NEURAL IMPLANTS: THE PROMISE, PERIL, AND REGULATORY CHALLENGES*

RICHARD S. SAVER** & JEFFREY L. SAVER***

Neural implants generate considerable enthusiasm. Already a staple of routine medical practice, implantable neural devices deliver targeted electronical stimulation or inhibition to treat chronic pain, Parkinson's disease, epilepsy, and other serious medical conditions. Next generation brain-computer interfaces have particularly captivated the public. Now entering widespread early stage testing, this technology translates thoughts into external actions on computers and other devices, offering possible treatments for stroke, spinal cord injury, and other severe afflictions. This Article explores the considerable promise offered by neural implants. But there are also reasons to be wary, as some degree of problematic hype exists. Indeed, much work remains before comprehensive brain-computer interfaces become ready for widespread clinical use. As use of neural implants rapidly expands, the suitability of current regulation takes on increased importance. Yet several dynamics pose thorny challenges for regulating neural implants, such as complicated risk-benefit assessments, difficulty in reversing course after implantation, and uncertain, variable long-term impacts.

This Article further analyzes downsides associated with neural implants, which, importantly, include more than just risk of physical harm. Of particular concern are the abandonment hazards that participants face when unable to maintain effective use of the device because manufacturers and providers no longer support the technology's continued use or it otherwise becomes obsolete. At the same time, we caution against excessive neuroexceptionalism. Singling out neural implants for special regulatory requirements may lead to overdeterrence. This Article concludes with some modest recommendations for improving the testing, approval, and clinical use of neural implants.

** Arch T. Allen Distinguished Professor, UNC School of Law; Professor (Secondary Appointment), UNC School of Medicine; Adjunct Professor, UNC Gillings School of Global Public Health. Special thanks to Nicholas Carros and Nathaniel Somma for excellent research assistance.

*** Distinguished Professor of Neurology, Carol and James Collins Chair (Endowed), David Geffen School of Medicine at UCLA; Director, UCLA Comprehensive Stroke and Vascular Neurology Program.

INTRODUCTION 1211
I. MEDICAL ASPECTS OF NEURAL IMPLANTS 1213
A. *How They Work, Why Enthusiasm, and Rapid Development* 1213
B. *Reasons To Be Wary: Problematic Hype* 1217
II. REGULATORY CHALLENGES 1221
A. *Initial FDA Approval Process* 1221
1. Risk Classifications and Premarket Approval Applications 1221
2. 510(k) Clearances and Breakthrough Device Designations. 1223
3. Under-Generation of Information/Complicated Risk-Benefit Profiles 1224
4. Limits of Traditional FDA Safety and Effectiveness Review 1227
B. *Post-Market Controls and Surveillance* 1229
C. *Informed Consent/Privacy* 1231
III. ABANDONMENT HAZARDS 1235
A. *Definition and Many Reasons for Abandonment* 1236
B. *Abandonment Examples* 1238
C. *Limited Legal Redress for Abandonment* 1240
1. Tort Remedies 1240
2. Contract Remedies 1242
3. Fiduciary Duties 1244
4. Federal Research Regulations 1245
5. FDA Approval Process 1247
D. *Ethics Guidance* 1248
E. *Expanded Post-Trial Support Obligations* 1250
1. Arguments in Favor 1250
2. Countervailing Considerations 1253
IV. NEUROEXCEPTIONALISM CONCERNS 1254
A. *Neuroexceptionalism Generally* 1255
B. *Are Neural Implants All That Exceptional?* 1257
C. *Overdeterrence* 1262
V. RECOMMENDATIONS 1264
A. *Robust Post-Study Plans: Termination Criteria and Escrowed Funds* 1264
B. *Interoperability Standards* 1267
C. *Registry* 1268
D. *Required Short Feasibility Studies* 1268
CONCLUSION 1269
APPENDIX 1270

INTRODUCTION

Neural implants generate much acclaim. The technology comprises a wide range of devices that are inserted into the brain, spinal cord, or other parts of the nervous system, and that excite, inhibit, record, or otherwise interact with neurons.[1] Put another way, neural implants "enable scientists to hack into the nervous system."[2] First wave "neuromodulation" devices that stimulate or inhibit specific nervous system targets have had wide success and become established treatments for epilepsy, Parkinson's disease, pain, hearing loss, and other conditions. Next-wave brain-computer interface devices, which are just now entering into wide, early-stage testing, have particularly captured the public's attention, with predictions about revolutionizing medical treatment and enhancing physical and cognitive abilities to superhuman levels.[3] These devices, which acquire, analyze, and relay neuronal signal information, can translate thoughts into external action on computers, robotic arms, and paralyzed limbs.[4] They include the prominent N1 device made by Neuralink, Elon Musk's neurotechnology company, as well as comparable devices made by BrainGate, Emotiv, Synchron, and numerous other startups.[5]

Neural implants have likely reached an inflection point after decades of investigation. Research and potential clinical use are rapidly expanding. From

1. Ashley N. Dalrymple, Sonny T. Jones, James B. Fallon, Robert K. Shepherd & Douglas J. Weber, *Overcoming Failure: Improving Acceptance and Success of Implanted Neural Interfaces*, at 1, *in* 11 BIOELECTRON MED. art. 6 (2025), https://bioelecmed.biomedcentral.com/articles/10.1186/s42234-025-00168-7 (click "Download PDF") [https://perma.cc/U6H7-EW3L (staff-uploaded archive)]. The insertion is usually done surgically but in some instances involves injections. *See* Jeremy Thomas, *Big Ideas Lab Highlights Potential for Medical and Research Breakthroughs Using Neural Implants*, LAWRENCE LIVERMORE NAT'L LAB'Y (Oct. 29, 2024), https://www.llnl.gov/article/51986/big-ideas-lab-highlights-potential-medical-research-breakthroughs-using-neural-implants [https://perma.cc/6HX3-MHSK]; Emily Waltz, *How Do Neural Implants Work?*, IEEE SPECTRUM (Jan. 20, 2020), https://spectrum.ieee.org/what-is-neural-implant-neuromodulation-brain-implants-electroceuticals-neuralink-definition-examples [https://perma.cc/5D7B-GMZZ].

2. Waltz, *supra* note 1.

3. *See, e.g.*, Sally Adee, *Smart Brain-Zapping Implants Could Revolutionize Parkinson's Treatment*, 643 NATURE 625, 625–26 (2025); Gary A. Fowler, *How Neural Implants Will Create Superhuman Capabilities*, MEDIUM (June 25, 2024), https://gafowler.medium.com/how-neural-implants-will-create-superhuman-capabilities-4cf6b367d4b4 [https://perma.cc/E6JU-2HK8 (staff-uploaded archive)].

4. *See* Jonathan R. Wolpaw, José del R. Millán & Nick F. Ramsey, *Brain-Computer Interfaces: Definitions and Principles*, 168 HANDBOOK CLIN. NEUROL. 15, 16 (2020); Emily Mullin, *The Race To Put Brain Implants in People Is Heating Up*, WIRED (Dec. 23, 2023, at 07:00 ET), https://www.wired.com/story/the-race-to-put-brain-implants-in-people-is-heating-up/ [https://perma.cc/W7XU-7LGW].

5. *See* Kitty Wheeler, *Neuralink: The Company Accelerating Human Potential*, TECH. MAG. (Mar. 26, 2025), https://technologymagazine.com/articles/neuralink-the-company-accelerating-human-potential [https://perma.cc/G57P-J42L (staff-uploaded archive)]; *Top 10 Companies Leading the Brain-Computer Interface Market in 2025: Key Players, Statistics & Future Trends (2024–2025)*, SPHERICAL INSIGHTS: BLOGS (June 2025), https://www.sphericalinsights.com/blogs/top-10-companies-leading-the-brain-computer-interface-market-in-2025-key-players-statistics-future-trends-2024-2035 [https://perma.cc/9DHJ-658L].

2017 to 2024, twenty-three neural implant experimental trials were registered in the United States, focusing on wide-ranging conditions such as spinal cord injuries, pain, alcohol use disorder, depression, stroke, and Parkinson's disease.[6] The money flow reflects this new level of enthusiasm. Neuralink and rival companies have made significant investments, while U.S. governmental research funding has also been substantial, principally through the National Institutes of Health's BRAIN Initiative.[7]

As use of neural implant technology enters a new, potentially transformative period, reassessment of its potential impact and the suitability of current regulation takes on increased importance. Underscoring the need for such examination is that the ongoing acceleration in development and commercialization of neural implants may, some commentators worry, outstrip sufficient legal and ethical controls.[8]

Indeed, as this Article examines, several dynamics make regulation of neural implants especially challenging, such as difficulty in reversing course after an implant and uncertain long-term impacts. The technology also presents perplexing risk-benefit profiles. On the one hand, researchers and clinicians perceive significant advantages over other treatments. On the other hand, there are ample reasons to be wary, as some degree of problematic boosterism exists and long-term durability has not yet been established. Indeed, much work remains before cutting-edge forms of this technology, such as comprehensive brain-computer interfaces, become ready for widespread clinical use. In addition, significant risks and atypical downsides can arise with neural implants, including more than just the danger of physical harm. Particularly worrisome are the abandonment hazards participants face when unable to maintain effective use of the device because manufacturers and providers no longer support the technology's continued use or it otherwise becomes obsolete. Admittedly, several of these varied concerns arise to a comparable degree with non-neural-implant therapies. Thus, any regulatory reforms addressing neural implants must account for exaggerated neuroexceptionalism, which can result in excessive deterrence and impede development and refinement of this important technology.[9]

6. Franziska Britta Schönweitz, Anja Kathrin Ruess, Stuart McLennan, Alena Buyx & Marcello Ienca, *Where Is the Exit? The Ethical Importance of Exit Plans in Clinical Trials with Neural Implants*, 17 BRAIN STIMUL. 1145, 1145 (2024).

7. Mullin, *supra* note 4.

8. *See, e.g.*, R. Bert Wilkins, Tara Coffin, Michelle Pham, Eran Klein & Megh Marathe, *Mind the Gap: Bridging Ethical Considerations and Regulatory Oversight in Implantable BCI Human Subjects Research*, at 2, *in* 19 FRONTIERS HUM. NEUROSCI. (2025), https://www.frontiersin.org/journals/human-neuroscience/articles/10.3389/fnhum.2025.1633627/full [https://perma.cc/YEP6-W78R (staff-uploaded archive)].

9. For more on neuroexceptionalism, and broader descriptions of the concept, see Part IV, *infra*.

Part I of this Article reviews the medical background on neural implants, their many applications and advantages over existing therapies, and why researchers and clinicians have broad enthusiasm for this technology. But, as Part I further explores, a considerable degree of hype surrounds next-generation neural implants, contributing to uncritical views about their supposedly successful integration into the healthcare system. Part II considers why neural implants pose thorny regulatory challenges and identifies troubling gaps in the current oversight scheme, including the Food and Drug Administration ("FDA") approval process and the federal research regulations. Part III focuses on the abandonment hazards that participants face, analyzing the limits of current law and ethics guidance in addressing abandonment problems. Part IV cautions, however, against excessive neuroexceptionalism, as certain of the abandonment risks and other concerns associated with neural implants arise with other therapies as well. Singling out neural implants for heightened regulation may lead to overdeterrence. Part V concludes with some modest recommendations for improving the testing, approval, and clinical use of neural implants.

I. MEDICAL ASPECTS OF NEURAL IMPLANTS

A. *How They Work, Why Enthusiasm, and Rapid Development*

Neural implants as a therapeutic class offer unique advantages over other treatment modalities. Pharmacologic drugs modify the molecular composition of the human body; mechanical implants perform physical functions in the human body (e.g., joint replacements, cardiac valves, blood vessel stents); and neural therapies modulate the intricate neuronal assemblies that mediate movement, sensation, perception, and cognition. Neural implants alone can directly communicate with and alter the neural-network-generated computational basis of many physiological functions and all human behavior.[10]

Several neural implant devices have market approval and have been employed clinically for decades with high efficacy, including cochlear implants for hearing loss, deep brain stimulation for Parkinson's disease, spinal cord stimulation for chronic pain relief, and surface electrocorticography and depth electrodes for mapping seizure sites.[11] An emergent category of neural implants generating much interest are brain-computer interfaces.

10. *See* Waltz, *supra* note 1.

11. Dalrymple et al., *supra* note 1, at 1; Santosh Chandrasekaran, Matthew Fifer, Stephan Bickel, Luke Osborn, Jose Herrero, Breanne Christie, Junqian Xu, Rory K.J. Murphy, Sandeep Singh, Matthew F. Glasser, Jennifer L. Collinger, Robert Gaunt, Ashesh D. Mehta, Andrew Schwartz & Chad E. Bouton, *Historical Perspectives, Challenges, and Future Directions of Implantable Brain-Computer Interfaces for Sensorimotor Applications*, at 2, *in* 7 BIOELECTRON. MED. art. 14 (2021),

The complete history of neuromodulation dates back to ancient times, when shocks from electric catfish were used to treat arthritis pain (ancient Egypt) and from torpedo fish and electric rays to treat headaches (first-century Rome).[12] Subsequent pioneering technological breakthroughs in machine-neural system interaction include Luigi Galvani's late eighteenth century discovery of "animal electricity," where electrical stimulation of frog nerve and muscle tissue caused muscle contractions, and Professor Hans Berger's 1920s development of the electroencephalogram to provide the first recording of the spontaneous electrical activity of the human brain.[13] In the 1950s, Professor José Manuel Rodríguez Delgado implanted radio-equipped electrode arrays in animals and humans, dramatically arresting aggression in bulls and controversially treating aggression in human patients.[14] William House, in 1969, installed the first cochlear implant not rejected by a patient's immune system.[15] Professor Jacques Vidal first coined the term "brain-computer interface" in 1976 as a description of his research program at UCLA to enable observable electrical brain signals to carry information to computers to control external apparatus such as prosthetic devices.[16] In 1997, the FDA first cleared deep brain stimulation with implanted electrodes as a treatment for Parkinson's disease and essential tremor (followed by clearance for dystonia in 2003 and epilepsy in 2018).[17] 2005 saw the advent of the neural prosthesis when a

https://bioelecmed.biomedcentral.com/articles/10.1186/s42234-021-00076-6 (click "Download PDF") [https://perma.cc/BU7V-QHD8 (staff-uploaded archive)].

12. *The History of Brain-Computer Interfaces (BCIs)—Timeline*, ROBOTICSBIZ (July 22, 2020), https://roboticsbiz.com/the-history-of-brain-computer-interfaces-bcis-timeline/ [https://perma.cc/2HW6-BW4P].

13. LUIGI GALVANI, COMMENTARY ON THE EFFECTS OF ELECTRICITY ON MUSCULAR MOTION 47 (Margaret Glover Foley trans., Burndy Library 1954) (1791); Hans Berger, *Über das Elektrenkephalogramm des Menschen* [*On the Electroencephalogram of Man*], 87 ARCHIV FÜR PSYCHIATRIE UND NERVENKRANKHEITEN [ARCHIVES OF PSYCHIATRY & NERVOUS DISEASES] 527 (1929) (Ger.), *reprinted in* HANS BERGER ON THE ELECTROENCEPHALOGRAM OF MAN 37, 45–46 (Pierre Gloor ed. & trans., 1969).

14. John Horgan, *Tribute to Jose Delgado, Legendary and Slightly Scary Pioneer of Mind Control*, SCI. AM. (Sep. 25, 2017), https://www.scientificamerican.com/blog/cross-check/tribute-to-jose-delgado-legendary-and-slightly-scary-pioneer-of-mind-control/ [https://perma.cc/22DU-UAS5].

15. Albert Mudry & Mara Mills, *The Early History of the Cochlear Implant: A Retrospective*, 139 JAMA OTOLARYNGOLOGY HEAD & NECK SURGERY 446, 449 (2013).

16. Jacques J. Vidal, *Toward Direct Brain-Computer Communication*, 2 ANN. REV. BIOPHYS. & BIOENG. 157, 163–64 (1973).

17. Jessica Frey, Jackson Cagle, Kara A. Johnson, Joshua K. Wong, Justin D. Hilliard, Christopher R. Butson, Michael S. Okun & Coralie de Hemptinne, *Past, Present, and Future of Deep Brain Stimulation: Hardware, Software, Imaging, Physiology and Novel Approaches*, at 2, *in* 13 FRONTIERS NEUROL. art. 825178 (2022), https://www.frontiersin.org/journals/neurology/articles/10.3389/fneur.2022.825178/full (click "Download PDF") [https://perma.cc/9GFC-ZLBN (staff-uploaded archive)].

tetraplegic patient became the first person to control an artificial hand using a brain-computer interface.[18]

Neural implants have now grown to encompass many form factors and stimulation mechanisms treating a wide range of nervous and systemic diseases. The Appendix lists disease states for which different categories of neural implants are currently approved or being developed, including for treatment of Parkinson's disease, epilepsy, motor recovery post-stroke, and pain.[19] For the cerebrum, devices may be implanted by increasing order of invasiveness: under the skin outside the skull (subcutaneous electrode arrays), under the skull outside the brain, on the cortical surface (electrocorticography), in cerebral veins within the brain (endovascular electrode arrays), and deep within brain neural tissues (depth electrodes).[20] Stimulation may also be applied directly to the spinal cord or its arriving and existing nerve roots.[21] Peripheral nerves traveling through the body, such as the sciatic, peroneal, or vagus nerves, can be individually stimulated for targeted therapeutics.[22] Implants such as cochlear implants or retinal prostheses are also embedded within sensory organs to restore impaired or lost sensory functions. The total number of neural implants deployed has not been well estimated, but as over one million cochlear implants alone have been placed worldwide, the impact upon clinical care is already substantial.[23]

Computational and biomaterial advances are now driving rapid developments in the most advanced category of neural implants: brain-computer interfaces. Their deployments in humans are targeting a widening

18. Leigh R. Hochberg, Mijail D. Serruya, Gerhard M. Friehs, Jon A. Mukand, Maryam Saleh, Abraham H. Caplan, Almut Branner, David Chen, Richard D. Penn & John P. Donoghue, *Neuronal Ensemble Control of Prosthetic Devices by a Human with Tetraplegia*, 442 NATURE 164, 164 (2006).

19. *See infra* Appendix.

20. Shujhat Khan & Tipu Aziz, *Transcending the Brain: Is There a Cost to Hacking the Nervous System?*, at 2 fig. 1, *in* 1 BRAIN COMMC'NS art. fcz015 (2019), https://doi.org/10.1093/braincomms/fcz015 [https://perma.cc/2LSZ-MRMH (staff-uploaded, dark archive)]; Ashley N. Dalrymple, Sonny T. Jones, James B. Fallon, Robert K. Shepherd & Douglas J. Weber, *Overcoming Failure: Improving Acceptance and Success of Implanted Neural Interfaces*, at 2–7, *in* 11 BIOELECTRIC MED. art. 6 (2025), https://link.springer.com/article/10.1186/s42234-025-00168-7 [https://perma.cc/7MZP-26LF]; Peter Mitchell, Sarah C.M. Lee, Peter E. Yoo, Andrew Morokoff, Rahul P. Sharma, Daryl. L. Williams, Christopher MacIsaac, Mark E. Howard, Lou Irving, Ivan Vrljic, Cameron Williams, Steven Bush, Anna H. Balabanski, Katharine J. Drummond, Patricia Desmond, Douglas Weber, Timothy Denison, Susan Mathers, Terence J. O'Brien, J. Mocco, David B. Grayden, David S. Liebeskind, Nicholas L. Opie, Thomas J. Oxley & Bruce C.V. Campbell, *Assessment of Safety of a Fully Implanted Endovascular Brain-Computer Interface for Severe Paralysis in 4 Patients: The Stentrode With Thought-Controlled Digital Switch (SWITCH) Study*, 80 JAMA NEUROL. 270, 271–73 (2023).

21. Dalrymple et al., *supra* note 1, at 1.

22. Adrien B. Rapeaux & Timothy G. Constandinou, *Implantable Brain Machine Interfaces: First-in-Human Studies, Technology Challenges and Trends*, 72 CURRENT OP. BIOTECH. 102, 102 (2021).

