) (explaining that the "traditional" 510(k) has the broadest applicability and can be used at any time); *see also* FDA Device Advice, How to Prepare a Traditional 510(k), http://www.fda.gov/cdrh/devadvice/3143.html (last visited Oct. 1, 2007).

154. 21 U.S.C. § 360c(f)(1)(A) (2006); *see also* FDA Device Advice, Premarket Notification [510(k)], http://www.fda.gov/cdrh/devadvice/314.html (last visited Oct. 1, 2007).

155. Ethicon, Inc., v. Food and Drug Admin., 762 F. Supp. 382 (D. D.C. 1991) (discussing the substantial equivalence standard).

156. 21 C.F.R. §807.87(g); *see also* FDA Device Advice, *supra* note 153 (stating that clinical data is increasingly required for devices that have different technological characteristics than a claimed predicate device); *see also* Lars Noah & Barbara Noah, Law, Medicine, and Medical Technology, Cases and Materials 246 (Foundation Press 2002).

157. Noah, *supra* note 156.

158. FDA Device Advice, PMA Overview, http://www.fda.gov/cdrh/devadvice/pma/ (last visited Oct. 1, 2007).

a device's effectiveness to include "well-controlled investigations, including [one] or more clinical investigations where appropriate," conducted by qualified experts.[159] In addition to clinical investigations, the FDA may also require significant non-clinical laboratory studies related to toxicology, immunology, biocompatibility, stress, wear, etc.[160] 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, or IDE, allowing a manufacturer to conduct clinical trials.[161]

b. Device Approval Process

Once all the requisite data on safety and effectiveness has been compiled, and clinical studies completed, staff experts at the FDA's CDRH will evaluate the pre-market application and decide whether to grant approval. As with drugs, the FDA will often bring in outside expertise to make device approval decisions that involve cutting-edge technology or controversial issues.[162] The 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."[163] These committees consist of representatives from industry and consumer groups as well as from

159. 21 U.S.C. § 360c(a)(C)(3) (2006).

160. FDA Device Advice, *supra* note 153.

161. An investigational device exemption ("IDE") allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a PMA or 510(k) submission to FDA. *See* 21 U.S.C. §360j(g) (2006) (authorizing exemption from otherwise applicable FDA requirements in order "to encourage . . . the discovery and development of useful devices intended for human use and to that end maintain the optimum freedom for scientific investigators in their pursuit of that purpose"); FDA Device Advice, IDE Overview, http://www.fda.gov/cdrh/devadvice/ide/index.shtml (last visited Jan. 11, 2008). *See also* 21 C.F.R. §812.42 (stating that both the FDA and an appropriate Institutional Review Board (IRB) must approve the IDE application before any investigation can begin); *but see* 21 C.F.R. §812.20 (noting, however, that independent FDA approval for an IDE is needed only when the device sought to be tested involves "significant risk"). *See generally* 21 C.F.R. §812.3 (stating that an IRB is any group formally designated by a given institution to review biomedical research involving subjects).

162. *See generally* Carlos Rados, *Advisory Committees: Critical to the FDA's Product Review Process*, 38 FDA Consumer Magazine, Jan.-Feb. 2004, *available at* http://www.fda.gov/fdac/features/2004/104_adv.html (noting that the decision to involve an Advisory Committee is a discretionary one); *see also* Dixie Farley, *Getting Outside Advice For 'Close Calls'*, FDA Consumer Special Report, Jan. 1995, *available at* http://www.fda.gov/fdac/special/newdrug/advice.html.

163. *See* FDA, FDA Advisory Committees, http://www.fda.gov/oc/advisory/default.htm (last visited Oct. 1, 2007) (for an overview of all Advisory Committees); *see also* FDA, Center for Devices and Radiological Health, http://www.fda.gov/oc/advisory/acdevices.html (last visited Oct. 1, 2007) (listing the 18 Committees on medical devices).

traditional academia and medicine.[164] Though the final regulatory decision rests with FDA, great weight is placed on committee discussions and recommendations. Committees not only provide the FDA with technical advice, but they may raise issues of safety or efficacy, or suggest additional studies.[165] Members can also raise relevant policy issues, and public comment is invited at committee meetings.[166]

c. Post-Approval Reports

The manufacturer is required to submit periodic reports to the 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 device,[167] and (2) "PMA supplements" whenever changes are made to the device that affect its safety or effectiveness.[168] Such changes may include new indications for use, labeling, technological characteristics, or manufacturing processes.[169]

