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# Catching Up with Convergence: Strategies for Bringing Together the Fragmented Regulatory Governance of Brain-Machine Interfaces in the United States

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# Catching Up with Convergence: Strategies for Bringing Together the Fragmented Regulatory Governance of Brain-Machine Interfaces in the United States

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## INTRODUCTION

After a decade of stalled innovation, the past five years have seen neurotechnologies such as brain-machine interfaces ("BMIs") make rapid advances by synthesizing ideas from and progress in multiple other emerging technologies.[1] In short, BMIs connect an individual's central nervous system to a computer or machine,[2] an innovation which could lead to better prosthetics and new potential treatments for neurological and mental health conditions, or even applications in entertainment and gaming.[3] In practice, however, the sheer technical complexity of these neurotechnologies will produce a complicated and incomplete regulatory environment because health, privacy, and equity concerns will likely be handled by different or overlapping decision-making bodies across governmental branches.[4] This may not only delay the potential benefits these innovations offer, but also cause a failure in the management of the risks BMIs may create for patients, consumers, and society.[5] This article traces both the technical underpinnings

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[1] *See generally* THE ROYAL SOC'Y, IHUMAN: BLURRING LINES BETWEEN MIND AND MACHINE 24 (2019) (demonstrating rapid development of BMIs and varied application to medicine and other disciplines).

[2] *Id.* at 9.

[3] Thomas Baldwin, *Foreword to* NUFFIELD COUNCIL ON BIOETHICS, NOVEL NEUROTECHNOLOGIES: INTERVENING IN THE BRAIN vii–viii (2013).

[4] *See* Part II, *infra*.

[5] *E.g.*, Anna Wexler & Peter B. Reiner, *Oversight of Direct-to-Consumer Neurotechnologies*, 363 SCIENCE 234, 235 (2019) (discussing how neurotechnology investors are reluctant to pursue technologies requiring FDA approval due to the costs and time involved).

and regulatory intricacies of BMIs which will create various challenges for decisionmakers.

BMIs have been made possible by what innovation scholars have termed "technological convergence."[6] Convergence is the process of combining multiple different technological and scientific disciplines together in order to accelerate innovation and create entirely new types of products and services.[7] In particular, BMIs have emerged and gained a wider set of potential uses due to the fusion of neuroscience, big data, artificial intelligence ("AI"), materials science, and engineering.[8] Yet, technological convergence can also result in significant challenges and problems greater than the sum of its parts.[9] Regulating these neurotechnologies will demand managing risks at the intersection of safety, effectiveness, cybersecurity, consumer protection, equity, and data privacy.[10] Further, these initially observable risks can blend to generate new risks ranging from cognitive enhancement to military applications to deep user reliance on BMI developers.[11]

Some BMIs have already become available in North America, Europe, and Japan.[12] These include products developed by various start-up companies, such as NeuroSky and Emotiv, as well as several high-profile, well-funded projects, including a Facebook project and Elon Musk's Neuralink.[13] Some

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[6] *See* William S. Bainbridge & Mihail C. Roco, *The Era of Convergence*, *in* HANDBOOK OF SCIENCE AND TECHNOLOGY CONVERGENCE 3 (Mihail C. Roco & William S. Bainbridge eds., 2016) (discussing the convergence of "nano-bio-information-cognitive technologies" as the result of the synthesis of efforts and expertise in multiple fields of science and technology).

[7] *See id.* (discussing that convergence is more than multidisciplinary collaboration and allows for the development of innovative and transformative technologies).

[8] Hermann Garden et al., *Responsible Innovation in Neurotechnology Enterprises* 9 (OECD, Working Paper No.5, 2019).

[9] ANDREW MAYNARD, FILMS FROM THE FUTURE: THE TECHNOLOGY AND MORALITY OF SCI-FI FILMS 20–21 (2018).

[10] *See* Hermann Garden & David Winickoff, *Issues in Neurotechnology Governance* 8, 12–13 (OECD Working Paper No. 11, 2018) (listing various concerns that BMIs raise); *see also* NUFFIELD COUNCIL ON BIOETHICS, NOVEL NEUROTECHNOLOGIES: INTERVENING IN THE BRAIN 134 (2013) (discussing how regulation needs to address safety and effectiveness in emerging technologies).

[11] Andrew D. Maynard & Marissa Scragg, *The Ethical and Responsible Development and Application of Advanced Brain Machine Interfaces*, 21 J. MED. INTERNET RES. 1, 3 (2019).