23. Fan-Gang Zeng, *Celebrating the One Millionth Cochlear Implant*, at 1, *in* 2 JASA EXPRESS LETT. art. 077201 (2022), https://pubs.aip.org/asa/jel/article/2/7/077201/2844572/Celebrating-the-one-millionth-cochlear-implanta [https://perma.cc/BW3R-7N2X (staff-uploaded archive)].

range of complex human neural functions, including: bypassing severed nerve circuits to enable patients to regain control of paralyzed limbs, walking, and speech; enabling patient interface with mechanical and robotic devices for limb function and speech; and implementing central decoding of visual and somatosensory inputs to restore vision and touch.[24] As of 2026, the number of patients who have received permanent brain-computer interfaces affording motor control is quite modest—less than 200—but is growing rapidly.[25]

Brain-computer interface technology is reaching the end of the initial discovery phase of technical development, and we now face the advent of the translation phase, which will feature a burgeoning number of device types, device use cases, device developers, and investigating countries.[26] A December 2023 review identified twenty-one different Western companies performing human clinical trials, and several more have initiated programs since.[27] The global market for this technology had a hefty two-billion-dollar valuation in 2023, with compound annual growth projected at over seventeen percent from 2024 to 2030.[28]

Business analysts project a market launch of first cleared devices as early as 2030, with Morgan Stanley estimating an early total addressable market of eighty billion dollars, encompassing three million U.S. adults, with potential to reach $320 billion with further advancements.[29] Apple announced an interface protocol in May 2025 to enable brain-computer interfaces to control Apple products.[30] The generative artificial intelligence revolution is primed to accelerate brain-computer interface development. For instance, Merge Labs, a brain-computer interface start-up, has announced plans to raise $250 million

24. Rapeaux & Constandinau, *supra* note 22, at 102–04.

25. Antonio Regalado, *Brain-Computer Interfaces Face a Critical Test*, MIT TECH. REV. (Apr. 1, 2025), https://www.technologyreview.com/2025/04/01/1114009/brain-computer-interfaces-10-breakthrough-technologies-2025/ [https://perma.cc/4QZY-6UAQ] [hereinafter Regalado, *Brain-Computer Interfaces*]; K. Michelle Patrick-Krueger, Ian Burkhart & Jose L. Contreras-Vidal, *The State of Clinical Trials of Implantable Brain-Computer Interfaces*, 3 NATURE REVS. BIOENG. 50, 54 (2025); Christopher Mims, *Coming to a Brain Near You: A Tiny Computer*, WALL ST. J. (May 16, 2025, at 20:00 ET), https://www.wsj.com/tech/brain-implant-musk-als-tbi-neuralink-f733998f?reflink=desktopwebshare_permalink [https://perma.cc/7QRY-SAS7 (staff-uploaded archive)].

26. Regalado, *Brain-Computer Interfaces*, *supra* note 25.

27. Patrick-Krueger et al., *supra* note 25, at 54.

28. Mohammed A. Almanna, Lior M. Elkaim, Mohammed A. Alvi, Jordan J. Levett, Ben Li, Muhammad Mamdani, Mohammed Al-Omran & Naif M. Alotaibi, *Public Perception of the Brain-Computer Interface Based on a Decade of Data on X: Mixed Methods Study*, at 11, *in* 9 JMIR FORM. RSCH. art. e60859 (2025), https://formative.jmir.org/2025/1/e60859 [https://perma.cc/E8YC-KAZR].

29. Jim Banks, *Silicon Synapses: The Bold Frontier of Brain-Computer Integration*, IEEE PULSE, May/June 2025, at 5, 5.

30. Omar Ford, *Apple Jumps into the Brain-Computer Interface Market with Synchron Collaboration*, MDDI (May 13, 2025), https://www.mddionline.com/neurological/apple-jumps-into-the-brain-computer-interface-market-with-synchron-collaboration [https://perma.cc/5K5Y-RUQ9 (staff-uploaded archive)].

from OpenAI and other investors.[31] Elon Musk's Neuralink brain-computer interface and artificial intelligence Grok chatbot have been linked, and Neuralink announced in June 2025 that it had raised $650 million in Series E funding.[32]

B. *Reasons To Be Wary: Problematic Hype*

Despite this considerable enthusiasm about neural implants, there are reasons to remain wary. Indeed, much work remains before comprehensive brain-computer interfaces and other cutting-edge forms of this technology become ready for widespread clinical use. The medical challenges, such as surgical risks, neural tissue damage, and confounding immune responses, are considerable.[33] Implantation involves inserting the devices into quite small pieces of brain matter, which contain millions of even smaller neurons.[34] To succeed, a device has the monumental task of activating activity with only certain targeted neurons while suppressing or having no effect on others. This delicate balance can easily become undone. For example, metal and wiring from the implant can damage fragile brain matter or trigger immune system responses, leading to complicating scar tissue around the device.[35] Even simpler events can cause significant disruption, such as when "[t]he patient smiles or moves . . . and it all goes wrong."[36] Background neuronal activity, such as competing physical movements or sensory distractions, can interfere with signals from the brain-computer interface for intended actions.[37]

More importantly, a fundamental problem of device-brain misalignment hampers the technology. Many brain-computer interfaces have designs based on simpler linear models for transmission of data and task-specific neuronal commands, which may operate incongruously with the brain's dynamic, variable

31. Ivan Levingston, George Hammond & James Fontanella-Khan, *Sam Altman Challenges Elon Musk with Plans for Neuralink Rival*, FIN. TIMES (Aug. 12, 2025), https://www.ft.com/content/04484164-724e-4fc2-92a2-e2c13ea639bd [https://perma.cc/DX7Y-KYJZ].

32. Antonio Regalado, *This Patient's Neuralink Brain Implant Gets a Boost from Generative AI*, MIT TECH. REV. (May 7, 2025), https://www.technologyreview.com/2025/05/07/1116139/this-brain-implant-gets-a-boost-from-generative-ai/ [https://perma.cc/GA5L-44QX]; *Neuralink Raises $650 Million Series E*, NEURALINK (June 2, 2025), https://neuralink.com/updates/neuralink-raises-650m-series-e/ [https://perma.cc/4WK5-SXD7].

33. Jackson Tyler Boonstra, *Ethical Imperatives in the Commercialization of Brain-Computer Interfaces*, 19 IBRO NEUROSCI. REP. 718, 718 (2025).

34. Josh Sims, *There Are Two Sides to the Brain Implant Story*, INSIDE HOOK (Mar. 27, 2024, at 06:26 ET), https://www.insidehook.com/wellness/two-sides-brain-machine-interface-implant-story [https://perma.cc/JT6V-ZYVN].

35. Caitlin McDermott-Murphy, *Sensors Go Undercover to Outsmart the Brain*, HARV. GAZETTE (Mar. 12, 2019), https://news.harvard.edu/gazette/story/2019/03/harvard-neuronlike-brain-implants-may-help-treat-disease-mental-illness/ [https://perma.cc/QTJ8-XGKA (staff-uploaded archive)].

36. Sims, *supra* note 34.

37. Boonstra, *supra* note 33, at 719.

networks.[38] Brain-computer interfaces also require constant recalibration in an open-ended, iterative process to match individuals' variable and evolving neural patterns with their reported experiences.[39] Not surprisingly, attempts to use brain-computer interfaces so that a paralyzed patient can complete complicated tasks, such as controlling a wheelchair's movements, have not yet been successful in real world conditions.[40]

Problematic hype and boosterism, however, have created an overly assured view about neural implants. Indeed, "public demonstrations and media narratives often portray [brain-computer interfaces] being on the verge of 'mind-reading' or seamless neural control of the newest technology . . . ."[41] Much of this emanates from Neuralink, which has generated outsized attention and interest, no doubt because of Musk's connection.[42] Neuralink made headlines in 2024 with the start of its first-in-human study of its brain-computer interface, consisting of its N1 implant, along with its R1 surgical robot device and software, to evaluate whether the system could enable paralyzed individuals to control external devices, such as directing a computer keyboard in order to play chess or using a smartphone to communicate.[43] Longer-range aims for Neuralink's various brain-computer interfaces include more significant improvements in mobility and communication, such as enabling paralyzed patients to comprehensively control computers simply by thinking or restoring sight for blind individuals.[44] Meanwhile, Musk has ultimate goals of using the technology for dramatic cognitive enhancement, such as boosting an individual's processing speed, and even merging artificial intelligence with the brain.[45]

38. *Id.* at 718.

39. *Id.* at 719.

40. Sims, *supra* note 34.

41. Boonstra, *supra* note 33, at 718.

42. *See id.* at 720 ("Neuralink often overpromises by suggesting devices will achieve seamless, long-term integration and high-fidelity neural decoding in humans within a few years, a continuously stated claim that remains unproven.").

43. *PRIME Study Progress Update*, NEURALINK (Apr. 12, 2024), https://neuralink.com/updates/prime-study-progress-update/ [https://perma.cc/9E9S-G4MN]; Bill Chappell, *What To Know About Elon Musk's Neuralink, Which Put an Implant into a Human Brain,* NPR (Jan. 30, 2024, at 13:31 ET), https://www.npr.org/2024/01/30/1227850900/elon-musk-neuralink-implant-clinical-trial [https://perma.cc/E2EG-LZP2].

44. The plan is for participants to be able to use multiple implants at once, with the whole brain interfaces in combination tackling multiple medical problems and offering many enhancements. NEURALINK, *Neuralink Update, Summer 2025*, at 22:50–24:00 (YouTube, June 27, 2025), https://www.youtube.com/watch?v=FASMejN_5gs (on file with the North Carolina Law Review); Robert Hart, *Experts Criticize Elon Musk's Neuralink Over Transparency After Billionaire Says First Brain Implant Works*, FORBES (Feb. 26, 2024, at 11:36 ET), https://www.forbes.com/sites/roberthart/2024/02/26/experts-criticize-elon-musks-neuralink-over-transparency-after-billionaire-says-first-brain-implant-works/ [https://perma.cc/Q9VM-7XX7].

45. News Release, Physicians Comm. for Responsible Med., Statement from the Physicians Committee on Neuralink's Purported Patient Implant (Jan. 30, 2024) [hereinafter Physicians

But Musk and the company have engendered criticism for how they have shared news of developments.[46] For example, Musk used social media to announce various successes with the first-in-human implant, including that initial results showed promising neuron spike detection and that the participant was recovering well.[47] But he glossed over key details, such as how much the participant could actually move the computer mouse and how the participant fared during post-surgery recovery.[48] As it turns out, the first participant had troubling setbacks because loose threads developed in his brain, and it initially looked like the interface would have to be explanted.[49]

Further, Neuralink's pattern of announcing key moments of progress through social media updates contravenes scientific norms of disseminating this information through peer reviewed publications, clinical trial repositories, presentations of preliminary data at academic medical conferences, and other traditional means.[50] This incremental, piecemeal approach to information sharing may obscure safety problems and hinder the scientific community from evaluating the actual effectiveness of claimed advances.[51] It has also likely contributed to overly-optimistic views about the technology by the general public.

Indeed, several of the social media posts reek of boosterism, focusing on dramatic benefits that are not yet feasible and skirting discussion of upfront risks. For example, on July 21, 2025, Neuralink shared news on the company's official X account that its N1 device had been implanted into the eighth and ninth patients, enthusiastically claiming both participants were "recovering well and in great spirits."[52] Musk doubled-down on the bravado surrounding this milestone, adding on his individual X account: "Neuralink will do live-changing

Committee], https://www.pcrm.org/news/news-releases/statement-physicians-committee-neuralinks-purported-patient-implant [https://perma.cc/G82B-9N2H]; Hart, *supra* note 44.

46. *See* Physicians Committee, *supra* note 45.

47. Elon Musk (@elonmusk), X, *The first human received an implant from @neuralink yesterday and is recovering well. Initial results show promising neuron spike detection.* (Jan. 29, 2024, at 17:37 ET), https://x.com/elonmusk/status/1752098683024220632 [https://perma.cc/QE66-5YG5].

48. Hart, *supra* note 44.

49. Sony Salzman, Cameron Harrison, Kirk Cohall & Leah Sarnoff, *Neuralink's First Brain Implant Patient Feared Device Would Have To Be Removed*, ABC NEWS (May 17, 2024, at 08:13 ET), https://abcnews.go.com/GMA/Wellness/neuralinks-brain-implant-patient-feared-device-removed/story?id=110325322 [https://perma.cc/VPR2-H6DV]; *see also infra* notes 252–53 and accompanying text.

50. Hart, *supra* note 44.

51. *See* Liam Drew, *Elon Musk's Neuralink Brain Chip: What Scientists Think of First Human Trial*, NATURE (Feb. 2, 2024), https://www.nature.com/articles/d41586-024-00304-4 [https://perma.cc/46X8-TKL2 (staff-uploaded, dark archive)] (noting frustration about lack of detailed information).

52. Neuralink (@neuralink), X, *We successfully completed both P8 and P9 this weekend, our first time performing two surgeries in one day. Both participants are recovering well and in great spirits. We are looking forward to supporting them on their Neuralink journey.* (July 21, 2025, at 13:07 ET), https://x.com/neuralink/status/1947342767887167768 [https://perma.cc/8RWQ-G858].

[sic] good for ultimately millions, maybe billions, of people. Imagine your loved one being able to walk again or your parent with dementia being able to recognize their child again."[53] Likewise, in earlier statements describing the implant insertion surgery procedure, Musk cavalierly reduced the complicated steps to "[y]ou remove a coin-sized piece of skull, and then the robot inserts the electrodes . . . [t]hen the device replaces the portion of the skull that was removed . . . . And then you can just walk around right afterwards. It's pretty cool."[54]

This concerning puffery also promotes neural implants to enhance cognitive functions.[55] The potential for these devices to boost brain power beyond normal levels, outside of therapeutic treatment, already attracts much attention and debate.[56] And, as previously noted, Musk envisions radical cognitive enhancement as a long-range goal for Neuralink.[57] But among the many potential uses of neural implants, this likely remains the furthest away from actually happening. Given the complexities of orchestrating vastly large numbers of neural systems to augment brain function, much remains unknown about how to actually achieve meaningful, long-lasting cognitive enhancement. Quick-fix engineering adaptions seem beyond what can be realistically achieved.[58] Or, as Stanford Law Professor Hank Greely has observed, "Elon Musk's dreams [concerning cognitive enhancement] are so far from reality that they need not be, at this point at least, anyone else's nightmares."[59]

53. Elon Musk (@elonmusk), X, *Neuralink will do live-changing good for ultimately millions, maybe billions, of people. Imagine your loved one being able to walk again or your parent with dementia being able to recognize their child again.* (July 21, 2025, at 13:22 ET), https://x.com/elonmusk/status/1947346507927326761 [https://perma.cc/56EB-C9JL].

54. Paul McClure, *Brain Implants Are Going Obsolete, Like Old Phones. What Happens Next?*, NEW ATLAS (May 4, 2024), https://newatlas.com/technology/brain-implant-obsolete/ [https://perma.cc/6U7J-JUSZ].

55. *See, e.g.*, Jim Reed & Joe McFadden, *Neuralink: Can Musk's Brain Technology Change the World?*, BBC (Feb. 3, 2024), https://www.bbc.com/news/health-68169082 [https://perma.cc/N2AH-8US9] (describing Musk's suggestion that brain-computer interfaces may enable storing and replaying your memories and his self-described long-term goal of "human/AI symbiosis").

56. *See, e.g.*, Caterina Cinel, Davide Valeriani & Riccardo Poli, *Neurotechnologies for Human Cognitive Augmentation: Current State of the Art and Future Prospects*, at 1, *in* 13 FRONTIERS HUM. NEUROSCI. art. 13 (2019), https://doi.org/10.3389/fnhum.2019.00013 [https://perma.cc/M6UL-GBWH (staff-uploaded, dark archive)].

57. Physicians Committee, *supra* note 45.

58. Sims, *supra* note 34.

59. Esther Shein, *Neurotechnology and the Law: How Closely Should Implants Be Regulated?*, at 17, *in* 65 COMMC'NS ASS'N FOR COMPUTING MACH. art. 8 (2022), https://cacm.acm.org/news/neurotechnology-and-the-law/ [https://perma.cc/MKE8-4PTL (staff-uploaded, dark archive)].

II. REGULATORY CHALLENGES

While neural implants offer increasing promise for the health care system, they also present considerable challenges as a matter of regulation. No single, uniform law comprehensively addresses these devices. Instead, a confusing patchwork of overlapping sources of authority covers neural implants, including statutory and regulatory requirements for FDA approval, federal research regulations governing clinical trials that test experimental devices, and common law rules for informed consent before patients undergo an implant. The current oversight framework generally addresses the more salient risks and represents a reasonable attempt to balance participant safety with development of beneficial technology. However, several dynamics, such as complicated risk-benefit assessments, variable long-term impacts, and difficulty in reversing course after an implant, seem insufficiently accounted for and exacerbate the regulatory complications.

A. *Initial FDA Approval Process*

1. Risk Classifications and Premarket Approval Applications

As medical devices, neural implants are subject to FDA regulation under the Medical Device Amendments of 1976 ("MDA").[60] These amendments updated the Federal Food, Drug, and Cosmetic Act ("FDCA")[61] to establish the current system of medical device review by the agency. Under the MDA, manufacturers must provide advance notice to the FDA of plans for general marketing of a device (i.e., supply for regular clinical use), except for certain exempt low-risk devices.[62] The FDA classifies devices into three risk tiers—low risk, intermediate risk, and high risk—as part of the initial regulatory review.[63] The FDA may approve a device, however classified, for the general market only after determining that, along with imposition of any necessary control

60. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

61. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 301–399i).

62. *See Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Aug. 22, 2024), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k [https://perma.cc/J7MD-4MWP (staff-uploaded archive)] [hereinafter *Premarket Notification*] (explaining the notification process for devices not otherwise subject to the more extensive notification requirement of Premarket Approval application to the FDA).

63. *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN. (Dec. 29, 2017), https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing [https://perma.cc/C8GE-37U7 (staff-uploaded archive)] [hereinafter *Learn if a Medical Device*].

measures, there is "reasonable assurance of the safety and effectiveness of the device."[64]

But the degree and comprehensiveness of FDA scrutiny differ for each risk tier. Class I designation is for lowest-risk devices, such as tongue depressors or bandages. These devices generally enjoy exemption from premarket investigation and receive clearance from the FDA as ready for clinical use, although they are expected to comply with general controls applicable to all devices, such as compliance with good manufacturing practices.[65] Class II devices are considered intermediate risk, such as powered wheelchairs and pregnancy test kits, and the FDA may require device-specific controls, such as specified performance standards, in clearing such devices for the market in addition to general controls.[66] Class III designation is for highest risk devices, such as implanted pacemakers, and these devices generally require extensive FDA scrutiny before market approval through agency review and assent to a detailed premarket approval ("PMA") application.[67] The FDA bases its decision whether to approve a device's PMA in large part on one or more clinical trials demonstrating safety and effectiveness, with the information from such trials included as part of the PMA.[68] Completion of these clinical trials can be expensive and time-consuming. For example, it took Neuropace sixteen years and more than $315 million to bring its device, a neural implant designed to treat epilepsy, to FDA approval.[69]

The FDA usually classifies neural technologies implanted in the brain as Class II or Class III devices. According to a review of the International Medical Device Database—a repository of recall and safety alert information for devices across the world[70]—fifty-seven percent of the neural implants in the database are Class II and forty percent are Class III.[71]

64. 21 U.S.C. § 360c(a)(1)(A), (B), (C).

65. *Id.* §§ 360(b)(1), 360c(a)(1)(A); *see also* Sara Gerke & David A. Simon, *New Case Law and Liability Risks for Manufacturers of Medical AI*, at 1138, *in* 388 SCIENCE no. 6752 (2025), https://www.science.org/doi/10.1126/science.adu4932 [https://perma.cc/3RS8-U3RQ (staff-uploaded, dark archive)].

66. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 882.5600 (2025); *see also Learn if a Medical Device*, *supra* note 63.

67. 21 U.S.C. §§ 360c(a)(1)(C), 360e(c).

68. *Id.* § 360c(a)(3)(A).

69. NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, BRAIN RESEARCH THROUGH ADVANCING INNOVATIVE NEUROTECHNOLOGIES (BRAIN) NEUROETHICS WORKING GROUP (NEWG) WORKSHOP ON CONTINUING TRIAL RESPONSIBILITIES 6 (2022), https://braininitiative.nih.gov/sites/default/files/documents/brain_newg_ctr_wkshp_rla_summary_052022_508c.pdf [https://perma.cc/8SVX-NEH2].