C. Restrictions on PMA Approvals

In granting a PMA, FDA may impose restrictions on the sale and distribution of a device.[170] 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.[171] 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, which is analogous to a prescription drug.[172] They may also include a requirement for prominent labeling or post-approval surveillance or monitoring measures.[173]

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164. *See* Rados, *supra* note 162. The reasoning is that a diverse committee membership can increase the quality and legitimacy of the decisionmaking. Of course, even consumer advocates on the committee must be technically qualified to analyze data, risks and benefits. *Id.*

165. *See* Rados, *supra* note 162.

166. 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).

167. 21 C.F.R. §814.84.

168. *Id.* at §814.39.

169. *Id.*

170. FDCA §515(d)(1)(B)(ii), 21 U.S.C. § 360e(d)(1)(B)(ii) (2006); The restrictions can be placed either in the PMA approval order itself, or by regulation subsequent to the order. FDA, Pre-Market Approval Overview, http://www.fda.gov/cdrh/devadvice/pma/ (last visited Jan, 12, 2008).

171. FDCA §520(e)(1), 21 U.S.C. § 360j(e)(1) (2006).

172. *Id.* at § 520(e)(1)(A), 21 U.S.C. § 360j(e)(1)(A)(2006).

173. 21 C.F.R. §§ 814.80, 814.82; *see infra* Part III.D.2.

However, while the 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, or instances where the device is used for purposes other than the intended use.[174] This approach is highlighted by the FDA's approach in the controversy over reprocessed single-use devices. The agency has allowed hospitals to reuse surgical tools, once the FDA approves the reprocessing, even though those medical instruments were originally approved by the FDA for a single use, followed by disposal.[175] In this respect, FDA device regulation resembles FDA regulation of pharmaceutical drugs.

D. Post-Approval Regulation

Finally, the FDA can require significant monitoring of device production and usage after approval.[176] FDA's post-approval control includes two forms of regulation: oversight of the device development process, and various surveillance and reporting requirements.[177] While the former aims to minimize problems from the beginning, the latter allows the FDA to take the longer view, and respond to issues of safety and effectiveness that arise during long-term use.

1. *Quality System Regulation and Design Controls*

First, the FDA requires that manufacturers of all medical devices, except for most Class I devices, implement a quality system for every

174. 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* Letter from A. Ralph Rosenthal, M.D., Director of Opthalmic and Ear, Nose, and Throat Devices, FDA Dept. of Health and Human Services, to Mr. A. Thomas Doyle, Regulatory Affairs Mgr., Med-El Corp., MED-EL COMBI 40+ Cochlear Implant System (Aug. 20, 2001), *available at* 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").

175. *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 reprocessors. Medical Device User Fee and Modernization Act (MDUFMA) of 2002, Pub. L. No. 107-250 (enacted Oct. 26, 2002); Presentation by Ginette Y. Michaud, AdvaMed Conference in Arlington, VA Reprocessing of Single Use Devices (May 24-25, 2006) (slides available at www.fda.gov/cdrh/present/advamed-052405-michaud.ppt) (detailing the FDA regulatory scheme for reprocessed devices).

176. *See, e.g.*, 21 C.F.R. § 820 (quality system regulation); 21 C.F.R. § 820.30 (design control regulation); 21 U.S.C. § 360i (provisions for medical device reporting); 21 U.S.C. §360l (2006) (provisions for postmarket surveillance of up to 36 months).

177. *See* sources cited, *supra* note 176.

step of the development process, including design, manufacture, packaging, and labeling.[178] 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.[179]

The part of the QS regulation that may be most crucial to the development of innovative neuroelectronic interfaces 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 of both the initial design and any modifications, so that problems can be recognized earlier and thus addressed earlier in the design process.[180] Because software plays a key role in the operation of many devices and creates risks of device failure, it is also significant that, Design Controls extend to any software underlying a device.[181]

Moreover, Design Controls 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."[182] These requirements are likely to take on new meaning and importance as neuroelectronic devices more routinely interface with the human body.

2. *Post-Market Surveillance and Medical Device Reporting*

A second type 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,

178. *See generally* 21 C.F.R. § 820.

179. *Id.*

180. CDRH, Design Control, http://www.fda.gov/cdrh/comp/designgd.html (last visited Jan. 12, 2008) (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 (defining "device master record").

