OVERVIEW: NEUROSCIENCE AND THE LAW*

JOHN M. CONLEY** & RAMI MAJOR***

INTRODUCTION

The last decade has seen a surge in the use of medical neuroscience, and the discipline's entanglements with the law have risen in tandem. Neuroscience is broadly defined as the study of the development, structure, and functioning of the nervous system, which includes the brain, spinal cord, and nerve cells,[1] with a focus on the brain and its impact on behavior and cognition.[2] The many subdisciplines of neuroscience look more particularly at such issues as the clinical treatment of neurological disorders, the biological bases of behavior, the relationship between the nervous system and the mind, and the use of engineering methods to replace or repair neural systems.[3] Neuroimaging—a branch of medical imaging that focuses on the brain—plays a critical role in

** William Rand Kenan, Jr. Professor, University of North Carolina School of Law.

*** Postdoctoral Fellow, Center for Bioethics and Program for Precision Medicine in Health Care, University of North Carolina School of Medicine.

1. *About Neuroscience*, NAT'L INSTS. OF HEALTH: *EUNICE KENNEDY SHRIVER* NAT'L INST. OF CHILD HEALTH & HUM. DEV. (Oct. 1, 2018), https://www.nichd.nih.gov/health/topics/neuro/conditioninfo [https://perma.cc/UKS2-3RBX].

2. Christian Nordqvist, *About Neuroscience*, GEO. UNIV.: DEP'T OF NEUROSCIENCE (June 26, 2018), https://neuro.georgetown.edu/about-neuroscience/ [https://perma.cc/H5G5-2BFP].

3. *Id.*

much of neuroscience.[4] Artificial intelligence ("AI") also plays a central and growing role, especially in the creation and interpretation of neuroimages.[5]

As the medical applications of neuroscience expand, novel legal questions about the relationships between neuroscience and the law arise. Examples include the law of evidence, where purported experts have attempted to testify about criminal defendants' diminished capacity by connecting neuroimages with the neuroscientific literature. Can such opinions satisfy state and federal standards for the admissibility of scientific evidence and, if so, who is qualified to offer those opinions? In the governance of medical practice, will clinical neuroscience require the development of new standards of care in malpractice cases? Collateral liability issues also seem likely, including who (manufacturers, doctors, or insurers) will be responsible if neuroengineered devices such as brain implants fail. Even in the absence of such failure, devices require battery replacements and other regular maintenance; whose duty will it be to take over if the manufacturer goes out of business? And in the regulatory realm, is the current approval system for drugs, therapies, and devices adequate to handle neuroscientific applications, or will new models be required?

The purposes of this Article are to provide an overview of the intersection of law and neuroscience and to introduce this Symposium issue. In Part I, we explain several significant initiatives in neuroscience, as they exist now and are likely to develop in the short- to medium-term. Then, in Part II, we examine the legal issues that neuroscience may present, beginning with a general outline and then commenting specifically on possible connections to the neuroscience examples we present. We analyze these legal issues in an effort to illustrate important themes at points where law and neuroscience may intersect. In Part III, the Article concludes with a summary of the contents of the Symposium.

I. EXAMPLES OF NEUROSCIENCE ADVANCES

A. *Neuroimaging and Artificial Intelligence*

The brain has long been recognized as an important component of the human body, though humanity's understanding of this importance has evolved significantly over time. Aristotle posited that its purpose was to cool the body from the workings of the heart.[6] Hundreds of years later, the Greek physician Galen proposed that the brain controls behavior and cognition through a

4. *Id.*

5. *See infra* Section I.A and examples cited therein.

6. Edwin Clarke & Jerry Stannard, *Aristotle on the Anatomy of the Brain*, 18 J. HIST. MED. & ALLIED SCIS. 130, 130 (1963), https://www.polyu.edu.hk/cbs/rclcn/images/cdl_articles/C/Clarke__Stannard._1963.pdf [https://perma.cc/386A-NJ86] (discussing broadly Aristotle's views on the brain as stated in ARISTOTLE, DE PARTIBUS ANIMALIUM, bk. II, ch. 7, 652a20).

concept he called the "psychic pneuma."[7] In 1906, neuroscientists Santiago Ramón y Cajal and Camillo Golgi were jointly awarded the Nobel Prize in Physiology or Medicine for their discovery of the brain's structure, which involved Ramón y Cajal crafting thousands of illustrations of individual structural units of the brain that he theorized were working in concert to spread information throughout the brain.[8] A colleague of Ramón y Cajal, Wilhelm von Waldeyer-Hartz, later dubbed these individual structural units "neurons."[9]

Human capabilities to image the brain have come a long way since Ramón y Cajal's illustrations. Today, information on the structure and function of the brain can be collected through a number of different modern techniques. Some of the most common structural neuroimaging methodologies include magnetic resonance imaging ("MRI"), diffusion tensor imaging ("DTI"), and computed tomography ("CT"), each of which allows medical professionals to understand a patient's brain structure in a noninvasive way.[10] MRI scans use a combination of a magnetic field and radio waves to track changes in protons to create images of internal structures, while DTI uses an MRI machine but instead tracks changes in water movement to predict the size of the brain's structural connections.[11] CT scans create images by taking many cross-sectional x-rays of the area of interest.[12] Some of the most common functional neuroimaging methodologies include functional MRI ("fMRI"), electroencephalography ("EEG"), and positron emission tomography ("PET") scans, which measure physiological changes to infer information about how the brain functions.[13] Like MRI, fMRI uses a magnetic field and radio waves but instead tracks changes in blood flow and oxygen levels to provide readouts on neural activity.[14] EEG involves the placement of electrodes on the head to measure the electrical activity of the brain.[15] PET scans use radioactive tracers to light up scanned

7. Frank R. Freemon, *Galen's Ideas on Neurological Function*, 3 J. HIST. NEUROSCIENCES 263, 263 (1994).

8. Joachim Pietzsch, *Speed Read: Exposing the Forest*, NOBEL PRIZE (Sep. 16, 2009), https://www.nobelprize.org/prizes/medicine/1906/speedread/ [https://perma.cc/MN7D-3ZPS].

9. *Id.*

10. Manasmita Das, *Neuroimaging Techniques and What a Brain Image Can Tell Us*, TECH. NETWORKS, https://www.technologynetworks.com/neuroscience/articles/neuroimaging-techniques-and-what-a-brain-image-can-tell-us-363422 [https://perma.cc/69M9-E7G7] (last updated Apr. 8, 2024).

11. *Scanning the Brain: New Technologies Shed Light on the Brain's Form and Function*, AM. PSYCH. ASS'N (Aug. 1, 2014), https://www.apa.org/topics/neuropsychology/brain-form-function [https://perma.cc/23AK-XSJE (staff-uploaded archive)] [hereinafter *Scanning the Brain*].

12. *Id.*

13. *See* Das, *supra* note 10.

14. *See Scanning the Brain*, *supra* note 11.