70. *International Medical Devices Database*, INT'L CONSORTIUM INVESTIGATIVE JOURNALISTS (2025), https://medicaldevices.icij.org/ [https://perma.cc/924Y-ZRVE].

71. Patrick J. McDonald, Chloe Lau, Iris Coates McCall, Nir Lipsman & Judy Illes, *Regulatory Oversights for Implantable Neurodevices*, 18 LANCET NEUROL. 913, 913 (2019).

2. 510(k) Clearances and Breakthrough Device Designations

A less onerous, alternative approval pathway is when a device obtains "510(k) clearance," named after the applicable section of the FDA statute.[72] Under 510(k) clearance, the FDA examines the proposed device for whether it is "substantially equivalent" to a predicate device of the same risk classification that is already legally approved for market.[73] If the FDA agrees that such substantial equivalence exists, the agency will approve the new device with general and specific controls as needed.[74] These control measures often do not require that the new device undergo any clinical trials before it is approved, but the FDA still has the authority to require such studies for limited purposes, such as determining whether the manufacturer's claimed intended use for the device matches that of the predicate device.[75]

Certain devices intended to treat life-threatening or seriously debilitating conditions may qualify for the FDA's Breakthrough Devices Program, created under the 21st Centuries Cures Act[76] and further amended by later statutes.[77] The FDA expedites the development and review of devices with the breakthrough designation in an effort to speed their entrance to the market.[78] Breakthrough designation can apply to devices reaching the market through either the PMA or 510(k) pathways.[79] To receive breakthrough designation, a device must first provide for more effective treatment or diagnosis of "life-threatening" or "irreversibly debilitating" conditions.[80] Second, the device must also represent a "breakthrough technolog[y]," have no approved or clear alternatives, offer significant advantages over already approved devices or existing alternative interventions, or further the best interests of patients through its wider availability.[81] Various neural implants may qualify for breakthrough designation under these criteria. Indeed, different aspects of Neuralink's N1 brain-computer interface system received FDA breakthrough

72. Federal Food, Drug, and Cosmetic Act § 510(k), Pub. L. No. 94-295, § 4(a)(9), 90 Stat. 539, 580 (1976) (codified at 21 U.S.C. § 360(k)); *see also* 21 C.F.R. §§ 807.92, 807.93 (2025); *Premarket Notification*, *supra* note 62, at 2.

73. 21 U.S.C. §§ 360(k), 360c(f).

74. *See Learn if a Medical Device*, *supra* note 63, at 1–2.

75. 21 U.S.C. § 360c(i)(1)(A); George Horvath, *Choosing Ignorance in the Courts and at the FDA*, 67 WM. & MARY L. REV. (forthcoming) (manuscript at 13) (on file with the North Carolina Law Review).

76. 21st Century Cures Act § 515C, Pub. L. No. 114-255, 130 Stat. 1033, 1121–25 (2016) (codified as amended at 21 U.S.C. § 360e-3).

77. U.S. FOOD & DRUG ADMIN., BREAKTHROUGH DEVICES PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 4 (2025) [hereinafter BREAKTHROUGH DEVICES PROGRAM].

78. *Id.* at 6.

79. *Id.* at 4.

80. 21 U.S.C. § 360e-3(b)(1).

81. *Id.* § 360e-3(b)(2).

designation, presumably because of its initial intended goal of improving communication capability for paralyzed patients, and eventually restoring motor and sensory functions.[82] Implants approved under the Breakthrough Devices Program must still meet the general requirement applicable to all devices: an agency finding of reasonable assurance of the device's safety and effectiveness.[83] However, the FDA will tolerate less firm evidence of safety and effectiveness in reaching an approval decision for a breakthrough device.[84]

In sum, more complex neural implants, which likely involve high risk and differ in material aspects from devices already on the market, will usually receive Class III designation and need to undergo clinical trial testing as part of satisfying the PMA pathway requirements. But other neural implants, usually devices that pose only intermediate risk and have Class II designation, are more likely to be substantially similar to what is already on the market. These implants may receive 510(k) clearance process without any required new clinical trials. For neural implants classified as breakthrough devices, whether going through the PMA or 510(k) pathways, the FDA will tolerate less rigorous evidence and more doubt about the device's safety and effectiveness before reaching its approval decision.[85]

3. Under-Generation of Information/Complicated Risk-Benefit Profiles

An apparent concern with the FDA approval process is that it allows neural implants to reach the market with a fair amount of uncertainty about their ultimate suitability for clinical use. Although the devices may treat serious medical conditions and alleviate pain and disability, they nonetheless present complicated risk-benefit profiles. To start, they pose substantial physical risks.

82. NEURALINK, *Neuralink Progress Update, Summer 2020*, at 21:37 (YouTube, Feb. 17, 2022), https://www.youtube.com/watch?v=DVvmgjBL74w&t=1291s (on file with the North Carolina Law Review); Rachel Metz, *Elon Musk Shows Off a Working Brain Implant—in Pigs*, CNN BUSINESS (Aug. 31, 2020), https://www.cnn.com/2020/08/28/tech/elon-musk-neuralink [https://perma.cc/7BPD-G5TX]; Brooke Becher, *What Is Neuralink? What We Know So Far*, BUILT IN, https://builtin.com/hardware/what-is-neuralink [https://perma.cc/YV52-SD6M] (last updated Jan. 21, 2026); *Neuralink Receives Breakthrough Device Designation for Speech*, NEURALINK (May 1, 2025), https://neuralink.com/updates/neuralink-receives-breakthrough-device-designation-for-speech/ [https://perma.cc/5JQU-DVZW].

83. 21 U.S.C. § 360c(a)(1)(A), (B), (C).

84. *See* BREAKTHROUGH DEVICES PROGRAM, *supra* note 77, at 7–8 ("FDA may accept a greater extent of uncertainty of the benefit-risk profile for these [breakthrough] devices if appropriate under the circumstance . . . such as the probable benefits for patients to have earlier access to the device . . . and adequate postmarket controls to support premarket approval.").

85. The FDA Modernization Act of 1997 additionally constrained FDA. This statute added a "least burdensome" principle, obligating FDA to limit data requests and leaving as much device evaluation as possible to post-market surveillance and controls. Food and Drug Administration Modernization Act of 1997, sec. 205, § 513(i)(1)(D), 111 Stat. 2296, 2337 (codified as amended at 21 U.S.C. § 360c(i)(1)(D)(i)); Horvath, *supra* note 75. This least burdensome principle applies to many devices, not just neural implants.

The surgical insertion procedure alone can introduce hazards of stroke, infection, intracranial bleeding, and pulmonary embolism.[86] The device can degrade or malfunction, leading to serious infection or chemical leaching.[87] Further, when the implant attempts to regulate cortical and subcortical pathways in the brain, as occurs with deep brain stimulation devices, seizures, speech disturbances, and additional harms can develop.[88] More importantly, even assuming the implant procedure succeeds, relying on the device over long periods to regulate sensitive neural system activity still introduces considerable risk. Apart from potentially impacting life-supporting functions, neural implants can negatively affect participants' personality, perception, cognition, and sense of identity.[89]

Given these dynamics, long-term risk becomes particularly hard to predict. Indeed, for many neural implants the total lifespan of the device remains unclear at the start of the study or actual implantation procedure.[90] Even for devices that undergo experimental trial testing as part of the PMA pathway, the endpoint risk assessment periods for safety and effectiveness are usually more limited than the length of time patients will use the device in clinical care. Experimental trials to support a PMA are thus poorly situated to capture an implant's long-term impact on users' personalities, thinking, emotional well-being, and general health. Moreover, because the MDA does not expressly require that manufacturers conduct shorter feasibility studies with neural implants before initiating trials with larger numbers of participants, this increases chances that failures will be discovered only after a significant number of subjects have received implants, creating wide-ranging problems even at the clinical-trial stage.[91]

Meanwhile, for neural implants that instead rely on the 510(k) pathway, often no new clinical trial information is developed for the FDA approval

86. Saskia Hendriks, Christine Grady, Khara M. Ramos, Winston Chiong, Joseph J. Fins, Paul Ford, Sara Goering, Henry T. Greely, Katrina Hutchison, Michael L. Kelly, Scott Y.H. Kim, Eran Klein, Sarah H. Lisanby, Helen Mayberg, Hannah Maslen, Franklin G. Miller, Karen Rommelfanger, Sameer A. Sheth & Anna Wexler, *Ethical Challenges of Risk, Informed Consent, and Posttrial Responsibilities in Human Research With Neural Devices*, 76 JAMA NEUROL. 1506, 1507 (2019) [hereinafter Hendriks et al., *Ethical Challenges*].

87. *See, e.g.*, Michael White & Roger G. Whittaker, *Post-Trial Considerations for an Early Phase Optogenetic Trial in the Human Brain*, 14 OPEN ACCESS J. CLINICAL TRIALS 1, 3 (2022).

88. Hendriks et al., *Ethical Challenges*, *supra* note 86, at 1508.

89. *Id.*

90. *See* NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at 4.

91. *See* Emily Underwood, *Researchers Grapple with the Ethics of Testing Brain Implants*, SCIENCE (Nov. 7, 2017), https://www.science.org/content/article/researchers-grapple-ethics-testing-brain-implants [https://perma.cc/YSA7-X2DZ (staff-uploaded archive)] (discussing concerns about BROADEN, the deep brain stimulation study of an implant for treating depression, where the device failed to produce promising effectiveness results, and questions arose whether more feasibility studies could have avoided the problem of introducing the device perhaps prematurely for a large number of participants); *see also infra* Section V.D.

decision, glossing over the problem of unexamined long-term impacts. Accordingly, some commentators have warned about "overreliance" on the 510(k) pathway for approval of neural implants.[92] Remember that the justification for using this pathway heavily relies upon the assumption that the new device does not differ, in terms of safety and effectiveness, from an already approved, predicate device because of a finding of substantial equivalence between the devices.[93] However, this assumption may not always be warranted. Limited premarket review can miss important safety and efficacy distinctions that become apparent only after more widespread clinical use.[94]

Not only are devices under the 510(k) pathway often not subject to new rounds of clinical trial testing, but they may be several generations removed, in a chain of substantial equivalence approvals, from an original device that was allowed on the market. This can happen when the manufacturer of a neural implant claims it has substantial equivalence to a predicate device but that predicate device itself received approval by claiming substantial equivalence to an even earlier predicate device on the market. In other words, today's approved device may represent multiple rounds of changes from the original predicate device that actually underwent rigorous testing through clinical trials.[95]

Thus, when the FDA must make the approval decision under either pathway, PMA or 510(k), considerable uncertainty remains about long-term effects of neural implants. Instead, the regulatory process favors quicker agency approval, with less overall pre-market testing and heavier reliance on an assumed system of strong post-market surveillance, which may not match what actually happens on the ground.[96]

The degree of FDA review just described, including largely deferring questions of long-term impacts to post-market surveillance, applies to most medical devices, not just neural implants. Yet this under-generation of long-term risk information in the initial FDA approval process, in addition to raising policy concerns, clearly does not square with public attitudes about neural implants. A Pew Research Center survey indicated that a large majority of the population worries that computer chip implants in the brain will be used before there is more robust understanding about how they will impact participants'

92. McDonald et al., *supra* note 71, at 913.

93. *See supra* notes 72–75 and accompanying text.

94. See generally Eli Y. Adashi, Katina M. Robison & I. Glenn Cohen, *Deadly Legacy—The 510(k) Path to Medical Device Clearance*, 157 JAMA SURG. 185 (2022), for a discussion of the "inherent shortcomings" of 510(k) medical device approvals.

95. *Medical Devices Harm Patients Worldwide as Governments Fail on Safety*, INT'L CONSORTIUM INVESTIGATIVE JOURNALISTS (Nov. 25, 2018), https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/ [https://perma.cc/XVC4-T8DT].

96. *See infra* Section II.B.

health, evidencing apprehension about long-term risks.[97] The same survey also indicated that the public has grave concerns about letting such neural implants reach the market without rigorous preapproval testing, even if this is the pathway for other devices. In the survey, eighty-three percent of respondents thought these implants "should be tested using a higher standard than is used for [other] medical devices."[98] Similarly, a study of social media posts on X indicated a strong undercurrent of public fear about brain-computer interfaces.[99]

In addition, the entrenchment of many neural implants raises the stakes. Neither the FDA nor patients can nimbly reverse course after the device reaches the market. For many participants, explantation of the devices may not be a feasible or readily available option should new safety or effectiveness concerns emerge.[100] Surgical removal carries significant risks.[101] Explantation may pose even more potential harm than the initial implantation, such as when the device becomes deeply embedded in sensitive neural tissue or has triggered confounding immune responses.[102] Patients can usually stop drug therapy quickly when safety issues materialize, but "[p]eople with an unnecessary or poorly functioning implant may end up with it inside their body for the rest of their lives."[103]

Even if surgical removal of the implant or rendering it inactive remains feasible, this does not mean that participants can be readily returned to their previous therapeutic states and made "not worse off" from the experience. Neural implants can create infection complications and problematic interference with neural activity if the devices leak, move, or otherwise disrupt neural networks.[104] Removal of the device can also lead to or exacerbate brain system changes that cause dangerous psychiatric side effects.[105]

4. Limits of Traditional FDA Safety and Effectiveness Review

Some neural implants offer dual potential for therapeutic care and cognitive enhancement, creating additional complications for the FDA's device-

97. Lee Rainie, Cary Funk, Monica Anderson & Alec Tyson, *Public Cautious About Enhancing Cognitive Function Using Computer Chip Implants in the Brain*, PEW RSCH. CTR. (Mar. 17, 2022), https://www.pewresearch.org/internet/2022/03/17/public-cautious-about-enhancing-cognitive-function-using-computer-chip-implants-in-the-brain/ [https://perma.cc/77SA-GK25].

98. *Id.*

99. *See* Almanna et al., *supra* note 28, at 6.

100. *See* Paul Tubig & Frederic Gilbert, *"The Trauma of Losing Your Own Identity Again": The Ethics of Explantation of Brain-Computer Interfaces*, *in* POLICY, IDENTITY, AND NEUROTECHNOLOGY 27, 29 (Veljko Dubljević & Allen Coin., eds., SPRINGER 2023).

101. *See, e.g.*, White & Whittaker, *supra* note 87, at 4.

102. Boonstra, *supra* note 33, at 720.

103. INT'L CONSORTIUM INVESTIGATIVE JOURNALISTS, *supra* note 95.

104. *See, e.g.*, White & Whittaker, *supra* note 87, at 3.

105. Tubig & Gilbert, *supra* note 100, at 28.

approval process. Certain brain-computer interfaces not only treat disease but also potentially augment a person's cognition, sensation, facial recognition, and general way of thinking compared to healthy members of the population. The devices can be used for enhancing performance across many dimensions, including educational testing and gaming.[106] For example, a brain-computer interface meant to help patients struggling with dementia or stroke recovery has the potential not only to address neural damage but also enhance cognitive skills to above average levels in domains such as memory, attention, and language.[107]

As previously noted, the FDA regulatory approval criteria require, at bottom, agency assurances that a device is reasonably safe and effective.[108] But this directive to assess for safety and effectiveness may be unduly narrow when applied to devices that have dual medical and cognitive-enhancement functions. FDA review has typically focused on traditional medical risks.[109] Thus, the FDA has looked to outcomes measures such as complication rates involving bleeding, scarring, infection, and damage to brain tissue.[110] But this type of assessment does not consider the value placed on a neural implant's potential for cognitive enhancement and how this should be squared with the regulatory safety and effectiveness criteria.

Incorporating prospects of cognitive enhancement into the FDA's traditional safety and effectiveness review necessitates consideration of subtle, nuanced issues that the agency may be ill-equipped to address. Enhanced performance, not therapeutic treatment, in dimensions such as cognition, memory, and reaction times will vary between participants, and, more importantly, individuals will likely have very different subjective impressions of the desirability of such nonmedical enhancements.[111] As for the risk side of the risk/benefit profile, neural implants present clear, objective medical risks like infection and damage to brain tissue. However, they also introduce potential harms that are harder to measure, such as the trauma of having to explant a device that is not working after the participant becomes dependent on

106. *See, e.g.*, Kardelen Çelik, *Exploring Brain Computer Interface Applications*, DIGITOPIA (Apr. 10, 2025), https://digitopia.co/blog/brain-computer-interface-applications/ [https://perma.cc/EP29-BRGP].

107. *Cf.* Hannah Maslen, Thomas Douglas, Roi Cohen Kadosh, Neil Levy & Julian Savulescu, *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*, 1 J.L. & BIOSCIS. 68, 70 (2014) (discussing dual enhancement and medical functions for transcranial direct current stimulators, which, although not implants, can similarly affect neural activity).

108. *See supra* notes 60–64 and accompanying text.

109. Charles E. Binkley, Michael S. Politz & Brian P. Green, *Who, if Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices?*, 23 AMA J. ETHICS 745, 746 (2021).

110. *Id.*

111. *Id.* at 747; Maslen et al., *supra* note 107, at 70.

it,[112] or the risk that a participant will have to return to a lower-functioning pre-implant state.[113]

Moreover, there are society-wide effects, both positive and negative, stemming from the wider use of neural implants that have cognitive enhancement features. For example, it may be concerning to introduce devices with cognitive enhancement advantages when, under the present health care delivery system, members of the community will have differential access to the technology, with some having no access at all. Or there may be problematic social stigma for persons who refuse to be enhanced in this manner. On the other hand, persons who embrace the technology may face social opprobrium as "artificially" enhanced and something less than human. Indeed, the public has considerable concern about the society-wide effects of widespread dissemination of brain-computer interfaces. A Pew Research Center opinion poll indicated that a large segment of the population (56%) considers that it would be bad for society to use computer chip implants in the brain to complete information processing tasks.[114] Yet the current FDA safety and effectiveness review criteria, as traditionally applied, seem underdeveloped and inadequate to weigh these society-wide effects.[115]

B. *Post-Market Controls and Surveillance*

The problematic gaps, including limited information generated, with FDA premarket review, make all the more important an effective monitoring system for already approved devices. But genuine concerns arise as to whether sufficient post-market controls apply to neural implants. The FDCA authorizes at least two forms of active post-market surveillance for approved devices. First, as part of a PMA review, the FDA can impose a requirement that the manufacturer conduct post-approval studies on safety and effectiveness, detailing the expected number of patients for evaluation and the types of endpoints considered.[116] Second, when particular safety concerns exist, the FDCA authorizes active forms of post-market surveillance for class II or III devices.[117] Many neural implants will likely fall under this active post-market surveillance. Several of the statutorily enumerated safety issues that trigger the monitoring expectation include situations very pertinent to neural implants, such as likelihood that failure of the device will have serious adverse health

112. *See infra* notes 249–54 and accompanying text.

113. Binkley et al., *supra* note 109, at 747.

114. Rainie et al., *supra* note 97.

115. Binkley et al., *supra* note 109, at 746–47.

116. 21 C.F.R. § 814.82(a)(2) (2025).

117. 21 U.S.C. § 360l(a)(1)(A); U.S. FOOD & DRUG ADMIN., POSTMARKET SURVEILLANCE UNDER SECTION 522 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2022).

consequences or that the device is intended to be implanted in the body for over one year.[118] The types of active surveillance the FDA may require, in its discretion, include new randomized clinical trials, cohort studies following groups of patients with the device forward in time, and study of reported adverse events or prospective and retrospective analysis of "real-world data" from existing patient records.[119]

The FDA also subjects devices to more passive post-market surveillance through its Medical Device Reporting process. Under this program, manufacturers and institutional providers such as hospitals and nursing homes must submit adverse event reports to the FDA when serious device-related events occur such as patient death, serious injury, or major malfunctions of the device.[120]

But considerable implementation problems undermine these various post-market control and surveillance efforts. First, the passive monitoring system of adverse event reports likely yields incomplete, untimely data for the FDA.[121] While the FDA has created unique identifiers for medical devices, payers and providers do not make use of the same identifiers in their own operations. This significantly complicates the ability to track device activity.[122] And substantial underreporting of adverse events likely occurs due to time and expense demands on mandated reporters, lack of financial incentives to complete such reports, and failure to enforce reporting requirements consistently through timely sanctions.[123] Meanwhile, the list of mandated reporters remains limited. While hospitals and other institutional providers must report device-related adverse events, physicians and patients are not required to do so, although the FDA encourages their voluntary action.[124] The omission of physicians and patients from the group of mandated reporters creates serious information gaps. Operating on the clinical front lines of outpatient care, they may have access to pertinent information concerning a device more readily than the institutional providers.