181. 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").

182. CDRH, What is Human Factors, Mar. 13, 2003, *available at* http://www.fda.gov/cdrh/humanfactors/whatis.html; *see also* Dick Sawyer, FDA, *Do It By Design*, Dec. 9, 1996, *available at* http://www.fda.gov/cdrh/humfac/doit.html.

called device user facilities,[183] must report regularly to the FDA regarding deaths or serious injuries that involve a device.[184] Manufacturers have the greatest reporting burden under this regulation.[185] They, along with importers, must also report device *malfunctions* that would be likely to contribute to death or serious injury.[186] 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.[187]

Lastly, the 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.[188] 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.[189] For example, the 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.[190] The FDA, at

183. 21 U.S.C. §360i(b)(6)(A) (2006); 21 C.F.R. §803.3 (defining a "device user facility" as "a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility").

184. FDCA §519(a)-(b), 21 U.S.C. §360i(a)-(b) (2006). 21 C.F.R. §§ 803.1, 803.10; CDRH, Medical Device Reporting – General Information, http://www.fda.gov/cdrh/mdr/mdr-general.html (last visited Jan. 12, 2008). 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.* at §803.30. User facilities must also submit annual report summarizing their incident reporting. *Id.* at §803.33.

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

186. *See* 21 C.F.R. §§ 803.10, 803.40, 803.50.

187. Barry Meier, *Implants with Flaws: Disclosure and Delay*, N.Y. Times, June 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).

188. FDCA §522, 21 U.S.C. §360l (2006).

189. *See* FDCA §519, 21 U.S.C. § 360i (2006); FDA, Postmarket Surveillance Studies, Aug. 29, 2007, *available at* http://www.fda.gov/cdrh/devadvice/352.html.

190. Letter from Donna Bea, Ph.D., M.P.A., Director, Office of Device Evaluation, FDA, to Kristine Floss, V.P. Clinical and Regulatory Affairs, Mentor Corp. (Nov. 17, 2006), *available at* http://www.fda.gov/cdrh/pdf3/P030053a.pdf (regarding Mentor MemoryGel™ Silicone Gel-Filled Breast Implants); Letter from Donna Bea, Ph.D., M.P.A., Director, Office of Device Evaluation, FDA, to Patricia S. Walker, M.D., Ph.D., Executive V.P., Allergan (Nov. 17, 2006), *available at* http://www.fda.gov/cdrh/pdf2/P020056.html (regarding Inamed® Silicone-Filled Breast Implants).

its discretion, can require surveillance of up to 36 months, or longer with the consent of the manufacturer, as with the breast implant studies.[191]

Unfortunately, despite potentially broad postmarket regulatory powers in this area, the FDA has not consistently or effectively regulated devices after approval. For example, the FDA has characterized its postmarket surveillance authority as an "available, but widely misunderstood and underutilized, tool."[192] Similarly, reporting of adverse device incidents is sporadic, disorganized, and difficult to analyze because of an outdated computer system and infrequent enforcement.[193] Eventually, this may change with the FDA's recent Postmarket Transformation Initiative.[194]

IV. THE ADVANTAGES AND SHORTCOMINGS OF EXISTING FDA DEVICE LAW

Asking the FDA to regulate brain-computer interface devices used solely for enhancement purposes is practical for two reasons. First, the FDA's jurisdiction is broad enough to cover enhancement devices, and the agency's existing infrastructure and administrative expertise provide strong reasons not to create a regulatory scheme from scratch.[195] Second, it is likely that the 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 and raise issues of safety and effectiveness.[196] Recent FDA decisions to regulate as devices two *cosmetic* products – decorative (color-changing) contact lenses[197] and silicone gel breast implants[198] – lend support to

191. FDCA §522, 21 U.S.C. §360l (2006).

192. CDRH, Report of the Postmarket Transformation Leadership Team: Strengthening FDA's Postmarket Program for Medical Devices, Nov. 9, 2006, *available at* http://www.fda.gov/cdrh/postmarket/mdpi-report-1106.html.

193. CDRH, Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program –Synopsis and Recommendations, Jan. 19, 2006, *available at* http://www.fda.gov/cdrh/postmarket/mdpi-recommendations.html.

194. CDRH, Medical Device Postmarket Transformation Initiative, Nov. 9, 2006, *available at* http://www.fda.gov/cdrh/postmarket/mdpi.html.