15. *See id.*

areas that are metabolically activated.[16] In the brain, this is accomplished by attaching a radioactive atom to glucose, which is used for brain metabolism.[17]

These neuroimaging techniques have rocketed the field of neuroscience forward. Structural neuroimaging provides medical professionals with the ability to identify abnormalities like tumors, to observe the effects of strokes, and to monitor structural changes of the brain over time in neurodegenerative conditions like Alzheimer's disease or psychiatric conditions like schizophrenia.[18] Beyond the clinic, advances in structural neuroimaging have enabled scientists to observe the structure of the brain in high resolution, rendering novel brain regions at the sub-millimeter scale.[19] Another subfield of neuroimaging, functional neuroimaging, has also had both clinical and research implications. Functional neuroimaging helps tie neural activity to behavior, which can be used for everything from helping surgeons with pre-operative imaging to helping researchers search for biomarkers of disease.[20]

Traditionally, neuroimaging analysis requires a qualified neuroradiologist to analyze results and detect abnormalities. This analysis takes time for even the most qualified and specialized practitioners.[21] Some readouts generated by neuroimaging have results that are inconclusive, requiring repeat scans that can cost the healthcare system time and money.[22] AI can be used to assist or even initiate a diagnosis from a patient's imaging data.[23] In the context of neuroimaging, AI typically refers to a machine learning approach in which an algorithm is trained on a dataset of images to detect patterns associated with

16. *Id.*

17. *Positron Emission Tomography (PET)*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/positron-emission-tomography-pet [https://perma.cc/6NRJ-JBF6 (staff-uploaded archive)] (last modified Jan. 23, 2026).

18. Chiahui Yen, Chia-Li Lin & Ming-Chang Chiang, *Exploring the Frontiers of Neuroimaging: A Review of Recent Advances in Understanding Brain Functioning and Disorders*, 13 LIFE 1, 1, 11 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10381462/ [https://perma.cc/Z8XY-8XGY].

19. *See id.* at 3.

20. *See, e.g.*, Dhairya A. Lakhani, David S. Sabsevitz, Kaisorn L. Chaichana, Alfredo Quińones-Hinojosa & Erik H. Middlebrooks, *Current State of Functional MRI in the Presurgical Planning of Brain Tumors*, 5 RADIOLOGY: IMAGING CANCER 1 (2023); Daniel Orringer, David R. Vago & Alexandra J. Golby, *Clinical Applications and Future Directions of Functional MRI*, 32 SEMINARS NEUROLOGY 466, 466 (2012); Gary H. Glover, *Overview of Functional Magnetic Resonance Imaging*, 22 NEUROSURGERY CLINICS N. AM. 133, 133 (2011).

21. Altaib Al Yassin, Mohammad Salehi Sadaghiani, Suyash Mohan, R. Nick Bryan & Ilya Nasrallah, *It Is About "Time": Academic Neuroradiologist Time Distribution for Interpreting Brain MRIs*, 25 ACAD. RADIOLOGY 1521, 1522–25 (2018).

22. Jalal B. Andre, Brian W. Bresnahan, Mahmud Mossa-Basha, Michael N. Hoff, C. Patrick Smith, Yoshimi Anzai & Wendy A. Cohen, *Toward Quantifying the Prevalence, Severity, and Cost Associated with Patient Motion During Clinical MR Examinations*, 12 J. AM. COLL. RADIOLOGY 689, 689–90 (2015).

23. *See generally* Robert Monsour, Mudit Dutta, Ahmed-Zayh Mohamed, Andrew Borkowski & Narayan A. Viswanadhan, *Neuroimaging in the Age of Artificial Intelligence: Current Applications*, 39 FED. PRAC. S14 (2022) (discussing the use of AI in neuroimaging to diagnose patients).

certain neurological conditions. This AI can be trained in an unbiased way, where the algorithm develops its own recognition of cues and patterns, or it can be provided with a sort of answer key in which provided images are tied to certain diagnoses.[24] Although the employment of AI in the neuroradiology world is still in its early stages, some studies have shown that it performs as well as and sometimes better than its human counterparts at identifying neurological conditions.[25]

As of December 5, 2025, the U.S. Food and Drug Administration ("FDA") has granted approval for 1,357 AI-enabled medical devices across the field of radiology.[26] Many of these algorithms are relevant for neuroradiology applications.[27] While AI can generally help increase efficiency by reducing the amount of time spent on imaging, it can also better imaging acquisition through its ability to deconvolute noisy data, decreasing the chances that patients will have to repeat the imaging process.[28] Some early evidence has shown that AI could help reduce the amount of radiation required to obtain conclusive imaging via CT and MRI.[29]

Over the past decade, many studies have explored the potential of neuroimaging coupled with AI in early detection of neurological disorders. These conditions include Parkinson's disease,[30] Huntington's disease,[31]

24. *Id.*

25. Andreas M. Rauschecker, Jeffrey D. Rudie, Long Xie, Jiancong Wang, Michael Tran Duong, Emmanuel J. Botzolakis, Asha M. Kovalovich, John Egan, Tessa C. Cook, R. Nick Bryan, Ilya M. Nasrallah, Suyash Mohan & James C. Gee, *Artificial Intelligence System Approaching Neuroradiologist-Level Differential Diagnosis Accuracy at Brain MRI*, 295 RADIOLOGY 626, 626 (2020).

26. *See generally Artificial Intelligence-Enabled Medical Devices*, U.S. FOOD AND DRUG ADMIN. (Dec. 5, 2025), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices?utm_medium=email&utm_source=govdelivery [https://perma.cc/ZH2W-27QF (staff-uploaded archive)] (outlining available AI-enabled medical devices in the United States).

27. Elisa R. Berson, Mariam S. Aboian, Ajay Malhotra & Seyedmehdi Payabvash, *Artificial Intelligence for Neuroimaging and Musculoskeletal Radiology: Overview of Current Commercial Algorithms*, 58 SEMINARS ROENTGENOLOGY 178, 178–79 (2023).

28. *See id.* at 179.

29. Aanuoluwapo Clement David-Olawade, David B. Olawade, Laura Vanderbloemen, Oluwayomi B. Rotifa, Sandra Chinaza Fidelis, Eghosasere Egbon, Akwaowo Owoidighe Akpan, Sola Adeleke, Aruni Ghose & Stergios Boussios, *AI-Driven Advances in Low-Dose Imaging and Enhancement—A Review*, 15 DIAGNOSTICS 689 (2025) (reviewing the role of AI-assisted low-dose imaging).

30. *See generally* Rohan Gupta, Smita Kumari, Anusha Senapati, Rashmi K. Ambasta & Pravir Kumar, *New Era of Artificial Intelligence and Machine Learning-Based Detection, Diagnosis, and Therapeutics in Parkinson's Disease*, at 1, *in* 90 AGEING RSCH. REVS. art. 102013 (2023)https://pubmed.ncbi.nlm.nih.gov/37429545/ [https://perma.cc/682K-J7MF].

31. Angela Rizk-Jackson, Diederick Stoffers, Sarah Sheldon, Josh Kuperman, Anders Dale, Jody Goldstein, Jody Corey-Bloom, Russell A. Poldrack & Adam R. Aron, *Evaluating Imaging Biomarkers for Neurodegeneration in Pre-Symptomatic Huntington's Disease Using Machine Learning Techniques*, 56 NEUROIMAGE 788, 788 (2011).

Alzheimer's disease,[32] autism,[33] and even drug addiction.[34] Although these applications are not universally routine, some health systems have already begun to integrate AI into their clinical care for neurological disorders.[35]

B. *Wearable Brain Devices*

Most standard neuroimaging technologies are housed in specialist facilities like emergency rooms, specialized imaging clinics, and hospital wings. The technologies require significant physical space and schedule coordination across patients and doctors to ultimately obtain patient data. These housing and use limitations make it more difficult to obtain information about the structure or function of a patient's central nervous system. However, one class of emerging neurotechnologies, wearable brain devices, can be worn and carried around by a patient as they perform specific tasks or move through their daily lives, alleviating some of these limitations.