[12] *See* Marcello Ienca et al., *Brain Leaks and Consumer Neurotechnology* 36 NATURE BIOTECHNOLOGY 805, 806 (2018) (providing examples of BMIs already on the market in varying countries).

[13] *See, e.g.*, Elon Musk & Neuralink, *An Integrated Brain-Machine Interface Platform with Thousands of Channels*, 21 J. MED. INTERNET RES. 755, 756 (2019) (providing an example of Neuralink's BMI technology); *see also,* Tekla S. Perry, *Here's How Facebook's Brain-Computer Interface Development is Progressing*, IEEE SPECTRUM (Feb. 25, 2020),

BMIs are available direct-to-consumer, while others may require a prescription from a physician.[14] Some higher-risk products have required approval by regulatory institutions before entering the market, while others have escaped the existing legislative mandates of federal agencies.[15] The most complex BMIs, involving invasive brain implants operating with continuously learning software, will certainly require regulatory oversight.[16] Yet, even when such neurotechnological devices clearly fall into an agency's jurisdiction, the applicable standards often remain uncertain.[17] This wave of sophisticated BMIs approaching and entering the market calls for regulatory action and clarity.

This essay will explore how convergence in BMIs can foster fragmentation in regulatory governance and offer policy strategies for closing these gaps. Part I reviews the emergence of neurotechnologies including BMIs, their applications, and the role of convergence in generating governance issues. Part II then turns to jurisdictional issues that create redundant regulatory efforts or allow risks to fall through governance gaps. In the United States, the Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC") already have authority to regulate some neurotechnologies.[18] However, each of these agencies has jurisdiction over varying subject matters which overlap in BMIs through technological convergence.[19] This technological convergence will ultimately create significant regulatory problems for BMIs and neurotechnologies more broadly.[20] The split in regulatory authority combined with the inconsistencies of judicial opinions and potential lawmaker inaction could yield both

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https://spectrum.ieee.org/view-from-the-valley/consumer-electronics/portable-devices/heres-how-facebooks-braincomputer-interface-development-is-progressing (providing an example of how Facebook is also developing its own BMI technology).

[14] *See* Karola V. Kreitmair, *Dimensions of Ethical Direct-to-Consumer Neurotechnologies*, 10 AJOB NEUROSCIENCE 152, 152 (2019) (depicting the difference between direct-to-consumer products for "wellness" and medical products to treat patients).

[15] *See id.* at 155 (discussing how regulatory requirements can vary depending on whether the technology claims a health-related intended use).

[16] Lucille M. Tournas & Walter G. Johnson, *Elon Musk Wants to Hack Your Brain: How Will the FDA Manage That?*, SLATE (Aug. 5, 2019, 7:30 AM), https://slate.com/technology/2019/08/elon-musk-neuralink-facebook-brain-computer-interface-fda.html.

[17] *Id.*

[18] Ishan Dasgupta, *Ethical Oversight of Direct-to-Consumer Neurotechnologies: The FDA, the FTC, or Self-Regulation?*, 10 AJOB NEUROSCIENCE 200, 200–01 (2019).

[19] *Id.*

[20] *See generally* Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201 (2006) (discussing how overlapping and underlapping agency jurisdiction can lead to conflicts between regulatory authorities and compromise the effectiveness of oversight).

redundancies and governance gaps.[21] This fragmented regulatory governance could ultimately reduce the effectiveness and efficiency of oversight for emerging neurotechnological products such as BMIs. Part III will draw on the interagency coordination and technology assessment literatures to propose and assess potential strategies for more comprehensively responding to BMIs. Developing such strategies to overcome fragmentation merit prompt attention by policymakers to ensure that neurotechnological oversight can adequately manage risks at reduced costs and without stifling the innovation which could be helpful to patients and consumers.

## I. CONVERGENCE IN BMI

Though the term "neurotechnology" is relatively new, the field it represents has several established applications in diagnosing, treating, and preventing medical conditions. Diagnostic neurotechnological devices such as electromyography ("EMG") or magnetic resonance imaging ("MRI") enable physicians to visualize the brain, spinal cord, or peripheral nerves to make diagnoses and plan surgeries.[22] Spinal cord stimulator devices allow patients to achieve some degree of control over their back and extremity pain by interfering with electrical signals encoding pain as they travel towards the brain.[23] BMIs should also readily fit within this umbrella of neurotechnologies, although fewer applications are currently developed and available on the market compared to older examples such as EMG, MRI, or spinal cord stimulators.[24] The British Royal Society highlights cochlear implants to address hearing loss as the most common and recognizable example of a BMI,[25] although defining hearing loss as a condition to be treated is heavily contested as marginalizing to the Deaf community.[26]