195. FDCA §201(h), 21 U.S.C. § 321 (2006) (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* 257 (Judy Illes ed., 2005) (noting that clothes can be said to "affect the structure or . . function" of the human body).

196. As discussed later, this is not the optimal solution.

197. *See* Pub. L. No. 109-96 (enacted Nov. 9, 2005) (codified at 21 U.S.C. §360j(n)) (amending FD&C §520(n) to classify all contact lenses as "devices"); CDRH, Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers - Decorative, Non-Corrective Contact Lenses, Nov. 24, 2006, *available at* http://www.fda.gov/cdrh/comp/guidance/

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.[199] 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.[200]

The FDA would choose, however, 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 to which the FDA would need to adapt. Additionally, these concerns should be weighed more heavily when enhancement, not just medical health, is at issue.[201] Second, and more importantly, the 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, including propriety, morality, and the societal impact of enhancing devices that the FDA does not, and is currently unable to, address.

1613.html (setting out FDA's nonbinding recommendations). Interestingly, FDA originally decided to classify decorative lenses as cosmetics, not devices, but Congress had other ideas. *Id.*

198. *See* eMaxHealth, Silicone Gel-Filled Breast Implants Approved by FDA, http://www.emaxhealth.com/57/8311.html (last visited Nov. 18, 2006).

199. 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.*, Press Release, National Organization for Women, FDA Approval of Dangerous Implants During Lame Duck Session Follows FDA Pattern of Favoring Money and Politics Over Science (Nov. 17, 2006), *available at* http://www.now.org/press/11-06/11-17.html. In some cases, the decision is not even the FDA's. Press Release, Prevent Blindness America, Briefing Builds Support for Cosmetic Contact Lens Regulation, (Oct. 8, 2005), *available at* http://www.preventblindness.org/news/releases/decorative_cl_briefing.html. It is unclear, however, how FDA also regulates the *effectiveness* of cosmetic devices.

200. It is unlikely that general or special controls, alone, can ensure the safety and 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." FDCA§513(a)(1)(C), 21 U.S.C. §360c(a)(1)(C) (2006). 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 195, at 257. If the FDA finds a cochlear implant that can "hear" ultrasound vibrations has new technological characteristics, 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 supra* Part II.B.1.

201. The effect that enhancement should have on the baseline for risk is discussed *infra*.

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: (1) risks of adverse body reaction; (2) risks of adverse brain feedback; and (3) risks related to device failure. First, there is always the possibility of some problem when a foreign object is placed inside the brain. As discussed earlier, pressing brain chip microelectrodes into the surface of the brain cortex provokes a complex, chronic brain inflammation response, which ultimately results in diminished chip function and effectiveness.[202] There is also the risk of infection involved in invasive surgery, which may be heightened if the implant needs regular replacement and multiple surgeries.[203] If the brain chips are coated with bioactive molecules or other components, which are currently the most promising solution to the inflammation problem, additional issues related to their safety must also be addressed.[204]

Second, the greatest care must be taken to ensure that signals that the brain *receives* from a given Brain Computer Interface ("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.[205] Hopefully, this class of risks will decline as more about the actual language of the brain

202. *See generally* Polikov, *supra* note 113 and accompanying text.

203. *See, e.g.*, Breastcancer.org, Surgery Risks, http://www.breastcancer.org/treatment/surgery/risks/ (last visited Jan. 10, 2008) (noting, in context of breast surgery, that risks of surgery include wound infections, excessive post-operative bleeding, problems with wound healing, such as accumulation of blood and fluid in a wound, and the risks of undergoing general anaesthesia).

204. In that case, the brain chips may also have to be regulated as drug-device combinations. Both CDER (the FDA center that regulates drugs) and CDRH (which regulates devices) may have jurisdiction over such a product. *See generally* Jeffrey Gibbs, *State of the Union: Drug-Device Combinations*, Device Link, http://www.devicelink.com/mddi/archive/06/11/009.html (last visited Jan. 12, 2008) (providing an excellent overview of the differing approval processes and timeframes for drugs and devices).