Scientists have employed wearable brain devices across a number of different disease contexts. Wearable EEGs have shown promise in the early detection of Alzheimer's disease[36] and of seizures in people with epilepsy.[37] They can provide information about users' brainwaves, called neurofeedback, that can be interpreted by machine-learning algorithms in real time.[38] Health

32. Mayur Kale, Nitu Wankhede, Rupali Pawar, Suhas Ballal, Rohit Kumawat, Manish Goswami, Mohammad Kalid, Brijesh Taksande, Aman Upaganlawar, Milind Umekar, Spandana Rajendra Kopalli & Sushruta Koppula, *AI-Driven Innovations in Alzheimer's Disease: Integrating Early Diagnosis, Personalized Treatment, and Prognostic Modelling*, at 1, *in* AGEING RSCH. REVS. art. 102497 (2024), https://www.sciencedirect.com/science/article/abs/pii/S1568163724003155?via%3Dihub [https://perma.cc/RZN6-94YK (staff-uploaded archive)].

33. Shinwon Park, Phoebe Thomson, Gregory Kiar, F. Xavier Castellanos, Michael P. Milham, Boris Bernhardt & Adriana Di Martino, *Delineating a Pathway for the Discovery of Functional Connectome Biomarkers of Autism*, 40 ADVANCES IN NEUROBIOLOGY 511, 511 (2024).

34. *See generally* Longtao Yang, Yanyao Du, Wenhan Yang & Jun Liu, *Machine Learning with Neuroimaging Biomarkers: Application in the Diagnosis and Prediction of Drug Addiction*, at 1, in 28 ADDICTION BIOLOGY, art, e13267 (2023), https://pubmed.ncbi.nlm.nih.gov/36692873/ [https://perma.cc/UT9X-H5TB] (discussing the application of AI in detecting drug addiction).

35. Susan Barber Lindquist, *Mayo Clinic Neurology AI Program Tests Platform to Detect Brain Diseases*, MAYO CLINIC (Dec. 17, 2024), https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-neurology-ai-program-tests-platform-to-detect-brain-diseases/ [https://perma.cc/M9BM-FNRP].

36. *Wrist Device That Monitors Activity Could Help Provide Early Warning of Alzheimer's*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (Mar. 11, 2024), https://publichealth.jhu.edu/2024/wrist-device-that-monitors-activity-could-help-provide-early-warning-of-alzheimers [https://perma.cc/9536-WZGH (staff-uploaded archive)].

37. Benjamin H. Brinkmann, Philippa J. Karoly, Ewan S. Nurse, Sonya B. Dumanis, Mona Nasseri, Pedro F. Viana, Andreas Schulze-Bonhage, Dean R. Freestone, Greg Worrell, Mark P. Richardson & Mark J. Cook, *Seizure Diaries and Forecasting with Wearables: Epilepsy Monitoring Outside the Clinic*, at 1–2, *in* 12 FRONTIERS NEUROLOGY art. 690404 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8315760/ [https://perma.cc/SB6H-68HY].

38. Xian-Na Wang, Tong Zhang, Bi-cheng Han, Wei-wei Luo, Wen-hui Liu, Zhao-yi Yang, Disi A., Yue Sun & Jin-chen Yang, *Wearable EEG Neurofeedback Based-On Machine Learning Algorithms for*

care providers can use neurofeedback to understand the impacts of targeted behavioral interventions in children with autism in real time, which can enable providers to modify their interventions to have the greatest therapeutic impact.[39] This approach showed success in improving both expressive language and cognitive awareness in children with autism.[40] Wearable EEGs have even helped researchers understand more about treatment-resistant depression ("TRD").[41] Researchers measured the brain waves of people with TRD at baseline before treating them with ketamine, which is sometimes effective at resolving TRD.[42] Researchers then looked at the brainwave data from patients who responded positively to ketamine treatment in order to predict what the brainwaves of people with the highest likelihood of symptom amelioration would look like.[43] This ability to predict drug responses based on wearable EEGs could have numerous implications.[44]

The integration of technology into human health has already been popularized through wearables like Fitbits and Apple Watches, which track heart rate and provide personalized scores on metrics like sleep patterns and activity levels.[45] The Apple Watch has been used to continuously monitor individuals with cognitive impairments in a study designed to understand the feasibility of its application in Alzheimer's disease patients.[46] A recent study of 23,000 U.S. adults showed that mild cognitive impairments could be classified remotely.[47]

Children with Autism: A Randomized, Placebo-Controlled Study, 44 CURRENT MED. SCI. 1141, 1141 (2024).

39. *Id.*

40. *Id.*

41. *See* Zehong Cao, Chin-Teng Lin, Weiping Ding, Mu-Hong Chen, Cheng-Ta Li & Tung-Ping Su, *Identifying Ketamine Responses in Treatment-Resistant Depression Using a Wearable Forehead EEG*, 66 INST. OF ELEC. & ELECS. ENG'RS: TRANS. BIOMED. ENG. 1668, 1668 (2019), https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=8502847 [https://perma.cc/DJ8X-SYHT (staff-uploaded archive)].

42. *Id.*

43. *Id.*

44. *Id.*

45. *Apple Watch User Guide*, APPLE, https://support.apple.com/guide/watch/workout-views-and-running-metrics-apd1f24d4d35/watchos [https://perma.cc/AJ3F-6CWM].

46. Colby T. Ford, Jake A. Galler, Yingnan He, Cathrine Young, Beeta Gabriela K. Simpson, Chao-Yi Wu, Jake Pfaffenroth, Eh So Wah, Steven E. Arnold, Hiroko H. Dodge, Jon A. Corkey & Sudeshna Das, *Using Apple Watches to Monitor Health and Behaviors of Individuals with Cognitive Impairment: A Case Series Study*, J. GERONTOL. A BIOL. SCI. & MED. SCI., July 19, 2024, at 1, https://academic.oup.com/biomedgerontology/article/80/4/glae250/7852945 [https://perma.cc/DJ8X-SYHT (staff-uploaded archive)].

47. Paul Monroe Butler, Jenny Yang, Roland Brown, Matt Hobbs, Andrew Becker, Joaquin Penalver-Andres, Philippe Syz, Sofia Muller, Gautier Cosne, Adrien Juraver, Han Hee Song, Paramita Saha-Chaudhuri, Daniel Roggen, Alf Scotland, Natalia Silveira, Gizem Demircioglu, Audrey Gabelle, Richard Hughes, Michael G. Erkkinen, Jessica B. Langbaum, Jennifer H. Lingler, Pamela Price, Yakeel T. Quiroz, Sharon J. Sha, Marty Sliwinski, Anton P. Porsteinsson, Rhoda Au, Matt T. Bianchi, Hanson

Beyond these commercially popular fitness wearables, other neurotechnology wearables can gather brain data beyond inferences from heart, movement, and breathing rates in real time. The biggest commercial market is currently for EEG wearables that provide users with data about everything from their sleep to their level of attentiveness.[48] Some particularly user-friendly wearables, like the Muse S, pair with an app that can be downloaded on a smartphone, where users can immediately see outputs scored based on their EEG data for sleep and meditation sessions.[49] Other wearables like the FocusCalm provide real-time neurofeedback in response to actions a user takes to meet goals or earn rewards while performing tasks or games in order to facilitate stress-relief.[50] Another type of wearable brain device measures blood flow and oxygenation in the brain through a technology called functional near-infrared spectroscopy ("fNIRS").[51] The Muse S Athena combines fNIRS with EEG data to help users "build[s] resilience against cognitive decline" and monitor their neurofeedback.[52] The Mendi uses just fNIRS to track blood flow to the brain's prefrontal cortex to track users' focus.[53] Beyond private use in personal health contexts, wearable brain devices can also be used to quantify driver fatigue[54] or optimize athletic training for elite athletes.[55]

Lenyoun, Hung Pham, Mithun Patel & Shibeshih Belachew, *Smartwatch- and Smartphone-Based Remote Assessment of Brain Health and Detection of Mild Cognitive Impairment*, 31 NATURE MED. 829, 829 (2025).