While EMGs or BMIs offer examples of this field, a definition of the word "neurotechnology" and the scope of the industries and innovations it encompasses remains under debate. At its broadest, the term

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[21] *See* Part II, *infra*.
[22] *Id.*
[23] *See* NUFFIELD COUNCIL ON BIOETHICS, *supra* note 10, at 26 (describing spinal cord stimulator technology and their use in pain treatment by applying "low voltage electrical pulses to afferent nerve fibers via an epidural electrode that is implanted surgically or through the skin.").
[24] BMIs are slowly beginning to enter marketplaces around the world. *See* Ienca et al., *supra* note 12, at 805–07 (highlighting certain direct-to-consumer neurotechnologies available in different countries).
[25] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 9, 38–39 (defining neural interfaces and noting the prevalence of cochlear implants). For a definition of BMIs, *see* Part I.A, *infra*.
[26] *See generally* Robert Sparrow, *Implants and Ethnocide: Learning from the Cochlear Implant Controversy*, 25 DISABILITY & SOC'Y 455 (2010).

"neurotechnology" includes any technology that interacts, directly or indirectly, with human neurology and psychology.[27] This conceptualization includes mobile phone applications and wearable devices which do not directly interact with the nervous system but hypothetically can indirectly result in some degree of change to neural circuitry.[28] Many of the technologies implicated in this sweeping definition raise pertinent, but unresolved social and regulatory issues.[29] However, this expansive idea of neurotechnologies may be too broad and overlooks the nuanced differences between a sea of existing technologies and a smaller cohort of nascent but transformative innovations.

Instead, a more limited, but still robust, definition from bioethicist James Giordano would categorize this nascent field as "those devices that are utilized to investigate, assess, access, and manipulate the structure and function of neural systems."[30] This definition narrows the term "neurotechnology" to a conceptually more manageable scope and focuses on those innovations which interact with human neural systems more directly. Adopting this definition of neurotechnologies should better enable decisionmakers to tailor policy to the benefits and risks of products such as spinal cord stimulators and BMIs, rather than trying to address these devices alongside others with substantially different policy considerations such as mobile phone applications.

Yet, even within Giordano's narrower definition of neurotechnologies, new and rapidly emerging devices such as BMIs may require special policy attention. A second, distinct wave of neurotechnologies has surfaced and begun to approach and enter the market in the United States over the last decade, including innovations in areas such as transcranial magnetic stimulation ("TMS"), deep brain stimulation ("DBS"), and BMIs.[31] At least two factors distinguish the second wave of neurotechnologies from the original. First, companies have begun to develop and market many of these new products directly to consumers rather than reserving them for use by

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[27] *See* Kreitmair, *supra* note 14, at 153–54 (offering a broad definition of neurotechnology).
[28] *Id.* at 154.
[29] *See* Saba Akbar et al., *Safety Concerns with Consumer-Facing Mobile Health Applications and Their Consequences: A Scoping Review*, 27 J. AM. MED. INFO. ASS'N 330, 331 (2020) (generally describing the regulatory issues involved in implanting devices).
[30] James Giordano, *Neurotechnology as Demiurgical Force: Avoiding Icarus' Folly*, *in* NEUROTECHNOLOGY: PREMISES, POTENTIAL, AND PROBLEMS 4 (James Giordano ed., 2012).
[31] *Id.* The terms "BMI" and "BCI" (brain-computer interface) both appear in the technical literature and various definitions have been proposed to distinguish between them. This essay will primarily use BMI for consistency and because an emerging consensus appears to use BMI as the more comprehensive and inclusive term.

patients and health care providers in a medical setting.[32] Second, the products are the result of synthesizing multiple, distinct disciplines of science and technology.[33] These two distinguishing features of BMIs and other novel neurotechnologies will require policymakers to address these innovations with even greater attention than established neurotechnologies such as MRIs.