118. 21 U.S.C. § 360l(a)(1)(A); U.S. FOOD & DRUG ADMIN., *supra* note 117, at 5–6.

119. U.S. FOOD & DRUG ADMIN., *supra* note 117, at 9–11, 14–16.

120. *See* 21 C.F.R. § 803.20(b) (2025); U.S. GOV'T ACCOUNTABILITY. OFF., GAO-24-106699, MEDICAL DEVICES: FDA HAS BEGUN BUILDING AN ACTIVE POSTMARKET SURVEILLANCE SYSTEM 5 (2024).

121. U.S. GOV'T ACCOUNTABILITY. OFF., *supra* note 120, at 5.

122. Dan C. Krupka, Natalia A. Wilson, Amanda J. Reich & Joel S. Weissman, *The Post-Market Surveillance System for Medical Devices Is Broken. Here's How CMS and the FDA Can Act to Fix It*, HEALTH AFFS. (Apr. 23, 2021), https://www.healthaffairs.org/content/forefront/post-market-surveillance-system-implanted-devices-broken-here-s-cms-and-fda-can-act-now [https://perma.cc/U528-9L2K].

123. *See* Frederic S. Resnic & Sharon-Lise T. Normand, *Postmarketing Surveillance of Medical Devices—Filling in the Gaps*, 366 NEW ENG. J. MED. 875 (2012).

124. 21 CFR §§ 803.1, 803.3 (2025); U.S. GOV'T ACCOUNTABILITY. OFF., *supra* note 120, at 5.

As for the more active forms of post-market surveillance, such as post-approval clinical trials and cohort studies, implementation and enforcement seem disappointingly incomplete. For example, one investigation found that approximately two out of three planned post-market studies were not completed and published for the examined high-risk devices within eight to ten years of FDA approval.[125] Manufacturers have limited incentives to design and complete high-quality trials for devices already approved and for which they actively earn money, unless strongly prodded to do so by the FDA.[126] The ultimate form of post-market control is, of course, not surveillance but FDA recall of a device off the market. But because the recall process largely depends on adverse event reporting data, which, as noted, is often spotty and incomplete, recall decisions often depend upon limited, time-lagging evidence.[127]

Moreover, neural implants appear underregulated in terms of post-market controls even compared to other devices. The FDA has a variety of regulatory tools to address a device's safety and effectiveness concerns post-market, such as issuing safety alerts or the ultimate "atom bomb" of recalling a device off the market. Yet such FDA action with neural implants seems relatively constrained. Of over 70,000 reports on devices concerning safety alerts and recalls in the International Medical Devices Database from 2008 to 2017, only 229 were for neural implants.[128] Even accounting for the likelihood that neural implants represent a small subset of approved devices, and so FDA activity for such devices should not represent large overall aggregate numbers, this seems a disproportionate response. Further, when recalls of neural implants may be warranted, the FDA has not acted quickly, illustrating the challenges of evaluating safety and effectiveness with incomplete information available. One analysis estimated that for recalled neural implants, the interval averaged fifteen years between when the device received initial approval by the FDA and when the recall process started.[129]

C. *Informed Consent/Privacy*

Providers must obtain participants' informed consent before proceeding with implantation. When the implant is done with an approved device in the context of regular clinical care, this means that providers must generally disclose

125. *See* Vinay K. Rathi, Harlan M. Krumholz, Frederick A. Masoudi & Joseph S. Ross, *Postmarket Clinical Evidence for High-Risk Therapeutic Medical Devices Receiving Food and Drug Administration Premarket Approval in 2010 and 2011*, at 1–2, *in* 3 JAMA NETWORK OPEN art. e2014496 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7455850/ [https://perma.cc/L5GF-RKCH].

126. *See* Sanket S. Dhruva, Jonathan J. Darrow, Aaron S. Kesselheim & Rita F. Redberg, *Experts' Views on FDA Regulatory Standards for Drug and High-Risk Medical Devices: Implications for Patient Care*, 37 J. GEN. INTERN. MED. 4176, 4179 (2022).

127. *See* McDonald et al., *supra* note 71, at 913.

128. *Id.*

129. *Id.*

the technology's material, foreseeable risks, and an explanation of medically reasonable alternative therapies before securing the participant's consent to proceed.[130] When the implant is investigational and done as part of a clinical trial, the federal research regulations require more detailed informed consent disclosures, including that participants receive a clear reminder that the device is experimental, an explanation of the purposes of the study, and identification of "any reasonably foreseeable risks or discomfort."[131]

While the legal requirements for informed consent are theoretically clear, disclosure and participant uptake of this information become particularly challenging with neural implants. First, any risk disclosure must address a considerable and potentially confusing array of risks, ranging from harms emanating from the surgical implantation (e.g., infection and stroke), to the structural integrity of the devices (e.g., migration of threads and connections once inside the body or device fracture), to problems once the devices interact with the neural system (e.g., seizures and mobility).[132] Second, long-term implantation of neural devices and their possible late-developing effects on critical neural functions increase the uncertainty of risk prognostication. Third, it is difficult for the consent disclosure to account for hard-to-describe, potentially irreversible, and somewhat "atypical" long-term risks, such as changes in personality, mood, and sense of identity.[133] Delineating and assigning appropriate salience to these risks becomes thorny as they are generally "poorly understood, variable, and unpredictable."[134]

Moreover, neural implant participants may have widely varying perceptions about the seriousness of these atypical risks. Some may find that technologies, like deep-brain stimulation implants for treating Parkinson's disease, enhance autonomy by providing greater ability to deal with current limitations. Yet others may view neural implants that potentially interfere with core features like cognition and emotion as "undermining their level of control and authenticity."[135] The comprehensiveness and degree of emphasis on atypical risks needed to satisfy informed consent are not at all clear given the likely wide variability in participant responses. Relying on legal concepts, such as what the

130. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 786–88 (D.C. Cir. 1972) (reflecting jurisdictions defining scope of informed consent disclosure as to what satisfies the reasonable patient's informational needs); Culbertson v. Mernitz, 602 N.E.2d 98, 100–04 (Ind. 1992) (reflecting jurisdictions defining scope of informed consent disclosure as what comports with what a reasonable, prudent physician would have disclosed).

131. HHS General Requirements for Informed Consent, 45 C.F.R. § 46.116(a)–(b) (2024) (HHS regulations); FDA Elements of Informed Consent, 21 C.F.R. § 50.25(a) (2025) (FDA regulations).

132. Hendriks et al., *Ethical Challenges*, *supra* note 86, at 1507–08.

133. *Id.* at 1508.

134. *Id.*

135. *Id.* at 1509.

fictitious reasonable patient would want to know,[136] may therefore prove especially difficult when applied to neural implants and involve a highly unsatisfactory amount of speculation and conjecture.

Further, even when disclosure of atypical risks occurs in some detail, it remains questionable how well participants will be able to process this information. As previously discussed, a considerable degree of hype surrounds neural implants,[137] likely contributing to overly optimistic community attitudes about the technology. The informed consent process with individual participants may not easily rebut these preformed views. The risk information is complex for most individuals, yet some neural device participants must deal with varying levels of cognitive impairment due to their underlying medical conditions, even if not lacking legal competence and decisional capacity altogether for providing informed consent.[138] It is likely that the typical "one-off" informed consent procedure of providing a participant with a written form to sign will be insufficient to ensure meaningful consent. Instead, multiple, targeted communications are needed.[139] Yet providers do not have sufficient incentives to take these additional steps, given the sorry state of current informed consent law, which does not do a very good job of ensuring useful information processing by patients and subjects.[140] The knowledge gaps patients and subjects face become even more pronounced when, as may occur with neural implants, the relevant risks involve intangible and often nonactionable harms, like affronts to autonomy and dignity, not physical complications.[141]

Indeed, studies of participants undergoing neural implants suggest that they have limited understandings about the key risks, despite having undergone informed consent. Consider, for example, the risk of abandonment and limited post-trial access to implant technology when the device is obtained through a clinical trial.[142] A focused discussion investigation with neural implant participants indicated that even a few days to a few weeks after initial informed consent conversations, approximately one third of participants had no recollections about discussions of post-study access details and, six months later, about the same proportion of participants still could not recall having discussed

136. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 786–88 (D.C. Cir. 1972) (reflecting jurisdictions defining scope of informed consent disclosure as what satisfies the reasonable patient's needs).

137. *See supra* Section I.B.

138. Hendriks et al., *Ethical Challenges*, *supra* note 86, at 1509–10.

139. *Id.*

140. *See, e.g.*, Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 903–04 (1994); Thaddeus Mason Pope, *Certified Patient Decision Aides: Solving Persistent Problems with Informed Consent Law*, 45 J.L., MED. & ETHICS 12, 16–18 (2017).

141. *See, e.g.*, Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 956–58, 963–65 (2006); Pope, *supra* note 140, at 17.

142. *See infra* Part III.

such risks.[143] Another interview investigation found that a fair number of neural implant participants receiving deep brain stimulation and responsive neurostimulation interventions across five different clinical trials were not accurately aware of the planned transition to post-study care, despite having received this information as part of the informed consent process.[144] They also were sometimes unclear about post-trial device access.[145] The investigation authors speculated that participants' short-term focus on symptoms and hope for therapeutic relief resulted in inattention to the downstream consequences of trial termination.[146]

Loss of privacy, a serious risk to neural implant participants, certainly warrants disclosure as part of informed consent. Devices like brain-computer interfaces can track cognitive activity and emotional reactions, offering glimpses into an individual's most interior, sensitive dimensions.[147] Many participants likely assume that general healthcare privacy laws, like the Health Insurance Portability and Accountability Act ("HIPAA"),[148] will offer protection as these laws do for their other medical information. But this may reflect a threshold misunderstanding of how these devices operate. Data generated by neural implants, which can provide continuous outputs from interfaces with the brain, can fall beyond the reach of HIPAA's protections for general health information. HIPAA generally shields healthcare information handled by providers, insurers, and a limited number of their business associates.[149] Yet brain-computer interfaces, along with other implants, often generate data about cognition patterns for use by the manufacturer, not the healthcare provider or

143. Gabriel Lázaro-Muñoz, Michelle T. Phamb, Katrina A. Muñoz, Kristin Kostick-Quenet, Clarissa E. Sanchez, Laura Torgerson, Jill Robinson, Stacey Pereira, Simon Outram, Barbara A. Koenig, Philip A. Starr, Aysegul Gunduz, Kelly D. Foote, Michael S. Okun, Wayne Goodman, Amy L. McGuire & Peter Zuka, *Post-Trial Access in Implanted Neural Device Research: Device Maintenance, Abandonment, and Cost*, 15 BRAIN STIMUL. 1029, 1031 (2022) [hereinafter Lázaro-Muñoz et al., *Post-Trial Access*].

144. Lauren R. Sankary, Megan Zelinsky, Andre Machado, Taylor Rush, Alexandra White & Paul J. Ford, *Exit from Brain Device Research: A Modified Grounded Theory Study of Researcher Obligations and Participant Experiences*, 13 AJOB NEUROSCI. 215, 222–23 (2021) [hereinafter Sankary et al., *Exit from Brain Device Research*].

145. *Id.* at 223.

146. *Id.*

147. *See, e.g.*, Lara Lewington, Liv McMahon & Tom Gerken, *The Man With a Mind-Reading Chip in His Brain—Thanks to Elon Musk*, BBC (Mar. 22, 2025), https://www.bbc.com/news/articles/cewk49j7j1po [https://perma.cc/7BYU-T692] (discussing privacy concerns with Neuralink device and quoting Professor Anil Seth, University of Sussex, as saying "[o]nce you've got access to stuff inside your head, there really is no other barrier to personal privacy left").

148. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29 and 42 U.S.C.); *see also* HHS Privacy of Individually Identifiable Health Information, 45 C.F.R. §§ 164.500–534 (2024).

149. 45 C.F.R. §§ 164.500–534; *see also* Stacey A. Tovino, *Artificial Intelligence and the HIPAA Privacy Rule: A Primer*, 24 HOU. J. HEALTH L. & POL'Y 77, 89–92 (2025).

insurer, and so this information may not be covered by HIPAA's confidentiality restrictions.[150]

Relatedly, neurologists have started to sound the alarm about consumer neural devices, such as headbands that monitor electroencephalogram data. Because these devices are sold directly to consumers, not prescribed by a health care provider in a treatment relationship, their information is subject to few privacy restrictions.[151] Neural implants warrant similar privacy concerns. Whether obtained in the course of treatment or as part of trial participation, these devices may generate neural data for manufacturers and other parties not subject to HIPAA and related confidentiality rules. Relying on informed consent disclosures about the potential privacy risks may be insufficient. Some states have moved to fill in the gaps and enact laws more protective of neural data privacy, but this represents only a minority, and more comprehensive regulation is lacking.[152]

III. ABANDONMENT HAZARDS

The challenging risk-benefit considerations for neural implants explored in Part II, which include uncertain long-term impacts, potential for atypical, intangible hazards, and participants' highly varied responses, complicate evaluation of the suitability of current regulation. Even-handed assessment of this technology must account for these complex dynamics. But in this Part III, we explore in further detail one particular concern that makes optimal regulation especially difficult: abandonment hazards. Neural implant participants face considerable risk of disrupted use of the device. Manufacturers and providers will no longer support the technology's continued use for a variety of reasons, including business considerations unrelated to clinical effectiveness. While such discontinuations can occur with surprising frequency, abandoned participants have limited legal recourse to ensure continued access. As this Part explores, potential claims arising under tort, contract, the federal research regulations, and related laws are unlikely to prevail as the rules are

150. Perla Khattar, *Neural Data and Consumer Privacy: California's New Frontier in Data Protection and Neurorights*, TECH POL'Y PRESS (Nov. 19, 2024), https://www.techpolicy.press/neural-data-and-consumer-privacy-californias-new-frontier-in-data-protection-and-neurorights/ [https://perma.cc/WE2D-ME38].

151. Sean Pauzauskie, Jared Genser & Rafael Yuste, *Protecting Neural Data Privacy—First, Do No Harm*, 82 JAMA NEUROL. 212, 212–13 (2025).

152. *See* Boonstra, *supra* note 33, at 721 (explaining privacy laws such as HIPAA were not enacted with neural data in mind and "[t]he lack of comprehensive, dedicated regulation enables commercial exploitation: companies can collect, store, and even sell neural data to third parties"); Kate Ruder, *States Pass Privacy Laws to Protect Brain Data Collected by Devices*, KFF HEALTH NEWS (July 23, 2025), https://kffhealthnews.org/news/article/colorado-california-montana-states-neural-data-privacy-laws-neurorights/ [https://perma.cc/MT6Z-SFZJ] (discussing recent legislation enacted in California, Colorado, and Montana).

poorly designed to address abandonment. Professional ethics guidance offers potentially stronger support for participants' continued use of an implant, but the scope and extent of such access remain unclear.

A. *Definition and Many Reasons for Abandonment*

"Abandonment," as defined by a thoughtful professional consensus statement following the Royal Society Summit on Neural Interfaces, means "a failure to actively support medical needs of patients who, through no fault of their own, do not possess the medical, technical, or financial capabilities to maintain the safe and effective use of a [neural implant]."[153] Abandonment of neural implant participants can occur for many reasons. The most straightforward situation is when the device does not perform well in clinical trials, and the manufacturer/sponsor no longer thinks it worthwhile to develop the implant for market. Nonetheless, individual participants who perceive benefits differently from the aggregate group of study subjects will desire continued utilization of the device, especially as it is already in the brain. If the manufacturer has decided not to move forward with developing the technology, participants' only recourse may be to pay for device repair, maintenance, and ongoing support themselves. Or the manufacturer may request that the device, and any associated proprietary data, be returned, which may require a surgical explantation procedure to remove the implant.

But abandonment surprisingly occurs even if the device performs well in the early stages of clinical testing. The manufacturer may, notwithstanding promising trial data, conclude as a business matter that it is not worth pursuing the implant further if, for example, the perceived market demand or ability to command favorable pricing has changed. In addition, manufacturers may run into economic difficulties and may not have available resources to continue the testing process or bring the device to market.[154] Or, the lead investigator may move to another institution, leading to unexpected loss of financial support for continuing the study at the medical center accessible to already enrolled participants.[155] Further, the manufacturer may have left it to a participant's health insurer to cover the device. However, payors generally exclude coverage for experimental therapies.[156] Relatedly, a neural implant may have passed the

153. Michael S. Okun, Timothy Marjenin, Jinendra Ekanayake, Frederic Gilbert, Sean P. Doherty, Jack Pilkington, Jennifer French, Cynthia Kubu, Gabriel Lázaro-Muñoz, Timothy Denison & James Giordano, *Definition of Implanted Neurological Device Abandonment: A Systematic Review and Consensus Statement*, at 2, *in* 7 JAMA NETWORK OPEN art. 2818077 (2024), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2818077 [https://perma.cc/ESD6-TXPV].

154. *See infra* notes 168–72.

155. NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at iv.

156. *See, e.g.*, CNTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE COVERAGE—CLINICAL TRIALS: FINAL NATIONAL COVERAGE DECISION (2020),

experimental stage, and received approval by the FDA, but be still so novel a technology that payers may not cover ongoing maintenance and repair costs until more comprehensive effectiveness data accrue.[157]

An additional form of abandonment occurs when the device, even if approved for clinical use, becomes outmoded and obsolete.[158] Switching to a newer model may be a formidable task for certain participants, as this can require costly and clinically risky surgical explantation of the current version. For example, replacing obsolete spinal cord stimulator implants to treat chronic pain has been estimated to cost $40,000.[159] Maintenance expenses alone, when switched from being paid by the manufacturer/sponsor during a clinical trial to being unsupported during regular therapeutic care post-study, can pose a significant barrier for many participants.[160]

A related form of abandonment occurs when the participant, to make effective use of the implant moving forward, depends on physicians and technicians with special expertise or on highly specialized equipment and facilities. Yet access to such resources is pragmatically restricted due to geographic distance, high cost, or because these providers are not within the networks covered by the participant's health insurance.[161] This problem likely recurs with neural implants because the technology is still evolving and depends on extensive infrastructure for support, often requiring specially trained personnel to do things as seemingly simple as adjusting settings and changing batteries.[162] This contrasts with other high-technology medical devices. For example, most hospitals with cardiology departments can provide needed technical support to patients with implantable pacemakers.[163]

https://www.cms.gov/medicare/coverage/clinicaltrialpolicies/downloads/finalnationalcoverage.pdf [https://perma.cc/3UMD-VQQ7] (explaining Medicare may pay for some routine costs associated with clinical trials but will not pay for the investigational intervention itself and associated data analysis and research expenses unrelated to ordinary clinical care).

157. *See, e.g.*, C. Joseph Ross Daval & Aaron S. Kesselheim, *Authority of Medicare to Limit Coverage of FDA-Approved Products: Legal and Policy Considerations*, 183 JAMA INTERN. MED. 999, 999–1000 (2023) (discussing discretion of the Medicare program to deny coverage for even FDA approved products).

158. *See* McClure, *supra* note 54.

159. Liam Drew, *Abandoned: The Human Cost of Neurotechnology Failure*, NATURE (Dec. 6, 2022), https://www.nature.com/immersive/d41586-022-03810-5/index.html [https://perma.cc/N4RU-ZTA6].

160. Lázaro-Muñoz et al., *Post-Trial Access*, *supra* note 143, at 1030–31.

161. NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at 5 (neural device participants describing how they had to move to participate in their clinical trials and relied on their families for care and financial support).

162. Saskia Hendriks, Nina Hsu, Andrea C. Beckel-Mitchener, John Ngai & Christine Grady, *Continuing Trial Responsibilities for Implantable Neural Devices*, 111 NEURON 3143, 3143–44 (2023) [hereinafter Hendriks et al., *Continuing Trial Responsibilities*].