48. Maria Dobroskokina, *Top 5 EEG Devices of 2025*, AJPROTECH (Apr. 23, 2025), https://ajprotech.com/blog/articles/top-10-eeg-devices-of-2025.html#Muse_S_Gen2 [https://perma.cc/38RL-EL4V].

49. *A Personal Meditation Coach in the Palm of Your Hand*, MUSE, https://choosemuse.com/pages/app?srsltid=AfmBOop-8ZlATmgqsFCnE-RdDlpcb-XmW1pEF9fZFrYEA3iZp6oYkQfN [https://perma.cc/4ZGV-38TF].

50. *How It Works*, FOCUSCALM, https://focuscalm.com/pages/how-it-works [https://perma.cc/X83F-4TFL].

51. *See* Wei-Liang Chen, Julie Wagner, Nicholas Heuge, Jeffrey Sugar, Yu-Wen Lee, Lisa Conant, Marsha Malloy, Joseph Heffernan, Brendan Quirk, Anthony Zinos, Scott A. Beardsley, Robert Prost & Harry T. Whelan, *Functional Near-Infrared Spectroscopy and Its Clinical Application in the Field of Neuroscience: Advances and Future Directions*, at 2, *in* 14 FRONT. NEUROSCI., art. 724 (2020), https://www.frontiersin.org/journals/neuroscience/articles/10.3389/fnins.2020.00724/full [https://perma.cc/9L77-E78V (staff-uploaded archive)].

52. *Muse S Athena*, MUSE, https://ca.choosemuse.com/products/muse-s-athena?variant=42181300584534 [https://perma.cc/6SF2-SNRF].

53. *The Mendi Headset*, MENDI, https://www.mendi.io/products/mendi [https://perma.cc/L2NR-FUHX].

54. José M. Morales, Carolina Díaz-Piedra, Héctor Rieiro, Joaquín Roca-González, Samuel Romero, Andrés Catena, Luis J. Fuentes & Leandro L. Di Stasi, *Monitoring Driver Fatigue Using a Single-Channel Electroencephalographic Device: A Validation Study by Gaze-Based, Driving Performance, and Subjective Data*, 109 ACCIDENT ANALYSIS & PREVENTION 62, 62 (2017), https://www.sciencedirect.com/science/article/pii/S000145751730355X?via%3Dihub [https://perma.cc/L65N-M74J (staff-uploaded archive)].

55. Ming-Yang Cheng, Chien-Lin Yu, Xin An, Letong Wang, Chi-Lun Tsai, Fengxue Qi & Kuo-Pin Wang, *Evaluating EEG Neurofeedback in Sport Psychology: A Systematic Review of RCT Studies for Insights into Mechanisms and Performance Improvement*, 15 FRONT. PSYCHOL. 1, 12 (2024),

The extent to which these wearable products store their customers' data is unclear and potentially problematic. Some wearables, like the FocusCalm, do not store or track users' EEG data over time,[56] while others, like the Muse 2, retain EEG data but prohibit users from exporting raw data without a software development kit.[57] An April 2024 report by the Neurorights Foundation found that nearly ninety-seven percent of companies with neurotech wearables on the market "provide no meaningful limitations" on third parties' ability to access their customers' neural data.[58] Although some of this data is currently viewed as innocuous, legislators have expressed concerns that it will become more significant down the road, especially with AI becoming increasingly more salient. In the words of Democratic State Senator Cathy Kipp of Colorado, "If you collect the data today, what can you read from it five years from now, because the technology is advancing so quickly?"[59] The global wearable EEG market is expected to grow to around $245 million by 2030.[60] Though most of these wearable brain devices are located externally, there has been an increase in research on implantable brain devices developed by companies like Neuralink and Precision Neuroscience that are surgically implanted into or atop a user's brain.[61] These devices could help people with disabilities control a computer cursor with their brains to generate artificial speech or move prostheses.[62] In the future, they may become commercially available more broadly for users who wish to surf the internet or play games using only their brains.[63]

https://www.frontiersin.org/journals/psychology/articles/10.3389/fpsyg.2024.1331997/full [https://perma.cc/RY6U-X7UB (staff-uploaded archive)].

56. *Privacy Policy: BrainCo FocusCalm Digital Application Privacy Policy Notice*, FOCUSCALM (Sep. 7, 2025), https://focuscalm.com/pages/privacy-policy/ [https://perma.cc/A9Q9-9CND].

57. *About EEG Data and Muse Biofeedback*, MUSE: THE BRAIN SENSING HEADBAND, https://choosemuse.my.site.com/s/article/About-EEG-Data-and-Muse-Biofeedback?language=en_US#:~:text=The%20Muse%20app%20doesn't,used%20by%20the%20Muse%20app [https://perma.cc/L6WQ-NVZV (staff-uploaded archive)].

58. JARED GENSER, STEPHEN DAMIANOS & RAFAEL YUSTE, SAFEGUARDING BRAIN DATA: ASSESSING THE PRIVACY PRACTICES OF CONSUMER NEUROTECHNOLOGY COMPANIES 2 (2024) https://perseus-strategies.com/wp-content/uploads/2024/04/FINAL_Consumer_Neurotechnology_Report_Neurorights_Foundation_April-1.pdf [https://perma.cc/RK77-UDBZ].

59. Kate Ruder, *States Pass Privacy Laws to Protect Brain Data Collected by Devices*, CBS NEWS: HEALTHWATCH (July 16, 2025, at 05:00 ET), https://www.cbsnews.com/news/state-privacy-laws-brain-data-devices/ [https://perma.cc/5YGN-CALZ].

60. *Wearable EEG Headsets Market Size, Share & Trends Analysis Report By Application (Trauma & Surgery, Disease Diagnosis), By Product, By End-Use, By Region, and Segment Forecasts, 2024 - 2030*, GRAND VIEW RSCH., https://www.grandviewresearch.com/industry-analysis/wearable-eeg-headsets-market-report [https://perma.cc/ND53-4SGY].

61. Jon Hamilton, *Click, Speak, Move: These Brain Implants Are Poised To Help People with Disabilities*, NPR: SHOTS—HEALTH NEWS (June 30, 2025, at 06:00 ET), https://www.npr.org/sections/shots-health-news/2025/06/30/nx-s1-5339708/brain-computer-interface-implants-disabilities-neuralink [https://perma.cc/W7ZE-3HSV].