### *A. New Possibilities for BMIs*

The concept of "technological convergence" describes how new innovations can result from bringing together different areas of science and technology and blending them to create something new.[34] In the world of neurotechnologies, a second, convergence-driven wave of innovation weaves together advances from multiple different scientific and technological disciplines to achieve potential benefits for patients and consumers not previously possible.[35] In particular, BMIs represent the perfect example of Bainbridge and Roco's original concept for technological convergence described in their report at the National Science Foundation.[36] Originally conceived in 2002, convergence was described as the process for bringing together insights and developments from "nanotechnology, biotechnology, information technology, and cognitive science" to create new possibilities, even enhancing human cognitive abilities.[37] Many neurotechnologies such as BMIs use information technologies to record and process data, applying cognitive science to interpret the information.[38] Neurotechnologies may also involve nano- or biotechnology, particularly in the materials of the interface selected.[39]

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[32] *See* Ienca et al., *supra* note 12, at 805 (demonstrating how rapid advances in neuroscience and neurotechnological development could have direct-to-consumer applications).
[33] Garden et al., *supra* note 8, at 9, 20.
[34] *Id.*; Suzy E. Park, U.S. Cong. Res. Serv., Technological Convergence: Regulatory, Digital Privacy, and Data Security Issues 1, 1–2 (2019), https://fas.org/sgp/crs/misc/R45746.pdf.
[35] Garden et al., *supra* note 8, at 9.
[36] *See generally* NAT'L SCI. FOUND., CONVERGING TECHNOLOGIES FOR IMPROVING HUMAN PERFORMANCE: NANOTECHNOLOGY, BIOTECHNOLOGY, INFORMATION TECHNOLOGY AND COGNITIVE SCIENCE ix (Mihail C. Roco & William S. Bainbridge eds., 2002) (discussing the concept of convergence and convergent technologies).
[37] *See id.* at ix–xi (defining the idea of technological convergence, especially in combining the fields of "nano-bio-info-cogno," and discussing the social and policy implications of such a phenomenon).
[38] *See generally* Gabriel A. Silva, *A New Frontier: The Convergence of Nanotechnology, Brain-Machine Interfaces, and Artificial Intelligence*, 12 FRONTIERS NEUROSCIENCE 1, 1 (2018) (discussing the use of advances in materials science and digital technologies, such as artificial intelligence, with BMIs).
[39] *Id.*

BMIs are devices which allow a patient or consumer's brain to "interface" with software, such as a computer cursor, or a piece of hardware, such as a prosthetic limb.[40] Such interfacing can involve the BMI either "reading" or "writing" human neural signals.[41] BMIs which "read" neural activity can allow the user to control or influence a machine's behavior, where the BMI reads and interprets signals from the brain (such as those associated with arm or finger movement) and translates those signals into an output such as moving a computer cursor, a prosthetic, or operating a device to replicate speech.[42] Read functions offer great promise to patients with paralysis or physical injuries, as these BMIs could enable new ways to interact with their environment and even enable "neurorehabilitation."[43] BMI "read" functions can also be used in consumer products, such as those used to help analyze an individual's level of concentration or meditation, by monitoring thought processes while the device is worn, and then providing an assessment and suggestions to the consumer.[44] Facebook is currently developing a commercial, wearable BMI to enable users to draft and send text-based messages solely using neural signals.[45]

While BMIs that "read" constitute the bulk of current products, another class of BMIs can also "write" by using electrical stimulation to modify brain signals or create new ones, rather than solely interpreting or "reading" those signals.[46] For example, existing cochlear implants operate by converting

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[40] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 3, 14 (discussing how neural interfaces interact with the nervous system to stimulate activity).

[41] *See* Richard A. Andersen, et al., *Selecting the Signals for a Brain-Machine Interface*, 14 CURRENT OPINION NEUROBIOLOGY 720, 720 (2004) (describing some processes behind read and write functions of current and emerging BMIs); *see generally* Pieter R. Roelfsema et.al., *Mind Reading and Writing: The Future of Neurotechnology*, 22 TRENDS COGNITIVE SCI. 598, 598 (2018) (describing progress in neurotechnologies towards the capacity to both "read" and "write" neural signals).

[42] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 22, 30, 72 (providing examples of BMIs); *see also* David A. Moses et al., *Real-Time Decoding of Question-and-Answer Speech Dialogue Using Human Cortical Activity*, 10 NATURE COMM., 1, 2, 8–9 (2019) (describing work towards BMIs which can interpret brain signals to produce speech for a user).

[43] *See generally* Yoji Okahara et al., *Long-Term Use of a Neural Prosthesis in Progressive Paralysis*, 8 SCI. REP. 1, 1 (2018) (explaining how BMI technology is expected to improve the quality of life for paralyzed individuals); Sylvan J. Albert & Jürg Kesselring, *Neurorehabilitation of Stroke*, 259 J. NEUROLOGY 817, 817 (2012).

[44] *See* Ienca et al., *supra* note 12, at 806 (describing the near-term potential of direct-to-consumer applications of neurotechnologies).