163. Tubig & Gilbert, *supra* note 100, at 30.

Further abandonment complications arise because of intellectual property rights. Participants who wish to adjust their devices post-study, such as changing software for implant maintenance and safety, may find that components or the whole device are protected by patents, copyrights, and related licensing agreements, meaning that participants cannot access and alter the device components without sponsor or component manufacturer permission.[164] A biotechnology company usually prefers to keep the devices' intellectual property rights unencumbered. This facilitates any needed restructuring or repayment of the firm's debtors and creditors. Accordingly, manufacturers may be reluctant to grant implant participants access to the needed proprietary materials and device components.[165]

B. *Abandonment Examples*

Despite the high foreseeability of these many forms of abandonment, sponsors and investigators often fail to address the problem sufficiently. Abrupt study terminations, both scheduled and unscheduled, which result in leaving the implantable device in the patient's brain with no clear mechanisms of support, occur with surprising frequency. While practices may be changing, the norm for brain implant trials of just a few years ago was that when an experimental trial concluded "most sponsors do not cover the cost of device removal or a rechargeable battery."[166] According to a Neuroethics Working Group of the National Institute for Neurological Disorders and Stroke, "[m]ost post-trial care needs are not consistently facilitated by non-patient stakeholders."[167]

Perhaps the most notorious example concerns the sad case of Rita Leggett, an Australian woman with epilepsy. As a participant in a clinical trial, Leggett received an experimental neural implant designed to monitor and provide warning signs of upcoming epileptic seizures.[168] She found the device quite beneficial in managing what had been very erratic and difficult seizure patterns that had plagued her for years.[169] However, midway through the clinical trial the company sponsor, Neurovista, went bankrupt after investors expressed

164. *See* McClure, *supra* note 54.

165. *See infra* notes 170–72 and accompanying text; *see also infra* notes 178–80 and accompanying text.

166. Gabriel Lázaro-Muñoz, Daniel Yoshor, Michael S. Beauchamp, Wayne K. Goodman & Amy L. McGuire, *Continued Access to Investigational Brain Implants*, 19 NATURE REV. NEUROSCI. 317, 317 (2018) [hereinafter Lázaro-Muñoz et al., *Investigational Brain Implants*].

167. NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at iv.

168. Jessica Hamzelou, *A Brain Implant Changed Her Life. Then It Was Removed Against Her Will*, MIT TECH. REV. (May 25, 2023), https://www.technologyreview.com/2023/05/25/1073634/brain-implant-removed-against-her-will/ [https://perma.cc/2683-6D47].

169. *Id.*

concern about risk and ongoing financial commitments.[170] With the company insolvent, there were no mechanisms in place to monitor the device or replace batteries when needed.[171] Her husband offered to buy the device, but Neurovista refused in part because of the implant's proprietary parts. In the end, Leggett had the device surgically removed, a result she very much wished to avoid.[172]

An apt illustration of the misalignment problems that arise when individual subjects experience different results than the aggregate study population comes from the BROADEN trial, an investigation of implantable electrodes in the brain to treat severe depression.[173] The sponsor, St. Jude Medical (later acquired by Abbott Laboratories), stopped the study after review at six months failed to show statistically significant improvement for subjects with the active implant, as compared to a control group.[174] But forty-four subjects who thought they had benefited asked to keep the devices.[175] Abbott Laboratories had agreed at the start of the study that when the trial concluded it would either pay for surgical removal of the devices or, for subjects who wished to keep them, rechargeable batteries.[176] But this limited post-trial commitment did not include covering device maintenance and additional needed surgeries, which were prohibitively expensive for some participants.[177] Without such additional funding, they could not, for all practical purposes, make effective use of the devices that they had become very dependent upon.

Another problematic abandonment example concerns Autonomic Technologies, which, in 2019, halted its clinical trials of a stimulator implant to treat cluster headaches.[178] Over 700 persons who used the device sought continued access post-study, but the company would not grant them permission to adjust the intellectual-property-protected software needed to recalibrate and support the implants going forward.[179] A change in position occurred only after another company acquired Autonomic Technologies' intellectual property, and the FDA granted breakthrough device designation, enabling participants' access to the necessary software going forward.[180]

170. McClure, *supra* note 54.
171. *Id.*
172. *Id.*
173. *See* Underwood, *supra* note 91.
174. *Id.*
175. *Id.*
176. *Id.*
177. *Id.*
178. McClure, *supra* note 54.
179. *Id.*
180. *Id.* For more on FDA breakthrough device designation, see *supra* notes 76–84 and accompanying text.

C. *Limited Legal Redress for Abandonment*

While abandonment hazards are highly foreseeable with neural implants, affected participants, for a variety of reasons, often have limited forms of legal redress.

1. Tort Remedies

Providers have a legal obligation to provide informed consent to patients about a proposed treatment and its material risks and available alternatives.[181] Through the informed consent process, patients agree to potentially incur all sorts of serious risks, including permanent disability and death. If a disclosed risk materialized, even if it harmed the patient, the provider still has generally discharged his informed consent duties.[182]

The informed consent process, by strongly deferring to autonomous choice, allows patients to make all sorts of difficult decisions and trade-offs that may leave them worse off, such as agreeing to high-risk surgery because it offers a slightly better chance of mobility recovery than less risky interventions.[183] Analogously, participants can legally consent to no post-trial (or, in the case of regular clinical care, no post-implant) support of an implanted device because they still value the chance of using the implant at all. Providers and sponsors can thus use informed consent to push post-trial and post-implant responsibilities onto participants, notwithstanding research questioning the effectiveness of informed consent in this context. Studies of disclosures to neural implant participants about post-trial access indicate poor subject recall about the basic details.[184] Researchers speculate that even when lack of post-trial access to the implant is expressly mentioned during the consent process, many participants may not view it as salient because it is a longer-term problem, even if this risk information becomes very material later on.[185]

Even if valid informed consent occurs, providers can face alternative liability under negligence law for "ordinary" malpractice claims and breaching the duty of care. In these malpractice actions, a provider's liability turns on unreasonable conduct in the procedure delivery as opposed to the information disclosure.[186] Proposing implant therapy without offering robust support for the

181. *See* Canterbury v. Spence, 464 F.2d 772, 779–83 (D.C. Cir. 1972).

182. *See, e.g.*, Acord v. Porter, 475 P.3d 665, 748 (Ct. App. Kan. 2020) (explaining how liability in informed consent claims turns on "the *undisclosed* risk of danger actually materialized" (emphasis added), as opposed to materialization of disclosed risks).

183. *See* Matthies v. Mastromonaco, 733 A.2d 456, 463 (N.J. 1999) ("[O]ne patient may prefer to undergo a risky procedure, such as surgery, to enjoy a better quality of life.")

184. *See supra* notes 142–46 and accompanying text.

185. Lázaro-Muñoz et al., *Post-Trial Access*, *supra* note 143, at 1031.

186. *See, e.g.*, McQuitty v. Spangler, 976 A.2d 1020, 1029–30 (Md. 2009) (discussing the difference between informed consent claims and ordinary medical malpractice claims).

device after the initial implant could, in theory, represent negligence in delivery of the underlying procedure. But proving negligence under ordinary malpractice claims usually requires proof that the physician deviated from the standard of care, typically referenced by professional custom.[187] As it apparently is the norm in many neural implant cases not to offer much support beyond the initial costs of the implant procedure and device,[188] proving negligence due to limited post-implant assistance will often become difficult because the professional custom standard does not seem clearly contravened.

A subset of the physician's duty of care is to avoid abandoning the patient.[189] Ordinarily, once the physician-patient relationship has been created, the physician must provide advance notice before terminating the relationship and provide time and assistance for the patient to transfer to another provider.[190] However, the law is so flexible on permitted terminations, which can be unilaterally initiated by the provider, that usually the physician does not even need to give a clear reason for the termination.[191] Further, some jurisdictions recognize actionable abandonment claims only when the patient is at a critical stage, or requires immediate medical attention, at the time of the physician's departure.[192] Despite the invasiveness of the technology, not all neural implant participants will meet these criteria for bringing cognizable abandonment claims.

Implant participants who receive their devices through experimental trials, and not regular clinical care, are even less well-positioned to bring abandonment claims. It remains unclear whether the duty of nonabandonment applies with equal force to the investigator-subject relationship as it does to the doctor-patient relationship. Because investigators have certain obligations and loyalties to the study as a whole, and do not assume the duty to provide individually tailored care like a regular physician takes on for the patient, more leeway may exist, as a matter of common law, to end the relationship with the experimental subject than the regular patient.

The remedy problem further complicates the ability of neural implant participants to bring abandonment claims. A clear causal connection to physical injury may be hard to establish as, in many of these scenarios, the investigators

187. *See, e.g.*, N.C. GEN. STAT. § 90-21.12 (providing that medical malpractice liability turns on finding the physician's care deviated from professional custom and, more precisely, that it was "not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities under the same or similar circumstances").

188. *See supra* notes 166–67 and accompanying text.

189. *See, e.g.*, King v. Fisher, 918 S.W.2d 108, 111 (Tex. App. 1996).

190. *See, e.g.*, T.L. v. Cook Child.'s Med. Ctr., 607 S.W.3d 9, 56 (Tex. App. 2020).

191. Mark A. Hall, *A Theory of Economic Informed Consent*, 31 GA. L. REV. 511, 529 (1997).

192. *See, e.g.*, Miller v. Greater Se. Cmty. Hosp., 508 A.2d 927, 929 (D.C. 1986); Surgical Consultants, P.C. v. Ball, 447 N.W.2d 676, 682 (Iowa Ct. App. 1989).

or sponsors can claim that aggregate study data did not demonstrate the technology was effective, or the testing is still in too early phases for effectiveness to be clearly proven, calling into doubt any negative impact of denying further access to the device.[193] Indeed, the harm that participants experience when denied post-trial access is often not straightforward physical injury, but instead intangible hazards. Primary aggrievements of abandoned research subjects include frustrated access, disruptions to identity, changes in personality, and threats to autonomy from disconnections with the device.[194] Yet ordinary malpractice actions are usually unsuccessful when not accompanied by clear proof of physical injury, as plaintiffs must establish a direct causal connection between the negligent act and their specific harm.[195]

2. Contract Remedies

Neural implant participants facing abandonment hazards seemingly have stronger grounds for asserting breach of contract, rather than ordinary malpractice and informed consent claims. Successful contract actions require showing that the sponsor, investigators, or providers promised some degree of post-trial or post-implant access and failed to honor such commitments. Yet many participants will find it difficult to prove the existence of binding contractual commitments concerning access. First, many sponsors make it quite clear that at the end of a trial their obligations become limited, such as providing rechargeable batteries but not covering the cost of maintenance of a device.[196]

Second, the law does not necessarily treat statements about post-trial or post-implant access in an informed consent document as binding provisions of a contract. Consent forms do not resemble typical privately bargained exchanges because the patient/subject may withdraw at any time without consequence and seemingly makes no promises other than presenting for diagnosis, observation, or treatment. Also, consent forms have non-contract purposes, such as facilitating the physician's discharge of information disclosure duties under tort law or the federal research regulations as well as standardizing and advancing the informed consent exchange. Accordingly, many courts have been reluctant to treat consent forms as contracts, instead viewing them simply as evidence that the informed consent process happened.[197]

193. *See supra* notes 173–77 and accompanying text.

194. *See supra* notes 87–89 and accompanying text.

195. *See generally* Saver, *supra* note 141, at 961–67 (explaining the difficulty of obtaining relief for several types of intangible harms to patients).

196. *See supra* notes 173–77 and accompanying text.

197. *See, e.g.*, Daley v. Regents of Univ. of Cal., No. A165440, 2024 WL 4290920, at *7 (Cal. Ct. App. 2024); Harden v. Univ. of Cincinnati Med. Ctr., No. 04AP–154, 2004 WL 2341713, at *4–5 (Ohio Ct. App. 2004). However, other courts have recognized contract-like claims based on the informed consent form. *See* Dahl v. HEM Pharms. Corp., 7 F.3d 1399, 1401, 1403 (9th Cir. 1993)

An additional complication for experimental trial participants is that when any promises or suggestions about post-trial access occur, they likely appear in the informed consent document that the subject signs upon enrolling in a study. However, the device manufacturer/sponsor is typically not a signatory to the informed consent document, which instead the subject executes after discussion with the research team. Thus, the manufacturer/sponsor may not be bound by any promises contained in the consent form. Yet the device manufacturer/sponsor, not the research team, usually controls access to the device and any proprietary components post-trial.

The problem in bringing a contract claim is illustrated in the Amgen cases.[198] These actions concerned individuals enrolled in multi-center studies of an investigational drug developed by pharmaceutical company Amgen to treat Parkinson's disease. After initial trial results proved disappointing, Amgen announced that it would end all clinical trials of the drug. Some subjects, convinced that the drug was working for them individually, wished to continue taking the medication. The FDA instructed Amgen that it could provide the drug to certain individuals going forward under its limited "compassionate use" program, but Amgen declined.[199] Several subjects then sued Amgen and alleged, among other claims, breach of contract and promissory estoppel in connection with alleged promises to provide post-trial access to the study medication. They pointed to comments in the consent form that they could elect to continue with the drug for another twenty-four months after the study ended as well as representations from one of the investigators that Amgen would keep providing the drug if it was at all effective.[200]

The courts ruled against the subjects on the contract and promissory estoppel claims.[201] The courts reasoned that the informed consent document was between the investigators and the subject, while Amgen was only party to a separate agreement, a distinct Clinical Trial Agreement, between itself and the investigators/universities for conducting the trial.[202] Because there was no direct contractual relationship between Amgen and the research subjects, the drug

(considering promises made in a consent form as if they were contractual promises); Grimes v. Kennedy-Krieger Inst., Inc., 782 A.2d 807, 818, 843–44 (Md. Ct. App. 2001).

198. Abney v. Amgen Inc., 443 F.3d 540 (6th Cir. 2006); Suthers v. Amgen Inc., 372 F. Supp. 2d 416 (S.D.N.Y. 2005); *see also* Andrew Pollack, *Many See Hope in Parkinson's Drug Pulled From Testing*, N.Y. TIMES (Nov. 26, 2004), https://www.nytimes.com/2004/11/26/business/many-see-hope-in-parkinsons-drug-pulled-from-testing.html [https://perma.cc/GX5X-MMZC] (explaining that Amgen pulled a drug used to treat Parkinson's Disease from testing due to potential dangers despite many users seeing benefits).

199. Andrew Pollack, *Patients in Test Won't Get Drug, Amgen Decides*, N.Y. TIMES (Feb. 12, 2005), https://www.nytimes.com/2005/02/12/business/patients-in-test-wont-get-drug-amgen-decides.html [https://perma.cc/6RCV-2G34].

200. *Suthers*, 372 F. Supp. 2d at 424–25.

201. *Id.* at 423–26; *Abney*, 443 F.3d at 547–50.

202. *Abney*, 443 F.3d at 547–50.

company could not be liable, the courts concluded, for any breach of contract claims.[203] Similarly, the promissory estoppel claims failed because Amgen made no direct communications or promises to the subjects, as all their communications were instead with the investigators.[204] While the Amgen cases involved an experimental medication, not implantable devices, the reasoning likely applies to the analogous situation of abandoned participants in neural implant trials.

3. Fiduciary Duties

While courts have not always been consistent, they generally treat the physician-patient relationship as fiduciary in nature, or at least as a special "confidential" relationship, leading to heightened duties of care and loyalty for a physician in transacting with the patient.[205] In theory, a physician who arranges for a neural implant in which clear abandonment hazards later materialize may violate fiduciary obligations to act solely for the patient's benefit. However, fiduciaries can transact with their principals even on unfavorable terms so long as the fiduciary clearly discloses salient details, including any of the fiduciary's conflicts of interests, to assist the principal in deciding about the transaction.[206] Thus, even physicians bound by heightened duties of care may partly mitigate liability for abandonment hazards so long as there is clear upfront disclosure to the patient about any limits on post-implant care.

Further, because many neural implants are still in the investigational phase and utilized in experimental trials, not clinical care, the underlying connection of the neural implant participant to the physician usually differs from an ordinary doctor-patient relationship. Instead, the relationship is investigator-subject. In such relationships, fiduciary obligations likely do not apply because an investigator's primary goal is to advance the aims of the study and develop

203. Some Clinical Trial Agreements contain provisions requiring the sponsor/manufacturer to offer some degree of post-trial device access and support. Subjects are not parties to these contacts. *See, e.g.*, Clinical Trial Agreement Template, University of Connecticut Health System (2013), Section 16.4, https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/10/OCTR-Sponsored-Program-Industry-CTA-Template.pdf [https://perma.cc/8288-V4G7] (sample Clinical Trial Agreement in which, upon termination, sponsor agrees to pay costs of continuing trial-related, medically advisable care for already participating subjects, but subjects themselves are not a party to the Agreement). In theory, subjects might be able to bring third-party beneficiary claims to the extent they can clearly prove they are intended beneficiaries of these post-trial support promises. But, as a practical matter, third-party beneficiary contract claims can be difficult to prevail upon. Subjects will likely require the cooperation and litigation support of the investigator/institution to obtain some form of post-trial support from the manufacturer/sponsor.

204. *Abney*, 443. F.3d at 547–50; *Suthers*, 372. F. Supp. 2d. at 424–26.

205. *See, e.g.*, Rupp v. Premier Health Partners, 268 N.E.3d 534, 557 (Ohio Ct. App. 2025); Maxwell J. Mehlman, *Fiduciary Contracting: Limitations on Bargaining Between Patients and Health Care Providers*, 51 U. PITT. L. REV. 365, 410, 414 (1990).

206. *See, e.g.*, ASPIC, LLC v. Poitier, 267 A.3d 197, 206 (Conn. App. Ct. 2021).

generalizable knowledge, not provide individually tailored care. Thus, unlike a classic fiduciary, the investigator cannot have primary loyalty to act always in the best interests of the subject/principal.[207] Indeed, in one of the Amgen cases, *Suthers v. Amgen*, the district court questioned whether the physician-investigators even had fiduciary-like relationships with the subjects.[208]

Moving beyond the investigators, imposing fiduciary obligations on research sponsors/manufacturers will be even more difficult. In the Amgen cases, the courts rejected claims by the subjects that the drug company sponsor had a fiduciary duty to provide study medication that was beneficial to them once the trial concluded. The courts reasoned that Amgen was in an indirect position too far removed from the subjects, who had more direct contact and communication with the investigators who enrolled them in the study and gave them the experimental medication. As such, Amgen could not have formed a voluntary fiduciary relationship with the participants.[209] Moreover, the courts reasoned, imposing a fiduciary duty on the sponsor would be inconsistent with its obligations to the study protocol as a whole and its need to maintain distance and separation from subjects to pursue appropriate research goals.[210]

4. Federal Research Regulations

Many neural implant participants receive the technology as part of an experimental trial in connection with the manufacturer developing evidence for FDA approval of the device. As such, the FDA's research regulations apply.[211] These regulations add additional requirements, supplementary to common law, for the informed consent process. They also obligate the investigators to obtain prior approval of the proposed research by an institutional review board ("IRB"), a specially comprised research review committee.[212] A parallel set of regulations from the Department of Health and Human Services ("HHS"),

207. *See* E. Haavi Morreim, *The Clinical Investigator as Fiduciary: Discarding a Misguided Idea*, 33 J.L., MED. & ETHICS 586, 588–93 (2005).

208. *Suthers*, 372 F. Supp. 2d at 427–28 & n.9. Some commentators view the relationship between investigators and subjects under the "partial entrustment" model, which considers that subjects are owed certain special duties of care because they have given permission to the investigators to collect data, perform tests, and have otherwise partially entrusted their health to the research team. *See, e.g.*, Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking about the Clinical Care That Researchers Owe Their Subjects*, 34 HASTINGS CTR. REP. 25, 27–28 (2004). While presenting an intriguing alternative to arms-length and fiduciary-like duties, the partial entrustment model has not yet been clearly adopted under the limited caselaw addressing medical research duties.

209. *Abney*, 443 F.3d at 550–51; *Suthers*, 372 F. Supp. 2d at 426–29.

210. *Suthers*, 372 F. Supp. 2d. at 429.

211. *See* 21 C.F.R. §§ 50.20–50.27 (2025) (informed consent provisions); 21 C.F.R. §§ 56.101–56.115 (2025) (IRB provisions).

212. 21 C.F.R. § 56.111 (2025).

with similar provisions, may also apply, if the study is partially or wholly funded by HHS, such as through a National Institutes of Health grant.[213]

Surprisingly, the federal research regulations have very little to say about trial termination and the post-study obligations to subjects that may arise. The rules do require, as part of informed consent, that subjects be told about "the expected duration" of their participation[214] and also that they have the ability to "discontinue participation at any time."[215] Further, the researchers must disclose "[a]nticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent."[216] While the regulations require disclosure of "consequences of a subject's decision to withdraw from the research,"[217] this relates only to when *the subject* wants to withdraw, as opposed to controversial post-study disputes involving neural implants when it is the sponsor/investigator that terminates the study.