62. *Id.*

63. *Id.*

The broader implications of readily accessible neural data are yet to be fully realized. Perhaps most strikingly, wearables can be integrated with external computers to create brain-computer interfaces ("BCIs"). BCIs enable users to transmit neurological signals, like brain waves collected via EEG, that are then interpreted by an external computer that recognizes patterns in an AI-assisted manner. The computer translation of brain waves subsequently initiates an action, such as the movement of a prosthetic limb. A 2025 study showed that the resolution of BCIs in prosthetics could be achieved at the level of individual fingers.[64] BCIs have broader commercial appeal, too, and several companies are exploring their potential for use in applications like smart environments or gaming devices, in which a user would imagine performing a certain task, like turning on a light or moving through an imaginary world, and the computer would interpret these brain signals and execute the imagined tasks.[65] It is anticipated that the first commercially available implantable BCIs will help paralyzed users communicate or control a computer cursor.[66]

C. *Interventional Neuroscience*

There are hundreds of neurological disorders.[67] Some are genetic in origin, with causality tied to defects in a single gene, while the causes of others are more ambiguous.[68] There are hundreds of approved treatments for neurological conditions on the market. Monoclonal antibodies target the immune system of people living with multiple sclerosis to reduce autoimmune activity.[69] Anticonvulsants can help people living with epilepsy mitigate their seizure episodes.[70] Some neurological conditions lack effective treatments that go beyond short-term symptom management, including rare genetic disorders like

64. Yidan Ding, Chalisa Udompanyawit, Yisha Zhang & Bin He, *EEG-Based Brain-Computer Interface Enables Real-Time Robotic Hand Control at Individual Finger Level*, at 14, *in* 16 NAT. COMMC'NS art. 5401 (2025), https://www.nature.com/articles/s41467-025-61064-x [https://perma.cc/DS5M-WH44].

65. Cesar Augusto Fontanillo Lopez, Guangye Li & Dingguo Zhang, *Beyond Technologies of Electroencephalography-Based Brain-Computer Interfaces: A Systematic Review from Commercial and Ethical Aspects*, at 7–9, *in* 14 FRONT. NEUROSCI. art. 61130 (Zhan Li ed., 2020), https://www.frontiersin.org/journals/neuroscience/articles/10.3389/fnins.2020.611130/full [https://perma.cc/6BZG-JRXT (staff-uploaded archive].

66. Hamilton, *supra* note 61.

67. *See Types of Brain Disease*, BRAIN FOUND. (Aug. 9, 2022), https://brainfoundation.org.au/types-of-brain-disease/ [https://perma.cc/KUC2-P337].

68. *See id.*

69. Stephen L. Hauser & Bruce A.C. Cree, *Treatment of Multiple Sclerosis: A Review*, 133 AM. J. MED. 1380, 1383–87 (2020), https://www.sciencedirect.com/science/article/pii/S0002934320306021?via%3Dihub [https://perma.cc/2G79-JSJX (staff-uploaded archive)].

70. Jaideep Kapur, Jordan Elm, James M. Chamberlain, William Barsan, James Cloyd, Daniel Lowenstein, Shlomo Shinnar, Robin Conwit, Caitlyn Meinzer, Hannah Cock, Nathan Fountain, Jason T. Connor & Robert Silbergleit, *Randomized Trial of Three Anticonvulsant Medications for Status Epilepticus*, 381 N. ENGL. J. MED. 2103, 2103 (2019), https://www.nejm.org/doi/pdf/10.1056/NEJMoa1905795 [https://perma.cc/T642-9G2A (staff-uploaded archive].

Huntington's Disease, which is a progressive neurodegenerative disorder that eventually erodes one's ability to move and think.[71] The promise and challenges associated with the development of novel genetic technologies like CRISPR-Cas9 gene editing treatments to address rare genetic disorders have been previously discussed in the context of the law.[72] Gene editing treatments are currently under development to address a wide range of neurogenetic conditions and have even been considered for prenatal interventions.[73]

For complex psychiatric conditions, treatments typically range from traditional talk therapy to approved pharmacological treatments like anti-depressants, anti-psychotics, and mood stabilizers.[74] Beyond traditional pharmacological interventions, there has been increased research into the efficacy of psychedelics in mitigating psychiatric conditions that are resistant to traditional interventions, leading to some calls for more widespread acceptance.[75] Other interventions for severe psychiatric cases utilize neurostimulation, in which doctors deliver electrical signals to interfere with neural circuits.[76] This practice is generally referred to as deep brain stimulation ("DBS"). DBS is FDA-approved to treat a handful of disorders, including obsessive-compulsive disorder and tremors, and is being explored for other disorders, including treatment-resistant depression and drug addiction.[77] DBS can either be accomplished with electrodes located outside of a patient's body or via a device implanted in a patient's brain.[78]

71. *Huntington's Disease*, MAYO CLINIC (Apr. 25, 2024), https://www.mayoclinic.org/diseases-conditions/huntingtons-disease/symptoms-causes/syc-20356117 [https://perma.cc/KYZ3-VY63].

72. *See generally* John Conley, *Introduction: A Lawyer's Guide to CRISPR*, 97 N.C. L. REV. 1041 (2019) (discussing articles that address CRISPR technology through a legal lens).

73. Rami M. Major & Eric T. Juengst, *Prenatal Gene Editing for Neurodevelopmental Diseases: Ethical Considerations*, 112 AM. J. HUM. GENET. 201, 201 (2025), https://www.sciencedirect.com/science/article/pii/S0002929725000035?via%3Dihub [https://perma.cc/P42Y-5Z4T (staff-uploaded archive)].

74. *Mental Health Medications*, NAT'L INST. OF MENTAL HEALTH (Dec. 2023), https://www.nimh.nih.gov/health/topics/mental-health-medications [https://perma.cc/LAR3-9DJA].

75. *See generally* Heather Stringer, *The Emergence of Psychedelics as Medicine: A Look at the Potential of MDMA, Ketamine, and Psilocybin to Help People with Treatment-Resistant Mental Health Conditions*, AM. PSYCH. ASS'N (June 1, 2024), https://www.apa.org/monitor/2024/06/psychedelics-as-medicine [https://perma.cc/55E3-YESK] (describing the potential benefits and shortcomings of psychedelics in medicine and the status of their usage or nonusage).

76. Christine A. Edwards, Abbas Kouzani, Kendall H. Lee & Erika K. Ross, *Neurostimulation Devices for the Treatment of Neurologic Disorders*, 92 MAYO CLIN. PROCS. 1427, 1427–28 (2017), https://www.mayoclinicproceedings.org/article/S0025-6196(17)30325-7/fulltext [https://perma.cc/D9DS-LHEA (staff-uploaded archive)].

77. *Id.*

78. *Id.*

II. POTENTIAL LEGAL ISSUES

As noted in the Introduction, the legal issues that may arise in connection with neuroscience include (A) the admissibility of expert evidence; (B) the standard of care to be applied in medical malpractice cases; (C) liability issues arising from neurological devices; and (D) the adequacy of the current regulatory approval system.