[45] Josh Constine, *Facebook is Building Brain-Computer Interfaces for Typing and Skin-Hearing*, TECHCRUNCH (Apr. 19, 2017, 12:55 PM), https://techcrunch.com/2017/04/19/facebook-brain-interface/.

[46] *See* Andersen et al., *supra* note 41, at 720 (describing how BMIs interface with brain tissue to "read" or "write" neural signals).

sound waves into electrical signals the brain can interpret as sound.[47] While further research and development is required, these BMIs offer novel possibilities to strengthen or correct deficient neural pathways associated with disease or injury, such as Parkinson's Disease or traumatic brain injuries.[48]

BMIs' reading and writing functionalities have benefited from progress in multiple disciplines.[49] Advances in neuroscience and neuropsychology have provided a higher-resolution and more quantitative understanding of how neural signals influence motor control, cognition, and mood.[50] Meanwhile, rapid progress in data sciences and AI has bolstered the ability to collect and analyze vast volumes of data quickly to better interpret and act on neural signals.[51] Engineering innovations in biocompatibility, micro- or nanoscale manufacturing, and materials science has facilitated new designs for devices with greater sensitivity to neural signals that pose fewer risks when placed on or in the body.[52] Convergence in these fields has sparked new possibilities for products to aid patients or offer novel benefits or services to consumers.[53]

### *B. New Risks for BMIs*

While interdisciplinary collaboration has allowed for the creation of new products with potential benefits for people with neurological or other medical conditions, as well as for consumers, this technological convergence also blends and multiplies the risks and uncertainties posed by each technology individually.[54] Uncertainty in neuroscience, the potential of algorithmic error

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[47] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 38 (describing how cochlear implants operate). It should be reiterated here that defining hearing loss as a condition requiring treatment is a contested view of disability. *See* Sparrow, *supra* note 26.

[48] *See* NUFFIELD COUNCIL ON BIOETHICS, *supra* note 10, at 2, 34 (describing the potential use of BMIs for rehabilitation in patients with impaired motor function from neurological injury or disease, such as Parkinson's Disease); *see generally* Dennis A. Turner, *Enhanced Functional Outcome from Traumatic Brain Injury with Brain-Machine Interface Neuromodulation*, *in* TRANSLATIONAL RESEARCH IN TRAUMATIC BRAIN INJURY (Daniel Laskowitz & Gerald Grant eds., 2016) (describing the potential use of BMIs to "facilitate recovery from the basic head injury" and restore function in the damaged areas).

[49] Garden et al., *supra* note 8, at 9, 12, 20.

[50] *Id.*

[51] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 49 (discussing the advantages AI may bring to neurotechnologies).

[52] Jong-ryul Choi et al., *Implantable Neural Probes for Brain-Machine Interfaces: Current Developments and Future Prospects*, 27 EXPERIMENTAL NEUROBIOLOGY 453, 463–64 (2018).

[53] *See e.g.*, Garden et al., *supra* note 8, at 11–17.

[54] *See* Garden & Winickoff, *supra* note 10, at 12–13 (listing potential ethical and governance issues in neurotechnology innovation and use); MAYNARD, *supra* note 9, at 20–21.

or cyberattacks, and the biocompatibility of new materials used in BMIs all present their own safety and effectiveness issues for these neurotechnologies.[55] For instance, devices implanted in the skull or spine can cause injury by damaging neural tissue where the device is placed, which could lead to chronic issues with muscle movement or psychological wellbeing.[56] For wearable and implantable BMIs alike, cyberattacks could reveal sensitive personal or medical data collected by devices or interfere with how the device operates.[57]

These individual safety and performance problems demand immediate oversight, but so do more complex risks which can arise at the nexus of the many technologies underlying BMIs. For example, data collected by BMI developers combined with advances in neuroscience could lead to "neuroprivacy" issues, where industry actors could gain increasingly invasive insights about the thoughts of its product's end users.[58] Particularly for implantable devices, the safety of materials and cybersecurity issues could combine to render patients or consumers reliant on BMI developers to keep cybersecurity protections updated and monitor for safety issues.[59] Should private actors not have strong incentives to provide these protections over time, or should they go out of business, the wellbeing of those BMI users could be jeopardized.[60] Additionally, knowledge gained from neuroscience and rapid insights from AI-driven big data may enable BMIs to enhance human performance, such as by improving cognitive performance or response times.[61] This enhancement may result in national security issues

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[55] *See* Garden & Winickoff, *supra* note 10, at 12–13 (listing potential ethical and governance issues in neurotechnology innovation and use).