205. *See* Kotler, *supra* note 90.

becomes known. As a cautionary tale, however, consider the very real seizure experienced by patient Jens Naumann that was caused by overstimulation of his cortical implant during a research session with William Dobelle.[206]

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, and people will not necessarily die if they fail.[207] 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 the following subsection. However it is defined, it is clear that the effectiveness of BCI 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.[208] The implanted electrical components of a device may also degrade, batteries can die or components might shift and weaken the connection with the brain, especially in a physically active patient.[209] 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, dif-

206. *Id.*

207. 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, at 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.

208. *See supra* Part II. E.1.

209. Sample, *supra* note 45, at 4.

ferent 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.[210] 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.[211] 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.

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, which, by definition are intended to extend human abilities beyond normal. Rather, a reasonable standard for effectiveness of an enhancement device might be whether the new device provides significantly greater benefit than normal human function. 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 is smart enough to decide for itself when it is worth the risk 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 the foreseeable future, the likely answer will be that body part replacement merely for enhancement's sake will rarely be worth the trouble. Accordingly, the shift in risk acceptance as a response to the shift from medical to enhancement use of neuroelectronic devices is an issue the FDA should consider when determining standards for safety and effectiveness.

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210. *See* Chorost, *supra* note 79, at 155.

211. *See, e.g.*, R.D. Wilkins & L.K. Holley, Risk Management in Medical Equipment Management, Address Before the Proceedings of the 20th Annual International Conference of the IEEE (Oct. 29 - Nov. 1, 1998), *in* Engineering in Medicine and Biology Society, 1998, at 3343-3345.

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: simply stated, once a device is found to be safe and effective, it can be marketed.[212] Underlying this approach is the assumption that medical devices are socially beneficial and need no further justification, because 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 enhancements? Will people discriminate against others with such enhancement devices? 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, the FDA already has the ability to regulate enhancement devices for their own sake, and not just for their medical implications.[213] In sum, the 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

212. *See generally* 21 U.S.C. § 360c (2006).

213. FDCA §201(h), 21 U.S.C. § 321(2006) (defining FDA jurisdiction over devices that affect "the structure or any function of the body").

action than would be required to build a competent regulatory agency from scratch.

2. *What Sorts of Substantive Concerns Arise?*

While the questions implicated by enhancement will not be fully fleshed out until BCI's become more widespread, the major categories of issues that must be dealt with by any regulatory scheme that encompasses 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.

a. 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 – (1) from a religious perspective (that man should not change what God has intended); (2) from an evolutionary standpoint that man should not change what natural selection or nature, intended; or (3) simply from a visceral, ill-defined repulsion towards such enhancements.[214] On the other hand, our society is fairly tolerant of other forms of body alteration and even self-mutilation – tattoos, body art, and plastic surgery are examples – 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.

b. 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 functional 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 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 prevent people from altering or "hurting" themselves (as some might consider such actions), in that manner by making that calculation for them.

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

c. Identity

Since neuroelectronic devices have the potential to integrate seamlessly with the human body, it's also possible that they might affect the way we view ourselves as human beings.[215] 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.[216] 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.

d. 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, implied coercion may arise where even individuals who don't want to enhance themselves feel compelled to do so just to keep competitive.[217]

e. Impact on Society

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

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215. 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 the 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.

216. 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 79, at 177-179.

217. *See* Greely, *supra* note 214, at 97-99 (for a comprehensive overview of coercion issues).

enhancement devices provide people with an incentive to cheat or commit crime? While these concerns are indeed relevant, they raise questions that are too broad to be resolved within the framework of device approval. As Congress is in a better position to address societal impact, perhaps such issues should not be part of the regulatory calculation except in extreme circumstances.

f. 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 is the development, testing, or surgical installation, overseas.[218] A transnational device regulation scheme may be required for truly effective regulation of BCI 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.[219]

V. 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 as well as the ethical, moral, and social issues of enhancement. During this process, the FDA should consider two overarching goals. First, both neuroelectronics and enhancement are long-term propositions; the 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, as

218. *See generally* CBC News Online, Medical Tourism: Need Surgery, Will Travel, June 18, 2004, http://www.cbc.ca/news/background/healthcare/medicaltourism.html (explaining the medical tourism phenomena, and noting the various reasons that individuals travel to foreign countries to receive urgent, specialty, or elective surgery). Interestingly enough, there has already been at least one instance of what Greely terms an "*enhancement* tourist," Greely, *supra* note 214, at 107. Canadian Jens Naumann, the blind man who drove a car around a parking lot using Richard Dobelle's artificial vision system, traveled to Portugal for brain implant surgery in order to avoid FDA rules. Kotler, *supra* note 90. It's unclear why Dobelle couldn't have applied for an FDA Investigational Device Exemption, *see supra* note 161, although the article implies that he expected that the FDA would not have given him permission.