A. *Admissibility Questions*

1. The Legal Standard

The admissibility of scientific and expert evidence, including neuroscience, is governed in federal courts by Federal Rule of Evidence 702 and in state courts by comparable state rules (a majority of states now follow the federal standard).[79] The original version of Rule 702 only required that the expert witness be qualified by "knowledge, skill, experience, training, or education," and that the expert's specialized knowledge would "assist the trier of fact to understand the evidence or to determine a fact in issue."[80] This version was interpreted in the 1990s by three Supreme Court cases often called the "Daubert Trilogy," and the rule was substantially amended in 2000 to take those cases into account.[81]

The original case, *Daubert v. Merrell Dow Pharmaceuticals*,[82] dealt with the admissibility of evidence purporting to show that the antinausea drug Bendectin caused birth defects.[83] The Court held that the admission of "scientific" evidence requires a showing of "reliability" and "fit."[84] In assessing reliability, the trial court should focus on whether the expert has followed the scientific method.[85] Courts evaluating an expert's methods were directed to consider four questions—the so-called *Daubert* factors: whether the method can be (and has been) tested;[86] whether it has been peer-reviewed and published;[87] its known or

79. *See generally* NAT'L CIV. JUST. INST., STATE-BY-STATE COMPENDIUM STANDARDS OF EVIDENCE, NAT'L CIV. JUST. INST. (2023), https://ncji.org/wp-content/uploads/2024/01/Evidence-Standards-by-State-7.12.23.pdf [https://perma.cc/UTA5-WFBY] (describing all states' standards of evidence).

80. FED. R. EVID. 702.

81. *Id.*; COMM. ON RULES OF PRAC. & PROC., JUD. CONF. OF THE U.S., REP. OF THE ADVISORY COMM. ON EVIDENCE RULES 5—7 (1999), https://www.uscourts.gov/sites/default/files/fr_import/EV05-1999.pdf [https://perma.cc/6SH2-LCBW].

82. 509 U.S. 579, 579 (1993).

83. *Id.*

84. *Id.* at 591, 594–95.

85. *Id.* at 590, 592–93.

86. *Id.* at 580.

87. *Id.*

potential rate of error (which the Court did not define);[88] and its general acceptance by the relevant scientific community.[89] Finally, the case begat the *Daubert* hearing: before admitting or excluding expert evidence, the trial court, following Federal Rule of Evidence 104(a),[90] conducts a hearing away from the jury to assess whether the proposed evidence meets the Rule 702 standard.[91] The trial court's evaluative process has come to be called its "gatekeeping" function.[92]

The second case in the trilogy, *General Electric Co. v. Joiner*,[93] which dealt with evidence suggesting that polychlorinated biphenyl exposure can cause lung cancer, made the important procedural point that the *Daubert* ruling on admissibility is to be reviewed under the abuse of discretion standard, under which deference to the trial court is the "hallmark" of review.[94] As a practical matter, the logical implication of this deference to the trial court is that its ruling will be difficult to reverse on appeal.

Finally, in *Kumho Tire v. Carmichael*,[95] the Court addressed the application of the *Daubert* standard to nonscientific experts, here a purported tire wear expert who relied largely on "visual inspection."[96] The Court held that the *Daubert* gatekeeping requirement applies to *all* expert evidence.[97] However, in a nonscience case like this, "*Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case."[98]

Rule 702 was substantially rewritten in 2000 (and slightly modified in 2023) to align the text of the rule with *Daubert* and the cases that followed it[99]:

> Rule 702. Testimony by Expert Witnesses.
>
> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise

88. *Id.* It is unclear how the "rate of error" factor would apply to the research discussed in *Daubert* because the Court did not apply the factor there.

89. *Id.* at 579–80 (acknowledging Rule 702's predecessor—the general acceptance standard established by Frye v. United States, 293 F. 1013 (D.C. Cir. 1923)—which is still followed in several states including California, New York, and Illinois). *See generally* NAT'L CIV. JUST. INST., *supra* note 79 (recording whether a state follows the *Daubert* or *Frye* standard and when each adopted a standard).

90. *See* Daubert, 509 U.S. at 580, 592–93.

91. *Id.* at 580.

92. *Id.* at 597; *see* FED. R. EVID. 702; COMM. ON RULES OF PRAC. & PROC., JUD. CONF. OF U.S., *supra* note 81.

93. 522 U.S. 136 (1997).

94. *Id.* at 143.

95. 526 U.S. 137 (1999).

96. *Id.* at 153.

97. *Id.* at 141.

98. *Id.*

99. FED. R. EVID. 702; COMM. ON RULES OF PRAC. & PROC., JUD. CONF. OF U.S., *supra* note 81.

> if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.[100]

2. Potential Neuroscience Issues

In thinking generally about how present and future neuroscience evidence might fare under the Rule 702 standards, several issues immediately come to mind. First, note in the preamble to the Rule that the burden of persuading the court rests with the proponent of the evidence (a 2023 addition)[101]: that party must sell the novel expert testimony; it is not up to the opponent to discredit it.

Second, at the current stage in the development of neuroscience, there are no established standards for qualifying experts on the various scientific questions that neuroscientific evidence may present. For example, courts have had years of experience in evaluating the qualifications of radiologists, but does being a radiologist qualify a witness to present and interpret brain images?[102] The problem is even more complicated when the image has been enhanced by AI.[103]

Third, as Rule 702(a) states, the testimony must *help* the trier of fact, not mystify or confuse the trier. Since this determination seems inherently subjective, it creates considerable leeway for judicial attitudes toward novel science to influence outcomes. Given *Joiner*'s prescription of abuse of discretion

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100. FED. R. EVID. 702.

101. *Id.*

102. *See* COMM. ON RULES OF PRAC. & PROC., JUD. CONF. OF U.S., *supra* note 81 (discussing "[w]hether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give").

103. See Laura López Gonzáles, *4 Ways Artificial Intelligence Is Poised To Transform Medicine*, UNIV. CAL. S.F. (Dec. 10, 2024), https://www.ucsf.edu/news/2024/12/429031/4-ways-artificial-intelligence-poised-transform-medicine [https://perma.cc/238X-PNFM], and *NIH Findings Shed Light on Risks and Benefits of Integrating AI into Medical Decision-Making*, NAT'L INSTS. OF HEALTH (July 23, 2024), https://www.nih.gov/news-events/news-releases/nih-findings-shed-light-risks-benefits-integrating-ai-into-medical-decision-making [https://perma.cc/4UEP-EHXH], for overviews of how AI can both enhance and complicate medicine.

appellate review,[104] it will be difficult to overturn a decision on helpfulness, whatever it might be.

Finally, courts will confront a lack of precedent—legal or scientific—with respect to every issue in Rule 702(b)–(d). What are sufficient facts or data in cutting-edge neuroscience? Are newly emerging principles and methods "reliable"? What does reliability even mean in this context? And given these questions, the standards for combining applicable principles and methods to facts and data (Rule 702(d)) would seem entirely speculative. While some cases are beginning to show recognition of these questions, the case law is not sufficiently well developed at this point to even suggest answers.[105]

B. *Standard of Care in Neuroscience Malpractice Cases*

Like any tort case, a medical malpractice case requires the plaintiff (the patient) to prove four elements: a duty of care, a breach of that duty, an injury caused by the breach, and actual damage.[106] Proving a breach of the duty of care requires establishing the standard of care for the given specialty: what "a qualified, careful physician would do under the same or similar circumstances."[107] At a basic level, standards of care for neuroscience are well established, since radiologists frequently make and interpret brain images for diagnostic purposes, and neurologists use such images in designing and monitoring treatment.[108] Although standards of care in all disciplines have traditionally varied by location (urban medical centers versus rural practice settings, for example), the growth in all forms of communication has led to more uniform national standards.[109] As a further wrinkle, the most advanced forms of neuroimaging—and those who regularly interpret neuroimages—are currently concentrated in university research hospitals.[110] This concentration could cause

104. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 136 (1997).