[56] *See generally e.g.*, Stephanie Cernera et al., *A Review of Cognitive Outcomes Across Movement Disorder Patients Undergoing Deep Brain Stimulation*, 10 FRONTIERS NEUROLOGY 419 (2019); Jürgen Voges et al., *Thirty Days Complication Rate Following Surgery Performed for Deep-Brain-Stimulation*, 22 MOVEMENT DISORDERS 1486 (2007).

[57] *See* Marcello Ienca & Pim Haselager, *Hacking the Brain: Brain-Computer Interfacing Technology and the Ethics of Neurosecurity*, 18 ETHICS & INFO. 117, 120–21 (2016).

[58] Marcello Ienca, *Neuroprivacy, Neurosecurity and Brain-Hacking: Emerging Issues in Neural Engineering*, 8 BIOETHICA F. 51, 52 (2015); Maynard & Scragg, *supra* note 11, at 1, 2, 4 (noting concern for the "misuse of an individual's data" if "users have limited control over implanted brain machine interfaces and the data they produce").

[59] *See* MAYNARD, *supra* note 9, at chapter 7 (anticipating social risks to implantable BMI users who do not have the skills to perform maintenance on their own devices, placing their long-term wellbeing related to the device primarily in the hands of the BMI company).

[60] *Id.*

[61] Caterina Cinel et al., *Neurotechnologies for Human Cognitive Augmentation: Current State of the Art and Future Prospects*, 13 FRONTIERS HUM. NEUROSCIENCE 1, 5–14 (2019).

when applied in a military setting or widen the wealth gap if only accessible to individuals of means.[62]

The individual disciplines that come together to create emerging neurotechnologies such as BMIs each pose their own risks, from safety and performance to privacy and security, yet their convergence blends these challenges and may create new ones. Emerging technologies in general create a pacing problem, where accelerating technological innovation develops faster than public regulators' efforts to understand and manage their risks.[63] BMIs appear to have begun outpacing policymakers already, with non-invasive BMIs available to consumers already posing data privacy and security risks that current law and regulators in the United States have struggled to address.[64] And further, by mixing different types of risks, technological convergence may accelerate this thorny pacing problem. By posing not only risks associated with each individual type of science or technology, but also new risks only possible through blending multiple different types of innovations, decisionmakers could find themselves increasingly behind the novel governance challenges that develop in the wake of convergence around BMIs.[65]

## II. FRAGMENTED REGULATORY GOVERNANCE OF BMIS IN THE UNITED STATES

Finding appropriate regulatory strategies for BMIs will require not only addressing safety issues for implantable devices, but also the complex social and ethical problems created by technological convergence.[66] Yet, the discussion on how to regulate the risks and benefits of emerging neurotechnology products has only just begun. As this discussion begins, the question of what broader goals regulation should accomplish is open for debate.[67] Specifically, scholars debate whether traditional regulatory agencies have the capacity to oversee these emerging products and whether

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[62] *Id.*

[63] Gary E. Marchant et al., *The Growing Gap Between Emerging Technologies and the Law, in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT 19–20 (2011).

[64] *See* Ienca et al., *supra* note 12, at 807–09.

[65] *Id.*; Marchant, *supra* note 63, at 5, 16–20.

[66] *See* NUFFIELD COUNCIL ON BIOETHICS, *supra* note 10, at 222 (noting governance concerns extend beyond safety to also include issues including "autonomy, privacy, equity, and trust").

[67] *See* Garden & Winickoff, *supra* note 10, at 14–17 (illustrating issues in neurotechnological innovation and use).

their regulation will undercut innovation.[68] Legal scholars Marchant and Tournas have raised the possibility of governments or non-state actors using "soft law" instruments, meaning voluntary standards, to govern neurotechnologies around the globe.[69] In December 2019, the Organisation for Economic Co-operation and Development ("OECD") issued the first such global soft law standard calling for public and private entities to incorporate elements of "responsible innovation" into their neurotechnology research and development activities.[70]

While transnational standards, such as the OECD's, will provide a meaningful source of norms for governing complicated issues raised by neurotechnologies, the role of existing regulatory bodies should not be dismissed. The FDA and FTC have delegations from Congress that empower them to oversee, to an extent, products arriving in the second wave of neurotechnologies such as BMIs.[71] However, the existing regulatory frameworks which the FDA and FTC will apply to these novel products were not specifically designed for neurotechnologies.[72] Thus, these frameworks may be a poor fit for regulating the risks and benefits of these new products, though the agencies must ultimately apply them nonetheless, as these preexisting regulatory tools are the instruments the agencies have available to them.[73]

The possibility that these current oversight frameworks may be poorly tailored to emerging neurotechnologies presents policy challenges, starting with appropriately adapting regulation to risks. But a more immediate concern arises from the need to coordinate multiple agencies, each with their own set of rules and mandates. Both the FDA and the FTC have a jurisdictional claim over cybersecurity in these products, creating a potential redundancy or inconsistency in oversight (see Table 1). [74] Bifurcated review

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[68] Marchant, *supra* note 63, at 16.