219. For more about FDA's current transnational regulation pilot program, Harmonization By Doing, with Japan, *see* CDRH, Japan - U.S. "Harmonization By Doing" HBD Pilot Program Initiative, http://www.fda.gov/cdrh/international/hbdpilot.html (last visited Jan. 12, 2008).

well as the user. Second, regulation can, and should, foster and encourage device development. In this respect, regulation should continue to follow what the FDA terms as "the least burdensome approach" – an approach that minimizes regulatory interference when possible.[220]

The following proposal sets 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 for the speculative issues surrounding enhancement, but rather a default regulatory scheme that provides a framework to handle new problems as they arise.

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

FDA should establish a Class IV category for any device that is (1) designed to send or receive commands "directly"[221] to the brain or nervous system, (2) engages in both input and output communication with the brain, and (3) 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 BCI 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.[222]

Devices classified into Class IV would be treated similarly to 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.[223] Second, Class IV devices with a significant potential to enhance normal human abilities would be sub-classified as Class IV-E devices. Devices in the 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.

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220. *See* CDRH, The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry, Oct. 4, 2002, *available at* http://www.fda.gov/cdrh/ode/guidance/1332.html (hereinafter [Least Burdensome Provisions]) (providing guidance for least burdensome approach required by law).

221. 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.

222. This would arguably exclude today's EEG and myoelectric devices (Kuiken's prosthetic arm and NASA subvocal speech devices), because they are non-invasive and can be removed. Permanent, invasive devices present the greatest ability to communicate with the brain, and present the greatest risks to safety and effectiveness.

223. *Infra* Part V.B.

B. Ensuring Safety and Effectiveness for Neuroelectronic User Devices

Today's FDA regulatory scheme for medical devices, in which the Pre-Market Approval event is the single, significant event, is modeled on the FDA experience in regulating pharmaceutical drugs.[224] However, a scheme based on a single event before approval does not make the 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 the FDA to finalize approval and requirements before such devices have been implemented. 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.[225] This reality should be incorporated into the regulatory process.

This paper proposes regulation of FDA Class IV devices in three separate phases: initial studies under an Investigational Device Exemption[226], 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 will be balanced by more stringent enforcement of the FDA's post market authorities on the back end.[227] In particular, at the front end neither conditional approval nor full approval status will require full-blown *clinical* trials, merely observational trials and other forms of data. By easing the product into market, and then beefing up enforcement of post-market regulatory measures such as surveillance and medical device reporting, the FDA can keep apprised of evolving risks to safety and effectiveness and deal with them effectively.

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224. *Compare* 21 U.S.C. § 355 (detailing standard for applications for new drug approval) *with* 21 U.S.C. § 360c (detailing standard for device approval).

225. 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 204.

226. An investigational device exemption ("IDE") allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a PMA or 510(k) submission to FDA. *See* Device Advice, *supra* note 161.

227. FDA has suggested this approach. *See* Least Burdensome Provisions, *supra* note 220 ("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* Strengthening FDA's Postmarket Program, *supra* note 192.

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.

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. The FDA should increasingly look to other kinds of evidence of safety and effectiveness from the very start of the approval process. 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 would also be a greater role in the development of neuroelectronics for animal testing, and perhaps for computer simulation and modeling, which would help predict what areas of stress, wear, injury, or discomfort might arise from the permanent implantation of a particular device.[228] Under an Investigational Device Exemption, the FDA should allow the device developer to install and develop prototypes in a small number of human subjects, with the results carefully monitored. The FDA should grant conditional approval 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 the 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, the FDA should then allow a number of small observational studies, perhaps of a few dozen individuals, conducted by the developer under the authority of the FDA's '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, that is, people may buy it and pay for its surgical installment. Such individuals, however, must do so with full knowledge of the risks. Also, devices intended primarily for

228. *See* FDA, Innovation or Stagnation: Challenge and the Opportunity on the Critical Path to New Medical Products, Mar. 2004, *available at* 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).