105. *See, e.g.*, Thompson v. Orkin, LLC, No. 1:20-CV-13085, 2025 WL 18639, at *22 (E.D. Mich. Jan. 2, 2025) (allowing psychiatrist-neurologist to testify that plaintiff suffered from PTSD and secondary depression but excluding his opinion that his symptoms were caused by pesticide exposure); People v. Lemons, 22 N.W.3d 42, 42 (Mich. 2024) (granting—after multiple appeals—a child abuse defendant a new trial based on erroneous exclusion of evidence, including testimony of a biomechanical engineer about "shaken baby syndrome," a neurological condition); Patterson v. Pirraglia, No. 4:24-CV-04014, 2025 WL 71857, at *11–12 (D.S.D. Jan. 10, 2025) (holding that state courts properly excluded defense experts, including a board-certified neuropathologist who could produce no studies supporting his opinion that abusive head trauma produces a particular profile that the victim in this case did not meet, in federal habeas corpus case on behalf of a state prisoner convicted of the murder of an infant).

106. Gregory Q. Hill & Robert K. Ryu, *A Primer to Understanding the Elements of Medical Malpractice*, 36 SEMINARS INTERVENT. RADIOLOGY 117, 118 (2019).

107. *Id.*

108. *See id.* at 117.

109. *Id.*

110. *See* López Gonzáles, *supra* note 103 (discussing four new technologies developed at an academic medical center with varying degrees of general availability).

multiple, location-dependent standards to reemerge. But medical science is already addressing this issue by seeking ways to make advanced technologies more readily available in remote locations,[111] suggesting that the urban-rural divide may become moot before the law has a chance to respond to it.

In any particular malpractice case, the expert admissibility issues just discussed are also crucial: Who is qualified to testify about what the standard of care is? And, once that standard is established by the court, what kinds of experts are qualified to testify about whether the defendant doctor met or fell short of it? As with neuroscience generally, the malpractice case law does not currently suggest answers to those questions.[112]

C. *Liability Issues Arising from Neurological Devices*

In earlier sections of this Article, we described some current and near-term uses of neurological devices for diagnosis and treatment, including wearable EEGs for real-time monitoring of brain activity[113] and the interventional use of deep brain stimulation, sometimes via devices implanted in the brain.[114] An overarching question is, if any kind of neurological device fails and causes injury, who is legally responsible? The entity that designed and manufactured it? The healthcare professionals who recommended its use and, in some cases, implanted it? Plaintiffs' lawyers will sue all remotely plausible defendants, of course, which will provide no guidance to courts as to who should actually be held legally responsible.

Even a functioning neurodevice will require monitoring and maintenance, from battery changes to potential repair and replacement. Who will be responsible for doing it? If a manufacturer goes out of business or otherwise becomes unwilling or unable to continue supporting the product, can some other party be compelled to step in, assuming that a competent substitute can be found?

D. *Regulatory Issues*

The regulation of neuroscience is already well established, but as neuroscience advances, it may produce novel challenges concerning how to apply existing frameworks to new technology. The U.S. FDA has responsibility

111. *See, e.g.*, Alyssa LaFaro, *He's Making Pregnancy Sonograms More Accessible*, UNIV. N.C. CHAPEL HILL (June 17, 2025), https://www.unc.edu/posts/2025/06/17/hes-making-pregnancy-sonograms-more-accessible/ [https://perma.cc/FF5M-8BCB] (describing a new app intended to facilitate ultrasounds in areas with limited access to medical facilities).

112. For examples, see Thompson v. Orkin, LLC, No. 1:20-CV-13085, 2025 WL 18639, at *22 (E.D. Mich. Jan. 2, 2025); People v. Lemons, 22 N.W.3d 42, 42 (Mich. 2024); Patterson v. Pirraglia, No. 4:24-CV-04014, 2025 WL 71857, at *11–12 (D.S.D. Jan. 10, 2025).

113. *See supra* notes 36–44 and accompanying text.

114. *See supra* notes 76–78 and accompanying text.

for overseeing the testing and marketing of drugs, biologics (chemically complex drugs made from natural sources, often using advanced biotechnology),[115] and medical devices.[116] Depending on their specific nature, neuroscience-based treatments and interventions could fall into any of these categories.[117]

The FDA currently has an Office of Neuroscience with five divisions that review a wide range of neurological drug, biologic, and medical device applications.[118] Most of the treatments and interventions described in this Symposium will fall into the medical device category. The FDA classifies medical devices as Class I (low risk), Class II (moderate risk), or Class III (high risk), with increasing levels of required approval and regulatory supervision.[119] The FDA notes that there are few Class I neurological devices, with most falling into Class II or III.[120] Class I devices include "ventricular needles and anvils used to form skull plates"; Class II devices include "neurostimulators, aneurysm clips, and blood clot retrievers"; and Class III devices include "deep brain stimulators and medical devices for the treatment of brain tumors."[121] Among the advanced devices discussed in this Symposium are imaging machines that produce the high-quality images that neuroscientists interpret,[122] AI-enhanced systems that both boost the quality and enhance the interpretation of such images,[123] and brain implants that perform a variety of functions.[124]

The FDA's longstanding approach to new medical technologies has been to adapt its existing regulatory framework through guidance, new pathways for approval, and enhanced staff expertise. In response to the growth of genome editing, for example, the FDA has issued guidance for industry[125] and has

115. *What Are "Biologics" Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers [https://perma.cc/BU82-HVP5 (staff-uploaded archive)].

116. *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN. (Mar. 29, 2024), https://www.fda.gov/about-fda/what-we-do/what-does-fda-regulate [https://perma.cc/9PWA-5X7U (staff-uploaded archive)].

117. *Office of Neuroscience*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2023), https://www.fda.gov/about-fda/cder-offices-and-divisions/office-neuroscience [https://perma.cc/4QP6-9938 (staff-uploaded archive)]; *Regulatory Overview for Neurological Devices*, U.S. FOOD & DRUG ADMIN. (Apr. 22, 2024), https://www.fda.gov/medical-devices/neurological-devices/regulatory-overview-neurological-devices [https://perma.cc/L4E3-ZFRK (staff-uploaded archive)].

118. *Office of Neuroscience*, *supra* note 117.

119. *Regulatory Overview for Neurological Devices*, *supra* note 117.

120. *Id.*

121. *Id.*

122. *See supra* notes 10–20 and accompanying text.

123. *See, e.g.*, López Gonzáles, *supra* note 103; LaFaro, *supra* note 111.

124. *See supra* notes 76–78 and accompanying text.

125. U.S. FOOD & DRUG ADMIN., HUMAN GENE THERAPY PRODUCTS INCORPORATING HUMAN GENOME EDITING: GUIDANCE FOR INDUSTRY (2024),

already approved the first gene therapies to treat sickle cell disease.[126] In neuroscience, the FDA issued guidance for industry and its staff in 2021 concerning "Implanted Brain-Computer Interface ("BCI") Devices for Patients with Paralysis or Amputation."[127] There is no reason to believe that this approach will change. The practical question will be whether the FDA can keep up with new technology. Notably, the BCI guidance is the only example of neuroscience technology industry guidance that the FDA has published so far.