[69] Gary Marchant & Lucy Tournas, *Filling the Governance Gap: International Principles for Responsible Development of Neurotechnologies*, 10 AJOB NEUROSCIENCE 176, 177 (2019).

[70] ORG. FOR ECON. CO-OPERATION & DEV., RECOMMENDATION OF THE COUNCIL ON RESPONSIBLE INNOVATION IN NEUROTECHNOLOGY 3 (2019).

[71] INST. OF MED. ET AL., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 41-46 (2011); *see* Parts II.A & II.B, *infra*.

[72] *See* Elen Stokes, *Nanotechnology and the Products of Inherited Regulation*, 39 J.L. & SOC'Y. 93, 94 (2012) (arguing that existing provisions may be ill-suited to regulate new technologies).

[73] *Id.*

[74] *See* Ishan Dasgupta, *Assessing Current Mechanisms for the Regulation of Direct-to-Consumer Neurotechnology*, DEV. NEUROETHICS & BIOETHICS 233, 246–50 (outlining how

of neurotechnology products for their safety and effectiveness by the FDA and for consumer protection concerns by the FTC could pose issues of regulatory inefficiency by needlessly duplicating resources spent by agencies and developers alike. Further, neither agency has jurisdiction to review the broader ethical and social concerns posed by neurotechnologies, opening gaps in the federal governance scheme for these technologies.[75] Without an adequate policy framework, these governance gaps on ethical and social issues, combined with overlapping or bifurcated risk regulation by the FDA and FTC, could lead to a system that is both inefficient and ineffective for BMI oversight. Further, the potential for litigation challenging new regulatory efforts, in which courts could become involved in new efforts to regulate the space through reviews of agency discretion, further complicates the stability of governance for BMIs.

This Part reviews the "regulatory space" into which BMIs fall, by taking stock of some major public decision-making institutions and regulatory regimes that apply,[76] and considers how these overlapping systems can drive fragmentation.

Table 1. Divergent Roles and Mandates for the FDA and FTC

| | FDA | FTC |
|---|---|---|
| Mandate | Public Health | Consumer Protection |
| Guiding Standard | Safety and Effectiveness | Unfair or Deceptive Practices |
| Scope of Authority | Health Risks and Benefits; Health Claims | Marketing Claims; Data Protection |

the FDA has authority to regulate any "device intended for use in the diagnoses of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body of man," while the FTC regulates consumer privacy and data).

[75] *See generally* Gersen, *supra* note 20, at 208–09 (explaining lack of jurisdiction).

[76] Colin Scott, *Analysing Regulatory Space: Fragmented Resources and Institutional Design*, 2001 PUB. L. 329, 331 (2001) ("The 'regulatory space' metaphor draws attention to the fact that regulatory authority and responsibility are frequently dispersed between a number of actors . . . . The regulatory space approach is 'holistic' in the sense that it looks at the interactions of each of the players in the space, and can recognize plural systems of authority.").

### *A. FDA Regulation*

The FDA oversees medical devices sold on the market in the United States to patients or consumers that make distinct health claims, acting as a gatekeeper to the marketplace.[77] Authorized by statutory authorities beginning with the Medical Device Amendments of 1976, the FDA uses a risk-based regulatory framework to evaluate the safety and effectiveness of devices and then applies increasing scrutiny to devices with higher risks.[78]

The agency uses a three-tiered classification scheme to determine the level of risk posed by a potential medical device and the degree of oversight required.[79] Class I devices, which may include personal protective equipment such as medical gloves, are considered low risk and must comply primarily with basic rules on manufacturing.[80] Class II devices generally involve medium-risk and an intermediate level of regulatory scrutiny by the FDA, and their route to the market can vary depending on whether they require significant premarket review.[81] The most common pathway to market for Class II devices involves limited premarket review by the FDA through its 510(k) process, which requires developers to show their device is "substantially equivalent" to an existing device on the market.[82] Conversely, Class III devices present higher risks to patient health and safety and may

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[77] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351–360 (2020); *see also* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 1 (2010).

[78] *Overview of Medical Device Classification and Reclassification*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2017), https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification.