More importantly, the federal research regulations do not expressly require disclosure to subjects of the wide-ranging reasons why a study may be abruptly terminated. Likely, most subjects assume that a trial will be halted for safety reasons or if the neural implant is not shown to be effective. Far less salient reasons, however, are business, market, and intellectual property considerations that may lead a sponsor to terminate a study and provide limited post-trial access to the implant.[218] Thus, simple, terse statements used in some actual neural implant consent forms, such as that a subject may be withdrawn from the study "if the research team feels it is your best interest" or that "costs of all battery replacement surgeries . . . will be the responsibility of you or your third party payer," likely comply with the federal research regulations, however incomplete the actual notice given to participants about what to expect.[219]

The federal research regulations also provide little guidance to IRBs in contemplating and assessing abandonment hazards as part of their decisions whether to approve proposed research studies. IRBs are supposed to approve proposed protocols only after finding, among other criteria, that risks to subjects are "minimized" through use of a "sound research design" and that such risks "are reasonable in relation to [the experimental intervention's] anticipated

213. 45 C.F.R. §§ 46.109–46.115 (2024) (IRB provisions); 45 C.F.R. §§ 46.116–46.117 (2024) (informed consent provisions).

214. 21 C.F.R. § 50.25a(1) (2025); 45 C.F.R. § 46.116(b)(1) (2024).

215. 21 C.F.R. § 50.25a(8) (2025); 45 C.F.R. § 46.116(b)(8) (2024).

216. 21 C.F.R. § 50.25(b)(2) (2025); 45 C.F.R. § 46.116(c)(2) (2024).

217. 21 C.F.R. § 50.25(b)(4) (2025); 45 C.F.R. § 46.116(c)(4) (2024).

218. *See supra* Section III.A.

219. *See*, *e.g.*, PATRICIA RIVA-POSSE, INFORMED CONSENT FORM: DEEP BRAIN STIMULATION FOR TREATMENT RESISTANT DEPRESSION 6, 19 (2020), https://cdn.clinicaltrials.gov/large-docs/10/NCT01984710/ICF_000.pdf [https://perma.cc/2LPL-9JBN] (trial of deep brain stimulation for treatment-resistant depression (approved by Emory University Institutional Review Board)).

benefits."[220] However, the rules do not discuss in any detail whether and how IRBs, in making these risk/benefit determinations, should consider potential access by subjects to the technology after a study has concluded. Much is left to each IRB's discretion, yet IRBs have more familiarity with evaluating more straightforward physical risks, not abandonment hazards.

An additional complication is that IRBs have limited enforcement power to address abandonment hazards. Even if an IRB requests changes to the study protocol to ensure provisions are made for some form of post-trial support, these obligations become practically difficult to implement. IRBs' basic regulatory powers are to approve proposed studies, monitor them once underway, and request potential changes or withdraw approvals as needed. But when a trial has concluded, an IRB has few available enforcement options. It cannot threaten to withdraw or terminate approval for a study now completed. It may only indirectly police post-trial commitments by threatening not to approve any future studies at the institution involving the same investigators and manufacturer.[221]

5. FDA Approval Process

As previously discussed, the FDA regulates neural implants as medical devices and manufacturers must obtain some form of approval from the agency before introducing the implants into regular clinical care. The traditional approval criteria require that the FDA find assurances of an implant's safety and effectiveness before it can be cleared for market.[222] For devices using the more rigorous PMA approval route, the agency usually requires clinical trials demonstrating safety and effectiveness.[223]

However, under any approval pathway—even the more rigorous PMA—nothing in the FDA statute or regulations clearly requires, as part of assessment of safety and effectiveness, that the agency consider risks of frustrated access to the technology post-study or post-implant.[224] The closest on point is FDA guidance, not formal regulation, that investigators should design FDA-regulated trials to account for participants' needs for evaluation and treatment of emergent medical conditions related to the study intervention, even if this

220. 21 C.F.R. § 56.111(a) (2025); 45 C.F.R. § 46.111(a) (2024).

221. Similarly, granting institutions, such as NIH, also have limited authority to monitor post-trial requirements, especially after funds have been spent by grantees. *See* NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at 9.

222. *See supra* notes 63–64 and accompanying text.

223. *See supra* notes 67–68 and accompanying text.

224. *See* NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at 14 (noting FDA regulations do not address "downstream adverse events" like device abandonment when the implant remains with the patient after the trial conclusion).

extends to the post-trial period.[225] This guidance applies only to urgent, unexpected situations, which will not cover all abandonment scenarios.

Neural implants that qualify for FDA clearance under the alternative 510(k) process are even less likely to be expressly evaluated by the agency for abandonment risks. As previously noted, 510(k) reviews focus on a neural implant's substantial equivalence to predicate devices on the market, not the more detailed safety and effectiveness assessment involved with the PMA pathway.[226] Thus, for regulatory review of neural implants following the 510(k) approval pathway, abandonment hazards appear even farther off the radar screen.

D. *Ethics Guidance*

Although current law offers neural implant participants limited redress for abandonment hazards, professional ethics guidance seemingly provide stronger support. Nonetheless, even under leading ethical standards, significant uncertainties remain about the scope and extent of post-trial access obligations.

The long-standing, widely followed ethics guidance on point is the Declaration of Helsinki provisions on medical research, adopted by the Word Medical Association.[227] The Helsinki Declaration provides that "[i]n advance of a clinical trial, post-trial provisions must be arranged by sponsors and researchers to be provided by themselves, healthcare systems, or governments for all participants who still need an intervention identified as beneficial and reasonably safe in the trial."[228] In addition, it recommends that participants receive specific information about post-trial access as part of the informed consent process.[229]

While highlighting the importance of planning for participants' post-trial access needs, the Declaration of Helsinki still leaves certain matters uncertain. For instance, what degree of benefit must the neural implant device offer to trigger the ethical obligation of researchers and sponsors to provide post-trial access? Many clinical trials, especially in early phases when testing safety more

225. According to the FDA guidance, "[s]ubjects should receive appropriate medical evaluation and treatment until resolution of any emergent condition related to the study intervention that develops during or after the course of their participation in a study, even if the follow-up period extends beyond the end of the study at the investigative site." U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: INVESTIGATOR RESPONSIBILITIES—PROTECTING THE RIGHTS, SAFETY, AND WELFARE OF STUDY SUBJECTS 7 (2009), https://www.fda.gov/media/77765/download [https://perma.cc/ZW7C-HNW3 (staff-uploaded archive)].

226. *See supra* notes 72–75 and accompanying text.

227. *Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS'N (2024), https://www.wma.net/policies-post/wma-declaration-of-helsinki/ [https://perma.cc/9PWX-8BQF].

228. *Id.* ¶ 34.

229. *Id.*

than effectiveness, fail to yield data that unreservedly shows the intervention offers clear benefit over existing treatments. Further, the sponsors and researchers may view effectiveness in terms of aggregate data, while the participant primarily focuses on his own experience. This leads to ambiguities in deciding that the triggering condition for post-trial access—the device has been "identified as beneficial"—has actually occurred. Second, the Declaration of Helsinki is unclear whether post-trial access is time limited. Some patients with neutral implants may battle chronic diseases and desire maintenance and support of their implants for the rest of their lives. But does the ethical imperative to provide access extend that far or weaken over time? Further, the provisions say very little about who should take the lead responsibility for providing post-trial aid or whether this obligation should be shared among all the many stakeholders.[230]

The Royal Society Summit on Neural Interfaces developed more recent ethical guidance on point.[231] This multi-stakeholder group, in addition to trying to define the scope of abandonment problems with more precision, identified initial consensus views that may pave the way for further ethical guidance. The Royal Society's key recommendations include: (1) informing subject about the possibilities of trial discontinuance and probable reasons why this may occur; (2) informing subjects when a study is terminated about the actual reasons for not continuing it; and (3) providing resources to participants post-trial to ensure access to other therapeutics that are standard of care for their condition.[232]

Other recent guidance includes best practices identified by the National Institute of Neurological Disorders and Stroke's Neuroethics Working Group ("NEWG") on Continuing Trial Responsibilities ("NIH Working Group").[233] Although this group did not draft formal guidelines, it did memorialize useful ways to close gaps in post-trial care for neural implant participants. Among the best practices identified were: (1) advance planning before the study starts about post-trial needs; (2) offering participants the chance to consent to follow-on studies in exchange for post-trial financial support to continue using the device;

230. *Id.* Similarly, the International Ethical Guidelines of the Council for International Organizations of Medical Sciences ("CIOMS") advises making available products developed through research to the host communities where investigators conducted their studies. COUNCIL FOR INT'L ORG. OF MED. SCIS., INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS 3 (2016). The applicability of the CIOMS provisions to neural implant studies in the United States may be limited as these provisions typically have in mind research undertaken in developing countries. In any event, as with the Declaration of Helsinki, it remains unclear under the CIOMS guidance how much benefit an implant would have to demonstrate to trigger any post-trial access obligations.

231. Okun et al., *supra* note 153, at 1.

232. *Id.* at 5.

233. NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69.

(3) providing study participants priority access to devices that do receive regulatory approval for regular clinical use; (4) including patients or patient advocates in device review processes; and (5) guaranteeing coverage of a device by governmental health care programs such as Medicare between a study's end and FDA approval.[234]

These more recent recommendations represent some improvement over the Declaration of Helsinki because they demonstrate important flexibility and pragmatism. The Royal Society Summit, for example, contemplates that researchers and sponsors can discharge ethical obligations by helping participants access standard therapeutics post-study, even if not continuing with the implant, which may be a more feasible expectation.[235] Also helpful are the Royal Society's and NIH Working Group's observations that advance planning for post-trial access should involve other necessary stakeholders, particularly health insurers who may have to pick up costs previously covered by the study.[236]

Nonetheless, significant questions remain even under these more recent recommendations. In particular, as seen with the Declaration of Helsinki, it remains unclear how much benefit an implant must provide to trigger post-trial access obligations. There is also the problem of differing perspectives of benefit, a recurring tension in post-trial access disputes involving neural implants.[237] How should we account for situations where individual participants claim outsized benefit but the aggregate study data suggests the implant was only marginally effective across all subjects? If the researchers and sponsors discharge their support obligations by providing resources for other standard-of-care therapeutics, what happens when participants view those alternatives as less beneficial than the investigational implant?

E. *Expanded Post-Trial Support Obligations*

1. Arguments in Favor

While applicable ethics guidance suggests researchers and sponsors have obligations to provide neural implant participants some post-trial support, it is helpful to take a step back and consider why, as a broader matter of ethics and health policy, this should be the case. First, this may simply match up with many subjects' reasonable expectations. A well-documented problem of therapeutic misconception arises in clinical trials generally, where subjects

234. *Id.* at vi.
235. Okun et al., *supra* note 153, at 5–6.
236. *Id.* at 6–7; NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at vi.
237. *See supra* notes 173–77 and accompanying text.

conflate experimental interventions with regular clinical care.[238] This misconception may be exacerbated with neural implants, because of the intermingling of unproven devices with ongoing standard of care interventions, the chronic conditions participants are combatting, and the necessary dependence that they have on the highly specialized medical centers and health care teams that support complex neural technology.[239] Thus, it is foreseeable that many neural implant participants will expect that, as with regular clinical care, ongoing health care support will ordinarily continue through their lengthy episodes of illness.

Second, participants in neural implant studies invest considerable personal resources, including making physical, emotional, and economic commitments, and expose themselves to significant risk of injury in support of data creation for the success of the overall investigations. General notions of reciprocity arguably require that investigators and sponsors "owe something back" to the subjects to honor their contributions, including some form of post-trial access.[240] As one neural implant participant somewhat caustically described the experience: "It felt like, hey look, I let you implant things in my brain, I'm walking around with this, you have some responsibility to um, you know, to look after me."[241]

Third, the key bioethics principle of nonmaleficence, or doing no harm,[242] emphasizes the importance of protecting vulnerable subjects. Some commentators contend this takes on increased importance with neural implant investigations because "[p]osttrial care responsibilities for neural devices are amplified, as the brain holds special meaning to patients and atypical effects may occur . . . ."[243] The nonmaleficence principle suggests an important obligation exists to provide a safe off-ramp to participants after the neural implant study has concluded.

Fourth, researchers and sponsors have ethical obligations to respect neural implant subjects as persons with individual autonomy and dignity, not means to an end.[244] Participants should not be discarded as used specimens once the study concludes, underscoring the importance of accounting for their post-study support claims.

238. *See* Paul S. Appelbaum et al., *Therapeutic Misconception in Research Subjects: Development and Validation of a Measure*, 9 CLIN. TRIALS 748 (2012).

239. Hendriks et al., *Ethical Challenges*, *supra* note 86, at 1508; Okun et al., *supra* note 153, at 5–6.

240. *Cf.* Roger Brownsword, *The Ancillary-Care Responsibilities of Researchers: Reasonable But Not Great Expectations*, 35 J.L., MED. & ETHICS 679, 680 (2007) (discussing reciprocity obligations to provide ancillary care to subjects during a clinical trial).

241. Sankary et al., *Exit from Brain Device Research*, *supra* note 144, at 222.

242. *See* TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS ch. 5 (8th ed. 2019).

243. Hendriks et al., *Ethical Challenges*, *supra* note 86, at 1511.

244. Lázaro-Muñoz et al., *Investigational Brain Implants*, *supra* note 166, at 317–18.

Fifth, and perhaps most important, neural implants present a high degree of foreseeability that subjects will become deeply attached to the devices and experience strong sense of harm if the implants become unsupported or have to be returned. Neural implants can permanently affect the subject's core personhood in movement, perception, thought, emotional regulation, and communication. The participant may identify the device as synonymous with his own body. Under this perspective, a neural implant's unwanted removal, or nonsupport, is akin to a threat to the participant's bodily integrity.[245] Somewhat analogously, the common law recognizes that at times individuals can form strong attachments to items and objects so closely associated with the person that they become the equivalent of the person's "second skin." For example, a plaintiff can bring a successful battery claim arising under tort law, an action understood to protect bodily integrity, when there is harmful or offensive touching of his cane, hand-held phone, or other object that has become so identified with the body that the law treats it equivalently.[246]

Because some neural device participants perceive the device as life-altering, their relationship to the implant becomes profound as "it provides the patient with a means toward sustaining personal agency."[247] At least one commentator has referred to device disconnection as a "a form of trauma."[248] Further, a return to the baseline state after device explantation or nonsupport harmfully reintroduce the subject's disabilities and limitations, resulting in the special agony of being injured all over again.[249]

Consider the Neurovista example previously discussed, when Rita Leggett had to unwillingly undergo explantation of the neural device that was helping her monitor seizures, because the device manufacturer had entered bankruptcy.[250] The episode was traumatic and identity-erasing. Leggett described it as "[t]he device and I were one. We were successful. It was like taking away that part of myself that made me complete."[251]

Likewise, quadriplegic Noland Arbaugh, the first subject to receive the experimental N1 Neuralink brain-computer interface, which allowed him to control a computer with his thoughts, became acutely distressed when loose threads developed in his brain.[252] Although later changes allowed the device to

245. Tubig & Gilbert, *supra* note 100, at 32.

246. *See* RESTATEMENT (SECOND) OF TORTS § 18 cmt. c (A.L.I. 1965).

247. Okun et al., *supra* note 153, at 2.

248. Hamzelou, *supra* note 168.

249. Tubig & Gilbert, *supra* note 100, at 32–33.

250. *See supra* notes 168–72 and accompanying text.

251. Liam Drew, *"Like Taking Away Part of Myself"—Life After a Neural Implant Trial*, 26 NATURE MED. 1154, 1155 (2020), https://www.nature.com/articles/d41591-020-00028-8 [https://perma.cc/69CY-BE8U (staff-uploaded, dark archive)].

252. Salzman et al., *supra* note 49.

be kept in, it initially looked like the interface would have to be explanted.[253] Contemplating this removal, Arbaugh said, "It was very, very hard to give up all of the amazing things that I was able to do."[254]

2. Countervailing Considerations

Despite these reasons favoring more robust post-trial support for neural implant subjects, countervailing considerations complicate the picture. Expanded post-trial access may not always be warranted and, moreover, may be counterproductive for health policy.

First, reciprocity notions do not necessarily justify widespread post-study access by neural implant participants. Yes, subjects may be owed something back for their sacrifices and contributions to an experimental investigation. But this does not necessarily mean a quid pro quo for continued access to the device, especially when very burdensome for researchers and manufacturers. Reciprocal obligations could be discharged with other forms of support, such as assisting participants with transition to existing standard of care treatments. Also, because they enrolled in a clinical trial, do the access demands of neural implant participants trump similar demands by other stakeholders? Other individuals facing the same medical conditions may have desired to participate in the study but could not because the opportunities were foreclosed due to geography, trial ineligibility, and other reasons.[255] In rewarding neural implant participants who were in the study, it is important not to displace other patients in need.[256]

Second, in some abandonment scenarios the aggregate study data indicates that the device is ineffective for most participants, even though individual subjects believe otherwise.[257] Denying post-trial access to subjects in these situations may represent the prudent allocation of limited resources and the necessity of standardized procedures for efficient operations, not problematic abandonment. Further, given the highly personal and emotional bonds that subjects can form with a neural implant,[258] their access demands may reflect subjective attachments, desperation to do something about their illnesses, or rest on provisional findings unsupported by more objective evidence.

Third, there is the question of setting appropriate limits on post-trial support obligations of manufacturers and investigators. Otherwise, the costs of bringing these devices through the investigational stage and to market could

253. *Id.*

254. *Id.*

255. *Cf.* Maria Merritt & Christine Grady, *Reciprocity and Post-Trial Access for Participants in Antiretroviral Therapy Trials*, 20 AIDS 1791, 1792 (2006) (discussing why participants in rationing antiretroviral therapy trials for HIV/AIDS should not have priority access to further treatment over nonparticipants).

256. *Id.*

257. *See supra* notes 173–77 and accompanying text; *supra* notes 193–95 and accompanying text.

258. *See supra* notes 247–54 and accompanying text; *supra* notes 168–72 and accompanying text.

increase significantly. But such line-drawing becomes difficult: for example, should support obligations end when the device becomes generally commercially available, even if an individual participant's insurer will not pay for it?

Fourth, why should subjects who were advised about no or limited post-trial access at the start of a study have any claims to expanded post-trial support? Demanding access when subjects were informed otherwise runs the risk of paternalism. Subjects may rationally believe participating in a trial with no post-trial access is still preferable to missing out on a neural implant opportunity altogether. Along these lines, an interview study of neural device participants revealed that some respondents thought it fair that participants themselves should bear some of the cost of post-trial access when this had been disclosed in advance. According to this reasoning, the participants "were told they would not receive continued access and had entered into the agreement, and so they ought to honor such agreements."[259]

Finally, manufacturers and investigators have valid liability concerns about robust post-trial access.[260] When a clinical trial is underway, the research team carefully monitors subjects and often reports information to a Data Safety Monitoring Board, which can independently review data for safety concerns.[261] But a device used outside of an ongoing clinical trial will not receive this same degree of oversight. Further, during the trial the research team is expected to follow the general study protocol and standardized procedures. But when use of the device continues post-study, manufacturers and providers become more vulnerable to negligence claims alleging failure to tailor treatment to the individual patient, as is expected in regular clinical care, as well as possible products liability claims.

IV. NEUROEXCEPTIONALISM CONCERNS

These complicated reasons both for and against expanded post-trial support could apply to many investigational technologies. But in contemplating significant changes to the current regulatory scheme for neural implants

259. Lázaro-Muñoz et al., *Post-Trial Access*, *supra* note 143, at 1033.

260. *Cf.* Meghan K. Talbott, *The Implications of Expanding Access to Unapproved Drugs*, 25 J.L., MED. & ETHICS 316, 318 (2007) (related liability concerns for sponsors and investigators because of access to unapproved drugs outside of a clinical study).