III. OVERVIEW OF SYMPOSIUM ARTICLES

The Articles in this Symposium issue deal with the scientific, ethical, and legal issues we have just reviewed, plus many more, and they do so from a broad range of perspectives. In this Part, we give a brief overview of each of the articles, arranged in the order in which they were presented at the Symposium.

Jane Campbell Moriarty was one of the first scholars of scientific evidence to focus on neuroscience, and she remains one of the most active and influential participants in the field. In her article, *Off-Label Neuroimaging*,[128] Moriarty applies a long-established drug use principle to the field of advanced neuroimaging. Off-label use, which is generally permitted by law, refers to the use of a drug or treatment that has been approved for one purpose to be used for a different purpose at the discretion of the prescriber. Moriarty defines off-label neuroimaging ("OLN") as the use of imaging technologies for non-clinically-accepted purposes or the use of research-stage imaging technologies that are not yet clinically adopted. Moriarty addresses the specific questions of whether and under what circumstances the courts should admit testimony about OLN. Using the examples of DTI and nuclear medicine, she identifies a set of problems that courts should consider and offers guidance on managing those problems.

Deborah Denno has been a pioneer in the detailed empirical study of the use and impact of neuroscience in the legal system. In her article, *The Science of*

https://www.fda.gov/media/156894/download [https://perma.cc/73KY-P5GQ (staff-uploaded archive)].

126. U.S. FOOD & DRUG ADMIN., FDA APPROVES FIRST GENE THERAPIES TO TREAT PATIENTS WITH SICKLE CELL DISEASE (Dec. 8, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease [https://perma.cc/UZ2Q-RN8Y (staff-uploaded archive)]. See Anna Tavridou, Dolça Rogers, Giada Farinelli, Iordanis Gravanis & Veronika Jekerle, *Genome-Editing Medicinal Products: The EMA Perspective*, 23 NAT'L REVS. DRUG DISCOV. 242, 242–43 (Apr. 2024), for a similar approach by the European Medicines Agency—the FDA's European Union counterpart.

127. U.S. FOOD & DRUG ADMIN., IMPLANTED BRAIN-COMPUTER INTERFACE (BCI) DEVICES FOR PATIENTS WITH PARALYSIS OR AMPUTATION—NON-CLINICAL TESTING AND CLINICAL CONSIDERATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2021), https://www.fda.gov/media/120362/download [https://perma.cc/MW2A-BMBC (staff-uploaded archive)].

128. Jane Campbell Moriarty, *Off-Label Neuroimaging*, 104 N.C. L. REV. 1185 (2026).

the Lie: Prosecutorial Reliance on Neuroscience to Challenge Defendants' Mental Health Claims,[129] Denno presents quantitative and qualitative results from her "Neuroscience Study," a remarkable data set of every criminal case in the United States (over 8,000 cases) that addressed neuroscientific evidence over twelve decades (1900–2020). Her specific focus here is on malingering—feigning or faking mental illness—which is one of the strongest arguments a prosecutor can make to exclude or rebut neuroscientific evidence that the defense seeks to offer. Denno's data reveals a massive increase in malingering claims by prosecutors, with potentially adverse effects on defendants and the broader potential to undermine the goals of the criminal justice system.

Richard S. Saver is a legal scholar who focuses on health law and tort law more broadly; Jeffrey L. Saver is a medical doctor who is a leading researcher and practitioner in neuroscience and its growing applications. In *Neural Implants: The Promise, Peril, and Regulatory Challenges*,[130] Saver and Saver review current and future neurotechnologies that can be implanted directly in the brain, including promising therapies for stroke, epilepsy, and dementia. They review the scientific issues that must be overcome before such therapies can be ready for clinical use and consider the novel regulatory challenges that these therapies pose, including complicated risk/benefit assessments, difficulty in reversing course after an implant, and uncertain long-term impacts. The authors then discuss risks beyond physical harm, particularly the "abandonment hazards" that patients face if manufacturers and providers no longer support a technology's continued use or it otherwise becomes obsolete. They conclude with some recommendations for improving the testing, approval, and clinical use of neural implants.

Gabriel Lázaro-Muñoz is a Ph.D. psychologist and a lawyer whose lab studies brain bioethics in connection with neurosurgery. Alex Foulkes Grafton is a practicing attorney who worked as a research neuroscientist before law school and has litigated a wide range of civil rights cases. Erika Versalovic is a Ph.D. philosopher who specializes in neuroethics and focuses her research on the intersection of neuroscience and society. Amanda R. Merner is a Ph.D. psychologist who researches emerging technologies in psychiatry and consults on health products research. In *Post-Trial Access to Beneficial Investigational Neural Devices*,[131] the authors review such technologies as brain-computer interfaces that generally target cortical regions of the brain and deep brain

129. Deborah W. Denno, *An Empirical Study of Malingering in Insanity Cases Across Twelve Decades*, 104 N.C. L. REV. 1141 (2026).

130. Richard S. Saver & Jeffrey L. Saver, *Neural Implants: The Promise, Peril, and Regulatory Challenges*, 104 N.C. L. REV. 1209 (2026).

131. Alexandra L. Foulkes, Erika Varsalovic, Amanda R. Merner & Gabriel Lázaro-Muñoz, *Legal and Regulatory Considerations for Post-Trial Access to Maintenance of Beneficial Investigational Neural Devices*, 104 N.C. L. REV. 1273 (2026).

stimulation systems that target deeper regions of the brain and consider their potential to manage symptoms of treatment-resistant conditions such as Parkinson's, depression, paralysis, or other functional impairments. Lázaro-Muñoz and Grafton address the specific question of how, following investigational neural device trials, participants who appear to benefit from these therapies can cover the cost of keeping the investigational device working and gain access to the hardware and software necessary for device maintenance and repairs. They explore the risk of "deprivation harms" to such participants, including a return to experiencing a severe, treatment-resistant condition or loss of function.

Leslie C. Griffin, a lawyer and religious studies Ph.D., has a unique perspective as both a scholar and traumatic brain injury survivor. In the memoire piece, *The Brain, Neuroethics, and Bioethics*,[132] she argues that a better understanding of the brain can support an enhanced neuroethics that adds new ideas to the four traditional bioethical principles of autonomy, nonmaleficence, beneficence, and justice. In developing this enhanced concept of neuroethics, Griffin explores a range of novel issues, including: organ donation seen from the perspective of the dying donor rather than the recipient; how insurance and medical diagnosis often relegate brain-injured patients to chronic care instead of rehabilitation; brain care as a civil right; the significant role of fear as part of victims' experience of tort law and criminal law; and the role of religion in defining what it means to be human. Griffin concludes with her insights on what neuroethics should say to bioethics.

CONCLUSION

As this overview of the Symposium reflects, our contributors have brought a remarkable range of expertise to this project. Drawing on this expertise, they have addressed our topic from almost every conceivable perspective, including science, law, ethics, policy, and religion. The rush of technology is likely to render many of their specific judgments obsolete, but the analytical framework that these articles offer is certain to have more enduring value.

132. Leslie C. Griffin, *Memoir: The Brain, Neuroethics, and Bioethics*, 104 N.C. L. REV. 1299 (2026).