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, as in its recent breast implant approvals,[229] 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 the FDA has not used these two powers to their fullest extent, they do have the potential to form the basis for solid, post-approval device regulation. As such, several modifications that may help improve the effectiveness of post-market regulation are outlined as follows.

a. Changes to Medical Device Reporting

First, MDR requirements are currently limited to the reporting of serious malfunctions or incidents resulting in injury or death.[230] They are, however, ambiguous on whether potential *flaws* that have not resulted in injury or death must be reported. As a result, the FDA should require the manufacturer to fully disclose such flaws 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.[231] Since neuroelectronics and other enhancing user devices will be designed for use *outside* hospitals, the FDA should establish a registration or licensing system for the users of Class IV devices, and require them to report serious incidents to their doctor or the manufacturer.

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229. *See* the discussion of post-market surveillance *supra* Part III.D.2.

230. *See generally* 21 U.S.C. §360i(a) (2006) (stating that MDR regulations "(1) shall require a device manufacturer . . to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices— (A) may have caused or contributed to a death or serious injury").

231. The MDR regulation is written in terms of the obligations of "device user facilities." *See id.*; 21 C.F.R. §803.3 (defining a "device user facility" as "a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility").

b. Changes to Postmarket Surveillance

The FDA can currently order a surveillance period longer than three years only if the manufacturer consents.[232] Given that neuroelectronic devices may one day be implanted for an entire lifetime, a longer discretionary period (5-10 years), and even a mandatory surveillance period of some length may be helpful in monitoring the effects of chronic, long-term implantation.

4. *Regulation of Device Use Activities*

Finally, while the general rule is that the FDA does not regulate off-label, post-sale use of a device[233], perhaps this rule should give way in certain circumstances in order to bolster the FDA's postmarket powers. In particular, the FDA should prohibit the *resale* and *reuse* of a used brain-computer interface, in situations, for example, where a user decides to surgically remove a device from his body and tries to sell it.[234] The FDA might also consider regulating the surgical procedures by which brain-computer interface devices are implanted.

C. Sub-Class IV-E: Examining Substantive Issues

Not all neuroelectronic user devices, especially the first ones developed, will enhance human abilities.[235] The final piece of this proposal is the establishment of the 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 subject to higher scrutiny of safety and effectiveness risks, since enhancement carries with it a different baseline for risk.[236] 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 abili-

232. *See* 21 U.S.C. § 3601 (2006).

233. *See* 21 C.F.R. §814.80 (containing no prohibition on "use" of a Class III device in violation of the terms of a PMA approval order).

234. 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 175.

235. A case in point is cochlear implants. *See* Chorost, *supra* note 79.

236. 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.

ties 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.

As such, how *should* the 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 the 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."[237]

Following this structure, the 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 previously, but relevant voices from bioethical and religious perspectives, as well, akin to the representation on the President's Council on Bioethics.[238] 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. Nevertheless, as with ordinary advisory committees, their advice would hold great weight.

Much in the same way that the 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.[239] Proceedings would be open to the public, and the panels would solicit public input. Thus, they may serve to raise awareness of both ethical and social issues, and the new technologies that implicate them. A structured examination of those is-

237. *See supra* Part III.B.2.b.

238. *See* Exec. Order No. 13237, 66 Fed. Reg. 59851 (2001), *available at* http://www.bioethics.gov/about/executive.html (establishing the President's Council on Bioethics, and describing its purpose as, among another things, "to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology" and "to explore specific ethical and policy questions related to these developments"); Press Release, White House, President Names Members of Bioethics Council, Jan. 16, 2002, *available at* http://www.bioethics.gov/about/whpress.html (noting appointment of 17 leading scientists, doctors, ethicists, social scientists, lawyers, and theologians to the Council).

239. *Cf.* Exec. Order No. 13237, 66 Fed. Reg. at 59851 (noting that additional goals of the President's Council on Bioethics include "to provide a forum for a national discussion of bioethical issues" and "to facilitate a greater understanding of bioethical issues").

sues in a public forum would enhance the legitimacy of whatever decisions the FDA ultimately makes.

This advisory approach recognizes that the 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 because enhancement issues are not directly the fault of a device's manufacturer the way that safety or effectiveness issues might be. Nonetheless, if the FDA needs to take such action for a class of enhancement devices, its decision will at least be well-informed.

VI. 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 the 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 the FDA's postmarket authorities, as well as the Enhancement Panel approach, should 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 would 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, the 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.[240] The alternative to action – incomplete, inadequate regulation of enhancement user devices by the 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.

240. 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.