261. To satisfy requirements that they monitor their ongoing studies, sponsors often utilize data safety monitoring boards, specialized review committees that analyze emerging trial data on an interim basis for questions of safety and efficacy. *See generally* U.S. DEP'T OF HEALTH & HUM. SERVS., GUIDANCE FOR CLINICAL TRIAL SPONSORS: ESTABLISHMENT AND OPERATION OF CLINICAL TRIAL DATA MONITORING COMMS. (2006), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishment-and-operation-clinical-trial-data-monitoring-committees [https://perma.cc/K8KP-5TDF (staff-uploaded archive)] (providing guidance on the use of Data and Safety Monitoring Boards for study monitoring).

(whether to address abandonment hazards or other concerning aspects of the devices discussed in Part II), one further consideration tips the balance for proceeding cautiously: avoiding problematic neuroexceptionalism. In this Part, we push back against the understandable inclination to apply more stringent legal standards and ethics guidelines to neural technologies because of the special nature of the brain. We question whether some of the reasons for subjecting neural implants to stricter oversight, such as informed consent challenges and abandonment hazards, sufficiently justify disparate regulatory treatment. Neural implants may not be all that exceptional, at least for purposes of regulation, as problems similar in kind and degree occur with many other medical interventions. Meanwhile, subjecting neural implants to heightened regulatory controls may result in counterproductive overdeterrence and impede development and refinement of this important technology.

A. *Neuroexceptionalism Generally*

Neuroexceptionalism refers to the concept that neural technology requires special, heightened regulatory safeguards and ethical guidance. This is akin to the exceptionalism approach earlier advocated for interventions addressing the human immunodeficiency virus ("HIV") and genetic diseases because of the novel medical considerations raised. Also, treatment information about these conditions was viewed as particularly sensitive as it could expose individuals to stigma, discrimination, and other worrisome risks. This concern resulted in distinct confidentiality and reporting laws concerning HIV and genetic testing.[262] Certainly, brain treatment and enhancement technology seems similarly deserving of special attention. Much bioethics literature has been devoted to how neural interventions raise pressing and often unique concerns because of the special nature and essential role of the brain itself, seen as "distinct from any other organ, . . . [and] foundational to human identity because it is the locus of fundamental human elements such as personality, desires, hopes, fears, memories, and free will."[263]

262. Stacey A. Tovino, *Functional Neuroimaging Information: A Case for Neuro Exceptionalism*, 34 FLA. STATE U. L. REV. 415, 482 (2007). For more on HIV exceptionalism, see generally Gerald M. Oppenheimer & Ronald Bayer, *The Rise and Fall of AIDS Exceptionalism*, 11 AMA J. ETHICS 988 (2009), https://journalofethics.ama-assn.org/article/rise-and-fall-aids-exceptionalism/2009-12 [https://perma.cc/GLW2-NY2W (staff-uploaded archive)]. For more on genetics exceptionalism, see generally James P. Evans & Wylie Burke, *Genetic Exceptionalism. Too Much of a Good Thing?*, 10 GENET. MED. 500 (2008).

263. Karen S. Rommelfanger, Sung-Jin Jeong, Arisa Ema, Tamami Fukushi, Kiyoto Kasai, Khara M. Ramos, Arleen Salles, Ilina Singh, *Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives*, at 23, *in* 100 NEURON 19 (2018), https://www.sciencedirect.com/science/article/pii/S0896627318308237 [https://perma.cc/V6LP-XVEE (staff-uploaded, dark archive)].

Also, as previously discussed, very concerning, atypical, long-range risks can arise with introduction and later nonsupport of neural implants, harms that can affect participants' personality, autonomy, dignity, bodily integrity, and sense of identity.[264] Additionally, there are privacy concerns.[265] Indeed, the burgeoning "neurorights" movement has called attention to the need for better protection of neural technology participants from deeply troubling hazards, including loss of privacy about one's brain activity, as well potential deprivation of free will and control because of potential external manipulation once intimate access to the brain is granted.[266]

At the same time, the neurorights movement and neuroexceptionalism positions have already engendered valid criticisms and concerns about overreach.[267] There may be some retrenchment in viewing neural interventions as fundamentally different from other medical technology, and questioning whether a distinct response hinders integrating these therapies into mainstream health care, similar to the diminishing support for HIV and genetics exceptionalism.[268] To a large degree, these critiques about have centered on: (1) whether some of the atypical hazards generating concern about neural interventions are too speculative, such as doubts that revealing the interior mind and thoughts of participants will ever come to pass; (2) overstating the technical complexity of neural interventions compared to other advanced therapies; (3) questions about the causal significance of neural information in terms of propensity for certain future behavior; and (4) recognition that other medical technologies and non-neural information also can be probing and revealing about participants' private behaviors and conduct.[269] Further, applying the

264. *See supra* Subsection II.A.3.

265. *See supra* Section II.C.

266. *See, e.g.*, NEURORIGHTS FOUND., https://neurorightsfoundation.org/ [https://perma.cc/V6JJ-EJT3] (exploring responsible and human-rights-centered approaches to neurotechnology); Marcello Ienca, *On Neurorights*, at 6–7, *in* 15 FRONTIERS HUM. NEUROSCI. 1 (2021), https://www.frontiersin.org/journals/human-neuroscience/articles/10.3389/fnhum.2021.701258/full [https://perma.cc/SR83-QFDP (staff-uploaded, dark archive)] (discussing unresolved ethico-legal challenges in neurorights).

267. *See, e.g.*, Robert Wachboit, *The Prospects for Neuro-Exceptionalism: Transparent Lies, Naked Minds*, at 3, *in* 8 AM. J. BIOETH. 1 (2008), https://www.tandfonline.com/doi/abs/10.1080/15265160701828576 [https://perma.cc/W6D4-7M8E (staff-uploaded, dark-archive)] (critically examining the underlying ideas behind neuro-exceptionalism); Simon Spichak, *The Controversial Push for New Brain and Neurorights*, at 2–3, *in* 27 J. MED. INTERNET RSCH. art. e72270 (2025), https://www.jmir.org/2025/1/e72270 [https://perma.cc/6SSP-74EP (staff-uploaded archive)] (comparing researchers' arguments for and against establishing new human rights to protect the brain).

268. *See, e.g.*, Adia Benton & Thurka Sangaramoorthy, *Exceptionalism at the End of AIDS*, 23 AMA J. ETHICS 410, 413–14 (2021), https://journalofethics.ama-assn.org/article/exceptionalism-end-aids/2021-05 [https://perma.cc/FWT8-KBEF (staff-uploaded archive)] (considering how HIV's exceptional status also helped to entrench inequities); Sonia M. Suter, *The Allure and Peril of Genetic Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U. L.Q. 669, 709–10 (2001).

269. *See, e.g.*, Wachboit, *supra* note 267, at 5–7; Spichak, *supra* note 267, at 2–3.

"exceptional" label to neural technologies suggests that across-the-board categorical distinctions exists between these technologies and other medical interventions when, more likely, there are gradations and mere differences in degree.[270]

Sidestepping these larger debates about the propriety of neuroexceptionalism and the neurorights movement generally, which are beyond this Article's scope, we consider more narrowly potential problems of misplaced neuroexceptionalism as applied to more immediate regulatory questions. In short, is there reason to regulate neural implants under stricter rules than other medical interventions? Different even from other neural therapies or other non-neural-implantable devices?

B. *Are Neural Implants All That Exceptional?*

For example, consider the earlier discussion about concerning gaps in the current FDA approval process for neural implants—particularly the under-generation of long-term risk information before devices are cleared for market, possible overreliance on the 510(k) approval pathway, and insufficient post-market surveillance.[271] While troubling, these worries apply to many medical devices, not solely neural implants. Indeed, there have been long-standing calls for complete replacement of the 510(k) pathway.[272] These critiques have often been prompted by alarming episodes with non-neural-implant technologies, such as when the FDA approved multiple laparoscopic power morcellator devices used in intraabdominal surgeries, and it took decades for information about serious safety risks to surface.[273] Likewise, the problem of weak implementation of FDA post-market surveillance requirements extends far beyond neural implants, with investigations suggesting planned surveillance studies are not completed and published for about two-thirds of high-risk devices within eight to ten years of approval.[274]

It may seem unsatisfactory to suggest caution in changing FDA rules for neural implants just because similar gaps exist in FDA regulation of other devices. Nonetheless, some appreciation for the larger regulatory landscape is warranted. If radical reworking of FDA rules, such as replacing the 510(k) pathway, seems necessary for neural implants, then why subject these devices to special treatment above all others? Further, changing the regulatory scheme, such as by imposing more stringent pre-market review solely for neural

270. Jan Christoph Bublitz, *Novel Neurorights: From Nonsense to Substance*, 15 NEUROETHICS 7 (2022), https://link.springer.com/article/10.1007/s12152-022-09481-3 [https://perma.cc/G62Q-LR8Y (staff-uploaded, dark archive)].

271. *See supra* Sections II.A, II.B.

272. *See, e.g.*, Adashi et al., *supra* note 94, at 185.

273. *Id.*

274. Rathi et al., *supra* note 125, at 2.

implants, strikes a different balance of competing policy interests than current FDA law does for most other devices. That balance boils down to less upfront testing and review of devices than for drugs, heavy reliance on substantial equivalence to already approved devices as a proxy for safety and effectiveness, and considerable dependence on somewhat incomplete post-market surveillance to catch long-range problems, all in favor of quicker approval and patient access to potentially beneficial devices.

Similarly, concerns about the sufficiency of informed consent for neural implants may overstate why this technology presents particular dilemmas. Recall that informed consent requirements are viewed as difficult to apply to neural implants because of the technology's complexity, unknown long-term impacts, and atypical risks such as changes in personality and identity, which remain poorly understood and confusing to describe.[275] Yet similar complex, long-term, and atypical risk information must also be disclosed for numerous other medical interventions as part of ensuring informed consent. Many medical technologies, such as gene therapies, nanotechnologies, and small molecular inhibitor targeted cancer treatments, present complex risk information because of the multitude of harms that can arise and the comprehensive penetration into basic bodily operations. As for atypical risks, non-implant neural therapies, such as psychiatric medications for depression, can lead to changes in personality, perception, and emotional regulation.[276] Even medications prescribed for reasons unrelated to behavior or neural disease, such as glucocorticoids for treatment of asthma and allergies, can have serious side effects that impact patient behavior and personality.[277]

Meanwhile, many interventions, such as investigational medications undergoing Phase 1 testing, have highly uncertain long-term impacts.[278] And other devices, such as pacemakers and breast augmentation implants, have similar permanence to neural implants, likewise raising questions of difficult

275. *See supra* Section II.C.

276. *See, e.g.*, U. CONN. SCH. PHARM., PATIENT SAFETY: AGGRESSION, IRRITABILITY, AND VIOLENCE: DRUG-INDUCED BEHAVIORS 6–7 (2020), https://pharmacy.uconn.edu/wp-content/uploads/sites/2740/2020/05/Aggression-Irritability-and-Violence-revised-FINAL.pdf [https://perma.cc/SUR8-H5PW] (discussing aggression side-effects of depression medications).

277. Anne-Sophie C.A.M. Koning, Merel van der Meulen, Daphne Schaap, Djaina D. Satoer, Christiaan H. Vinkers, Elisabeth F.C. van Rossum, Wouter R. van Furth, Alberto M. Pereira, Onno C. Meijer & Olaf M. Dekkers, *Neuropsychiatric Adverse Effects of Synthetic Glucocorticoids: A Systematic Review and Meta-Analysis*, 109 J. CLIN. ENDOCRINOL. METAB. e1442, e1447–48 (2024), https://pubmed.ncbi.nlm.nih.gov/38038629/ [https://perma.cc/X44Y-RXNJ (staff-uploaded archive)].

278. In the initial Phase 1 round of clinical trials for experimental medications, the drugs are examined for safety and toxicity and appropriate dosage levels, while whether the drugs even work is left to later stages of testing. *See Phases of Clinical Trials*, MD ANDERSON CANCER CTR., https://www.mdanderson.org/patients-family/diagnosis-treatment/clinical-trials/phases-of-clinical-trials.html [https://perma.cc/Q9PT-NS6X].

device-body disconnections in the long term. Finally, the poor uptake of certain disclosed risk information observed with neural implant participants,[279] while concerning, may simply reflect more comprehensive barriers to meaningful informed consent in most health care settings. Indeed, numerous other studies have demonstrated poor recall and comprehension of subjects undergoing informed consent for a variety of medical treatments, including hip replacements,[280] antibiotic medications,[281] and therapies targeting cholesterol levels to combat heart disease.[282]

Additional worries arise that neural device participants must make consequential decisions about whether to utilize the technology against a backdrop of limited risk information and considerable stress. After all, consenting to implantation of something like a brain-computer interface seems quite dramatic and far more monumental than initiating a course of antibiotic therapy. However, patients and research subjects regularly have to make high-stakes decisions, including literal life and death choices, amid much uncertainty, intense pressure, and personal strain, conditions not conducive to optimal decision-making. For example, they may have to decide whether to have high-risk surgery when battling advanced cardiac disease or whether to enroll within minutes of onset into trials of treatments for acute stroke.[283]

Similarly, consider the special privacy concerns identified with neural implants, with fears that certain devices will reveal participants' most sensitive thoughts and provide manufacturers and others with unrestricted access to participants' cognitive activity.[284] But many technologies raise privacy concerns, including the previously mentioned consumer headbands that monitor electroencephalogram data.[285] Many treatments, such as a simple prescription for medication, can be revealing of sensitive activity likely affecting the

279. *See supra* notes 137–46 and accompanying text.

280. Eoghan Pomeroy, Shahril Shaarani, Robert Kenyon & James Cashman, *Patient Recall of Informed Consent at 4 Weeks After Total Hip Replacement with Standardized Versus Procedure-Specific Consent Forms*, 17 J. PATIENT SAF. e575, e575 (2021).

281. Angela Huttner, Elodie Von Dach, Virginie Prendki, Stephan Harbarth & Laurent Kaiser, *Patient and Proxy Recall After Providing Written or Oral Informed Consent to Participate in an Interventional Trial*, at 3, *in* 5 JAMA NETWORK OPEN (2022).

282. Joan M. Griffin, James K. Struve, Dorothea Collins, An Liu, David B. Nelson & Hanna E. Bloomfield, *Long Term Clinical Trials: How Much Information Do Participants Retain from the Informed Consent Process?*, 27 CONTEMP. CLIN. TRIALS 441, 445 (2006).

283. *See, e.g.*, Jeffrey L. Saver, Sidney Starkman, Marc Eckstein, Samuel J. Stratton, Franklin D. Pratt, Scott Hamilton, Robin Conwit, David S. Liebeskind, Gene Sung, Ian Kramer, Gary Moreau, Robert Goldweber & Nerses Sanossian, *Prehospital Use of Magnesium Sulfate as Neuroprotection in Acute Stroke*, 372 N. ENGL. J. MED. 528, 528 (2015).

284. *See supra* Section II.C.

285. *See supra* notes 151–52 and accompanying text.

patient's mental state.[286] Moreover, rather than always representing a fundamental threat to participants' confidentiality, neural implants can actually *enhance* privacy. For example, Noland Arbaugh, the paralyzed patient who received the first Neuralink brain-computer interface, credited the device with allowing him to unilaterally undertake simple tasks such as playing games. This represented a dramatic change as previously, he always had to depend on others for initiating such actions. He described his pre-implant life as "[y]ou have no control, *no privacy*, and it's hard."[287]

Neuroexceptionalism concerns also arise in thinking about abandonment. To recap, commentators view participants as particularly vulnerable to abandonment, with disconnection from a neural implant even considered a form of trauma, because of the special relationships participants form with the devices, the many ways in which the technology can affect identity, bodily integrity, autonomy, and other key aspects of personhood, and the difficulty in returning to the same pre-implant state.[288]

However, these claims of exceptionality, while quite moving, must be taken with a grain of salt. Patients can form similarly deep attachments to other medical interventions. Cardiac implants may stabilize the patient and allow for resumption of actions critical to sense of identity and autonomy, such as walking, feeding oneself, or other essential daily activities. Likewise, consider artificial limbs or breast reconstruction with implants after a patient undergoes a mastectomy. Participants may come to view the implants as literal extensions of their own body and the means to exercise self-determination and move beyond limiting physical disabilities or perceived inadequacies. Removal or nonsupport of these non-neural devices similarly affects highly sensitive matters of bodily integrity and identity that neural implants do.

Other commentators point to the long-term placement of a neural implant and the long-lasting relationship of the patient to the device as raising special concerns. Under this view, participants undergoing other treatments, such as drug therapy, are less likely to be left worse off after the intervention, even if treatment is withdrawn, because "[w]ith investigational pharmaceuticals . . . a product's active substance will be cleared from the body over time."[289] However, this may be too simplistic a distinction. Some devices, when turned off and inactive, have no long-lasting impact on the body. On the other hand, an episode of drug therapy is not necessarily time-limited in impact and can lead to permanently altered health status. For example, a population study suggests

286. *Cf.* Bublitz, *supra* note 270, at 7 ("What, for instance, is special about neurodata with respect to regulation compared to various others forms of legally recognized sensitive data, such as logs of one's Google searches, movement profiles stored by smartphones, banking data, health data?").

287. Lewington et al., *supra* note 147 (emphasis added).

288. *See supra* Subsection II.A.3, Section III.B.

289. White & Whittaker, *supra* note 87, at 3.

that taking benzodiazepine drugs for simply more than three months increased the chances, by a statistically significant amount, of being diagnosed with Alzheimer's disease later on, even after the course of treatment had long concluded.[290]

In addition, compelling instances of abandonment have arisen with neural therapies that do not have the permanence of implants. Consider again the Amgen cases.[291] While Amgen decided to discontinue its trials of the study drug after Phase I and Phase II testing,[292] some subjects, convinced that the medication allowed them to better manage their Parkinson's disease than conventional treatment, sued Amgen to try to continue access. Just as with neural implants, the subjects had to undertake significant risks to obtain the technology. They had complicated surgery to facilitate delivering the medication directly into their brains through tubes connecting to the abdomen.[293] Further, they had developed significant, palpable attachment and dependence on the experimental medication, which they credited with being able to walk and undertake essential daily activities without the crippling effects of Parkinsons' disease. One subject-plaintiff explained that because of the study medication, "[t]he feeling of malaise [due to disease symptoms] went away" but when he had to stop taking the drug he had "to move slow and slothlike again . . . [and] the rigidity causes constant pain."[294] Another subject-plaintiff viewed the technology as transformative, stating simply that the study medication "gave me back my life" and questioned how Amgen could deny access to a drug that "relieve[s] human suffering."[295]

Neural implant participants often turn to experimental forms of the technology because conventional treatment fails or offers limited prospects. As such, commentators have depicted them as particularly vulnerable to exploitation and abandonment hazards because continued access may represent the only effective chance to prevent further harm.[296] Commentators further caution that uncertainty about neural implants' long-term effects, combined with perceptions that the devices represent the only hope available, create

290. *Two Types of Drugs You May Want To Avoid for the Sake of Your Brain*, HARV. HEALTH PUBL'G (Mar. 2, 2021), https://www.health.harvard.edu/mind-and-mood/two-types-of-drugs-you-may-want-to-avoid-for-the-sake-of-your-brain [https://perma.cc/5BKF-59EF].

291. *See supra* Subsection III.C.2.

292. For a description of the general phases of clinical trial testing of drugs, see *Phases of Clinical Trials*, *supra* note 278.

293. Andrew Pollack, *Parkinson's Patients Suing Amgen Over Drug*, N.Y. TIMES (Apr. 27, 2005), https://www.nytimes.com/2005/04/27/business/parkinsons-patients-suing-amgen-over-drug.html [https://perma.cc/99ET-NZGC (staff-uploaded, dark archive)].

294. Karla Ward & Linda Blackford, *Parkinson's Patients Denied Drug They Say Really Helps*, HERALD-SUN, Jan. 2, 2005, at 48.

295. Complaint and Jury Trial Demand ¶ 74, Suthers v Amgen, Inc., 372 F. Supp. 2d. 416 (S.D.N.Y. 2005) (No. 05cv4158).

296. *See, e.g.*, Lázaro-Muñoz et al., *Post-Trial Access*, *supra* note 143, at 1034.

conditions for "coercive optimism" and exacerbate participants' vulnerability.[297] But this describes the difficult situation of many trial subjects, not just neural implant participants. Many individuals enroll in clinical trials for altruistic reasons of contributing to medical knowledge. But a substantial number sign up because they are facing dire prognoses, such as when battling advanced stages of cancer, and the study of an unproven intervention seemingly offers their only hope.[298] Thus, even outside neural implant trials subjects have demonstrated desperation in wanting access to new technology. And participants who have already started a clinical trial may highly value continued access, almost in a sense of path dependency, even in the face of discouraging data about the experimental technology. Indeed, estimates suggest that "thousands of patients" regularly seek access to experimental, unproven medications each year, although the probability of benefitting from early-testing phases is quite low, leading to quite analogous concerns of subject vulnerability and suboptimal decision-making.[299]

In sum, many of the background conditions claimed to create special susceptibility to abandonment for neural device participants can be seen in other medical and research contexts. Introduction and discontinuation of a wide range of technologies, while not exactly the same, implicate similarly weighty, personality-altering, and even life-changing considerations as can arise with neural implants. The differences arguably represent matters of degree more than fundamental distinctions requiring disparate regulatory responses.

C. *Overdeterrence*

Counterproductive overdeterrence may result from singling out neural implants for heightened regulatory controls and ethical constraints to address problems that ultimately seem similar in kind to what arises in a wider range of medical interventions. Given neural implants' potential for significant benefits, it remains important to avoid disproportionate impediments in the development and refinement of this critical technology. For example, changing the current regulatory balance of competing interests within the FDA device

297. Boonstra, *supra* note 33, at 720.

298. *See* David Wendler, Benjamin Krohmal, Ezekiel J. Emanuel & Christine Grady, *Why Patients Continue To Participate in Clinical Research*, at 1296 tbl. 2, *in* 168 ARCHIVES INTERN. MED. 1294 (2008) (explaining that the "single most important reason" for continuing in the study of interleukin and retroviral therapy for treatment of HIV given by survey participant was to obtain direct medical benefit); CTR. FOR INFO. & STUDY ON CLINICAL RSCH. PARTICIPATION, REPORT ON GENERAL PERCEPTIONS AND KNOWLEDGE ON CLINICAL RESEARCH 4 (2017), https://www.ciscrp.org/wp-content/uploads/2019/06/2017-CISCRP-Perceptions-and-Insights-Study-Perceptions-and-Knowledge.pdf [https://perma.cc/FBH9-Q52L] (discussing survey participants' perceived benefits on research participation, with direct medical benefit among top reasons).

299. Jonathan J. Darrow, Ameet Sarptawari, Jerry Avorn & Aaron S. Kesselheim, *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 N. ENGL. J. MED. 279, 284 (2015).

approval system, which tolerates gaps in pre-market review in favor of quicker access,[300] creates disincentives for manufacturers to commercialize neural implants relative to other technologies with less burdensome regulatory requirements. Likewise, attempts to strengthen informed consent rules for neural implants must better acknowledge how the identified consent problems resonate far more broadly than just these devices. Additional requirements, such as avoiding "one-off" form signings in favor of repeat and targeted communications, while possibly beneficial, would seemingly target neural implants for atypical regulatory treatment. Why move the needle only on informed consent for neural implants, or start only with these devices, when similar informed consent problems seem so pervasive in the health care system?

Similarly, it becomes debatable why regulatory rules should prioritize participants' continued ability to maintain safe and effective use of neural implants, when many individuals face abandonment hazards in accessing other important treatments and technologies.[301] Requiring robust post-trial access for neural implant participants, but not for individuals utilizing other interventions, could disproportionately increase the costs of bringing these devices to market. Manufacturers and investigators may prioritize commercialization of other technologies over neural implants, wary of being encumbered by too many post-trial access claims.

Disparate regulatory controls for neural implants may also introduce problematic scaremongering. To justify extra precautions surrounding this technology, regulators may understandably point to dangerous uses, however rare and, at present, unlikely.[302] It remains, of course, important to counter some of the problematic hype about neural implants, but over-correction should be avoided.[303] Neural implants' long-term effects on participants' personality, sense of identity, free will, and other atypical risks merit serious consideration.[304] Similarly, uses of brain-computer interfaces for cognitive enhancement and other non-therapeutic reasons warrant additional attention. But it might be as important to remember that neural implants represent another form of treatment, with considerable potential to offer meaningful therapeutic improvement for many individuals confronting serious neural conditions. As Mt. Sinai School of Medicine's Dr. Helen Mayberg, who works with implants to manage patients with treatment resistant depression, has aptly emphasized, "Instead of fearing that we're using these devices to make cyborgs

300. *See supra* Sections II.A, II.B.

301. *See supra* notes 198–204 and accompanying text.

302. Bublitz, *supra* note 270, at 7 ("It is easy to evoke deep-running fears about novel technologies, but this might not be the best mindset for good policymaking.").

303. *See supra* Section I.C.

304. *See supra* Subsection II.A.3.

or for mind control, everyone needs to remember: There are people who are suffering because their brains cannot be repaired in other way . . . ."[305]

V. RECOMMENDATIONS

In light of the valid concerns about excessive neuroexceptionalism and overdeterrence, yet also the troubling gaps in the current oversight system for neural implants, it becomes important to find a reasonable balance and consider tailored regulation. This Part concludes with some modest recommendations for improving the testing, approval, and clinical use of this technology.

A. *Robust Post-Study Plans: Termination Criteria and Escrowed Funds*

First, abandonment hazards need to be better addressed upfront when initiating testing and potential commercialization of neural implants. Moreover, this strategy should be applied uniformly to all technologies presenting abandonment risks, including non-neural-implant interventions. Numerous commentators have pointed to the need for more post-trial planning of this sort, but unfortunately, details are often lacking amid the generalized insistence to do more and develop good plans.[306] And, as previously noted, it will be difficult for IRBs and other stakeholders to police and enforce even well-developed post-trial plans when the need arises.[307] Further, any reforms must be careful about not undercutting manufacturers' and investigators' validly supported safety and efficacy concerns that continuation with a device is not warranted. Otherwise, requiring continued post-trial access will discourage stakeholders from developing neural implants for fear of being "locked in" to initial pathways, unable to pivot feasibly to more promising alternatives. More helpful in these situations would be clear delineation in the research protocol and informed consent documents of the particular criteria (type of risk, degree of efficacy difference from current treatments, etc.) by which manufacturers and investigators could decide to halt a trial or not support a device for safety and efficacy reasons.[308] Further, any discontinuation decisions related to

305. Zara Abrams, *Breakthroughs in Brain Implants*, IEEE PULSE (Mar. 19, 2024), https://www.embs.org/pulse/articles/breakthroughs-in-brain-implants/ [https://perma.cc/YG9P-699A].

306. *See, e.g.*, Franziska Britta Schönweitz, Anja Kathrin Ruess, Stuart McLennan, Alena Buyx & Marcelo Ienca, *Where Is the Exit? The Ethical Importance of Exit Plans in Clinical Trials with Neural Implants*, 17 BRAIN STIMUL. 1145, 1152 (2024) (discussing need for "a well-structured exit plan for investigational neural device (IND) clinical trials" but short on many details, including enforcement, other than upfront collaboration among many stakeholders); Hendriks et al., *Continuing Trial Responsibilities*, *supra* note 162, at 3147–48; White & Whittaker, *supra* note 87, at 7 (making similar calls for sponsors to develop long-range plans at start of trial for post-study support but unclear how any access obligations would ultimately be funded or enforced).

307. *See supra* Subsection III.C.4.

308. For example, Harvard's Multi-Regional Clinical Trials Center has developed a list of possible criteria that ideally should be considered in deciding whether to grant a participant continued access to

proffered safety or efficacy concerns should be subject to external review by expert neutral third parties,[309] such as a Data Safety Monitoring Board[310] or the medical review organizations that analyze and provide a second check on medical necessity determinations of health insurers.[311]

Particularly egregious and alarming are abandonment situations that arise because of the manufacturer's and research team's changed economic circumstances or business plans.[312] It seems especially unreasonable and even cruel to ask subjects to volunteer for a study and risk harm for larger data generation but then leave them with an unsupported device in the brain from a study that did not really matter for knowledge generation because of poor business planning on the front end. Here, too, requirements for more upfront plans concerning post-trial support may be empty and unfortunately fall flat if they cannot be enforced, for example, against a now-bankrupt manufacturer. More practical regulatory responses are needed.

Therefore, updated regulations should direct IRBs not only to consider abandonment hazards expressly, but also to require, waivable only with written justification by an IRB, that the manufacturer or research team post a bond, obtain insurance coverage, or segregate funds in a special earmarked account to back their post-study support commitments.[313] In this way, even if the manufacturer or other stakeholders become insolvent, some form of funds will be available to participants to explore other options for accessing the device or transitioning to alternative standard of care treatments. Similarly, granting organizations, like the National Institutes of Health ("NIH"), have begun demanding that grantees address post-trial needs in their applications for neural implant studies.[314] These requirements should direct the grantees to create

an experimental significant risk device, including the impact of discontinuation, whether the device is addressing an otherwise unmet medical need, and whether continued access will negatively impact the viability of continuing research on the product generally. *See* MULTI-REG'L CLIN. TRIALS CTR. OF BRIGHAM & WOMEN'S HOSP. & HARV., POST-TRIAL, CONTINUED ACCESS RESPONSIBILITIES TO INVESTIGATIONAL SIGNIFICANT-RISK DEVICE FRAMEWORK: SCENARIOS THAT REQUIRE FURTHER CONSIDERATION 3 (2025), https://mrctcenter.org/resource/framework-post-trial-continued-access-responsibilities-to-investigational-significant-risk-devices-scenarios-that-require-further-consideration/ [https://perma.cc/RNV6-QHLX].

309. *Cf.* Lázaro-Muñoz et al., *Investigational Brain Implants*, *supra* note 166, at 317 (recommending that the risk-benefit analysis about whether to provide continued access to the device should involve an independent clinician to represent the participant's interests).

310. *See supra* note 261 and accompanying text.

311. *See Defining IRO*, NAT'L ASS'N INDEP. REV. ORGS., https://www.nairo.org/defining-iro [https://perma.cc/G6T4-Q4QG].

312. *See supra* Section III.B.

313. *Cf.* Hendriks et al., *Continuing Trial Responsibilities*, *supra* note 162, at 3148 (discussing similar options of stakeholders funding insurance plans or putting resources in escrow to support post-trial care).

314. NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at 9.

distinct funding mechanisms, like a trust, for any post-trial support.[315] These approaches are consistent with the idea that while manufacturers and the research team may, under ethical notions of reciprocity, owe something back to subjects for their participation, this does not necessarily translate into continued access to the device itself post-study, as sometimes broad financial support for standard of care treatments is an appropriate and more feasible alternative.[316]

Further, segregating funds that are earmarked for post-trial support offers, importantly, a self-executing remedy, which helps navigate around the limited ability of IRBs and granting organizations to enforce any post-trial support requirements after a study's completion.[317] Moreover, establishing a distinct, stand-alone funding mechanism in advance will mitigate inevitable disagreements among manufacturers, hospitals, insurers, and other stakeholders about who should be responsible for which types of post-trial support when the need arises. Consider the ominous example of NeuroPace, a small biotechnology company that worked at great expense and for multiple years to develop a neural implant to treat epilepsy.[318] When the company encountered financial problems and looked to other stakeholders to help support post-study care for trial participants, a pass-the-hot-potato dust-up ensued, with academic medical centers and insurers unwilling to cover these costs.[319] In the end, the company had to donate the device and physicians agreed to provide implant-related care for free for participants without insurance coverage, yet even then hospitals did not make similar commitments, offering only to attempt to find reduced or free device-related care for the participants.[320]

It must be acknowledged that there are limits to what even segregated funds for post-trial support can successfully accomplish. If, for example, the manufacturer goes bankrupt or a trial involving a cutting-edge device is halted altogether, participants, even with the ability to draw funding, may not be able to obtain continued care from the remaining institutions and physicians with the special expertise necessary to support the device.[321] The funding will, however, still enable participants to obtain support for standard-of-care treatments and alternatives, which can partially mitigate abandonment concerns.

Related abandonment risks arise when another firm acquires the initial manufacturer or the manufacturer sells the device's intellectual property rights to another business. The entity that ends up controlling access to the product

315. *Id.* at vi.
316. *See, e.g.*, Okun et al., *supra* note 153, at 5.
317. *See supra* Subsection III.C.4.
318. NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *supra* note 69, at 6–7.
319. *Id.*
320. *Id.* at 7.
321. *Id.* at 9.

after this business cycle change may no longer wish to provide continued access to existing participants. Nor is it clear that any commitments by the initial manufacturer of continued access will inevitably follow the product after such a business cycle change. Accordingly, IRBs and granting organizations should consider requiring that sponsors and investigators proposing to study neural implants plan for and develop "legacy programs," in which continued access will be funded and provided to the investigational implant even after such a business cycle change.[322]

Careful advance planning for trial discontinuations and post-trial support can also be augmented and improved simply by requiring more disclosure of the post-study obligations actually undertaken by manufacturers, investigators, and other stakeholders. At present, there is limited public transparency regarding post-study commitments. A review of published deep brain stimulation studies indicated that fewer than one-fifth revealed information about the underlying exit procedures for participants.[323] This lack of transparency may conceal problematic variability in post-study commitments for similarly situated trials, information which, if more visible, would call attention to disparate treatment of subjects.[324] Further, the lack of transparency in exit plans deprives manufacturers, investigators, and other stakeholders from learning about customary practices of their peers and potentially feasible post-study access plans.

B. *Interoperability Standards*

A second recommendation is tasking industry stakeholders with developing interoperability standards for neural implants. These devices, notably, are still in early phases of development relative to implant technology in other fields, such as pacemakers in cardiology, and many investigational neural implants have not been approved by the FDA for other conditions.[325] All of this increases the chances of incompatibility between different neural implants' components. A goal of required interoperability standards would be to provide better assurances that most manufacturers, investigators, and providers in the industry have capability of working with the technology across different settings. This facilitates continued safe and effective use of the devices.

322. MULTI-REG'L CLIN. TRIALS CTR. OF BRIGHAM & WOMEN'S HOSP. & HARV., *supra* note 308, at 5.

323. Lauren R. Sankary, Akila M. Nallapan, Olivia Hogue, Andre G. Machado & Paul J. Ford, *Publication of Study Exit Procedures in Clinical Trials of Deep Brain Simulation: A Focused Literature Review*, at 4, *in* 14 FRONTIERS HUM. NEUROSCI. art. 581090 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7609884/ [https://perma.cc/J2UM-VYM6 (staff-uploaded archive)].

324. *Id.*

325. Hendriks et al., *Continuing Trial Responsibilities*, *supra* note 162, at 3147.

For example, it would be much easier to replace a device's batteries if all companies in the field used the same batteries.[326] Also, if the original manufacturer becomes insolvent or geographic distance and other barriers make it hard for participants to continue access with the original team of investigators, greater interoperability increases chances of other feasible options for device maintenance and adjustment. Development of consistent interoperability standards also increases the prospects that an implant will be compatible with newer technology still in the pipeline, extending the useful life of the device.[327]

C. *Registry*

Third, given concerns about the gaps in the FDA approval process and less than rigorous pre-market assessments for some devices, it becomes important, at a minimum, to track and make more transparent safety issues as they arise. One suggestion is to develop a mandatory registry for neural implants that is publicly searchable and contains all adverse event reports and recall information associated with each device.[328] And to improve upon the adverse event reporting process itself, physicians and other front-line clinicians should be added to the list of mandatory reporters for advising the FDA about instances involving unexpected harm with the devices.[329]

D. *Required Short Feasibility Studies*

Finally, the FDA approval process would benefit from express requirements for shorter feasibility studies before a sponsor proceeds to broader experimentation with the implant. Despite the potential for wide-ranging problems when a neural implant fails, the FDA rules do not clearly require that manufacturers testing devices for the PMA pathway start with smaller feasibility trials, involving a limited number of participants and short term measurement end points.[330] Required feasibility studies for neural implants would allow for modifications and improvements before initiating trials over longer time frames with more participants, where implant failure will be far more consequential and where path dependency and investment commitments may make it difficult for sponsors to change study plans.

326. Hamzelou, *supra* note 168.

327. *See, e.g.*, White & Whittaker, *supra* note 87, at 5.

328. McDonald et al., *supra* note 71, at 913.

329. *Id.*

330. *See* Underwood, *supra* note 91 (discussing concerns about BROADEN, the deep brain stimulation study of an implant for treating depression, where the device failed to produce strong effectiveness results and questions arose whether short feasibility studies could have avoided the problem of prematurely introducing the device for a large number of participants).

CONCLUSION

Neural implants captivate the public for understandable reason. Hacking into the nervous system, restoring damaged neuronal activity, and connecting the brain with computers are indeed exciting applications and represent just the tip of the iceberg. The technology continues to be refined as researchers and clinicians perceive significant advantages in deploying the devices widely to treat serious illness and disability. But along with great promise, the shift to more extensive use of neural implants presents peril. The technology has complicated dynamics, including uncertain long-term impacts, atypical, intangible hazards, difficulty in reversing an implant, individuals' deep attachment to the devices, and the potential for participant abandonment.

The current regulatory scheme has troubling gaps in addressing these considerations. While it is therefore tempting to conclude new, comprehensive regulation is needed, we caution against excessive neuroexceptionalism. Counterproductive overdeterrence may result from singling out neural implants for heightened regulatory controls and ethical constraints to address problems that ultimately seem similar in kind to what arises in a wider range of medical interventions. Instead, incremental, tailored regulation represents the best path forward for improving the testing, approval, and clinical use of this important technology.

APPENDIX: EXEMPLAR NEURAL DEVICES THAT HAVE BEEN IMPLANTED IN HUMANS AND THEIR TARGET DISEASE STATES[331]

Technology	Disease States Treated	
	Investigational	Active Clinical Use
Deep Brain Stimulation	Depression Addiction Dystonia Other movement disorders	Parkinson disease Essential tremor Obsessive compulsive disorder Refractory epilepsy
Electrocorticography	Computer cursor control	Seizure localization
Depth Electrodes	Computer cursor control	Seizure localization
Intracortical Electrode Array	Prosthetic limb control Reanimate paralyzed muscles Vision Speech/handwriting production Computer cursor control	
Endovascular Electrode Array	Speech production Computer cursor control	
Subcutaneous Electrode Array	Epilepsy monitoring	
Cochlear Implant		Hearing

331. *See* Dalrymple et al., *supra* note 1; Chandrasekaran et al., *supra* note 11; Jonghyun Lee, Sung Yong Han & Young Woo Kwon, *Technological Advances and Medical Applications of Implantable Electronic Devices: From the Heart, Brain, and Skin to Gastrointestinal Organs*, *in* 15 BIOSENSORS 543 (2025), https://pubmed.ncbi.nlm.nih.gov/40863003/ [https://perma.cc/GY4W-PP4G]; Chunxiao Tang, Ping Wang, Zhonghua Li, Shizhen Zhong & Lin Yang & Guanglin Li, *Neural Functional Rehabilitation: Exploring Neuromuscular Reconstruction Technology Advancements and Challenges*, *in* 21 NEURAL REGEN. RSCH. 173 (2026), https://pubmed.ncbi.nlm.nih.gov/39665789/ [https://perma.cc/2A2W-R3GC]; Guido Rubboli, Margrete Halvorsen Bø, Kristin Alfstad, Sidsel Armand Larsen, Mads Due Holm Jacobsen, Maria Vlachou, Sigge Weisdorf, Rune Rasmussen, Arild Egge, Oliver Henning, Morten Lossius & Sandor Beniczky, *Clinical Utility of Ultra Long-Term Subcutaneous Electroencephalographic Monitoring in Drug-Resistant Epilepsies: A "Real World" Pilot Study*, *in* 65 EPILEPSIA 3265 (2024), https://pubmed.ncbi.nlm.nih.gov/39340394/ [https://perma.cc/J52K-GYUB (staff-uploaded archive)].

Technology	Disease States Treated	
	Investigational	Active Clinical Use
Retinal Prosthesis		Vision
Vagus Nerve Stimulation	Crohn disease Arthritis Heart failure	Epilepsy Depression Motor recovery post-stroke
Intramuscular Electromyography	Prosthetic limb control Reanimate paralyzed muscles	
Peripheral Nerve Stimulation	Sensory restoration	Pain
Spinal Cord Stimulation	Locomotor function Arm function Sensory restoration Blood pressure management	Pain Spasticity
Dorsal Root Ganglion Stimulation	Blood pressure management	Pain
Sacral Nerve Stimulation		Urinary control Fecal incontinence
Intraspinal Microstimulation	Urinary control	