[79] *Id.* In seeking approval, device developers must select one of the FDA's pre-existing regulatory pathways and send the appropriate materials to the FDA. *See Overview of Medical Device Classification and Reclassification*, *supra* note 78 (outlining information developers must provide the FDA based on the review mechanism selected and noting device types exempt from premarket requirements).

[80] *See General Controls for Reclassification Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 22, 2018), https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices. For an overview of FDA device classification and regulatory requirements for each class, *see generally, Regulatory Controls*, U.S. FOOD & DRUG ADMIN. (Mar. 27, 2018), https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.

[81] *See* JUDITH A. JOHNSON, U.S. CONG. RES. SERV., FDA REGULATION OF MEDICAL DEVICES 1, 6 (2016), https://fas.org/sgp/crs/misc/R42130.pdf.

[82] *Id.*; *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Mar. 13, 2020), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k; *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-190, FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 9, 16–19 (2009), https://www.gao.gov/assets/290/284882.pdf (illustrating how most Class II submissions to the FDA are through the 510(k) pathway).

involve implantable devices,[83] typically requiring extensive review through a Premarket Approval ("PMA") involving clinical trials.[84]

Placing emerging neurotechnological medical devices on the market will require classifying the device under the FDA's risk-based regime and then working with the agency to determine what requirements should be met prior to marketing the device.[85] Some neurotechnologies have already undergone FDA clearance or approval,[86] including implantable spinal cord stimulators and DBS devices.[87] The FDA retains regulatory authority over these devices in the post-market setting, and has previously exercised its recall powers on, for example, cochlear implants.[88] Developers of newer neurotechnological products such as implantable BMIs should similarly be prepared to comply with the FDA's post-market regulatory powers including recalls and reporting.[89] Notably, relatively few non-invasive neurotechnologies such as wearable TMS devices have been cleared through the FDA, so developers of these products may benefit from working closely with the agency to determine the most appropriate pre-market steps.[90]

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[83] *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN. (2017), https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.

[84] Premarket Approval of Medical Devices, 21 C.F.R. § 814 (2020); *see Premarket Approval (PMA)* U.S. FOOD & DRUG ADMIN. (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma; *see generally* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 82.

[85] *See generally Regulatory Controls*, *supra* note 80.

[86] A successful PMA application to the FDA results in "approval" while a successful 510(k) results in "clearance." *See* JOHNSON, *supra* note 81, at 4.

[87] *See, e.g.*, *Boston Scientific Spinal Cord Stimulation System – P030017/S275*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/recently-approved-devices/boston-scientific-spinal-cord-stimulation-system-p030017s275 (last visited Oct. 5, 2020) (providing examples of a spinal cord stimulator device approved by FDA through the premarket approval pathway); *Medtronic DBS System for Epilepsy – P960009/S219*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/recently-approved-devices/medtronic-dbs-system-epilepsy-p960009s219 (last visited Oct. 1, 2020) (providing examples of a DBS device approved by FDA through the premarket approval pathway).

[88] *Medical Device Recalls: Advanced Bionics Corporation*, U.S. FOOD & DRUG ADMIN. (2006), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/resCollection_2.cfm?ID=44868&CREATE_DT=2006-04-1 (last visited Oct. 1, 2020); *see generally Postmarket Requirements (Devices)*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/postmarket-requirements-devices.

[89] *See generally Postmarket Requirements (Devices)*, *supra* note 88.

[90] *See* Tournas & Johnson, *supra* note 16 (arguing neurotechnology developers should work closely with the FDA to anticipate potential risks and determine the most appropriate review mechanisms).

The most complex neurotechnologies, including BMIs, present greater challenges to both the FDA and the industry. These devices contain hardware and software components, both of which require separate safety and effectiveness reviews, and can create cybersecurity vulnerabilities for patients relying on these devices when connected to the internet that might change the device's safety or performance.[91] These devices will likely require extensive pre-market approval applications if intended to be implanted in a patient's body.[92] Non-invasive BMI devices hold lower safety risks than implantable BMI devices, but may be less effective if the skull and skin dull neural signals read by the BMI.[93] The FDA has already begun considering how to regulate BMIs with a draft guidance in 2019 and has solicited comments from stakeholders on the document.[94] This draft guidance would clarify what types of data the FDA would want to review when considering BMIs, such as information on how BMI software and electrodes functions,[95] although a finalized guidance may take time to issue depending on the volume and character of comments submitted to the agency.

Notably, the FDA does not regulate products which do not make health claims, even if they appear to be medical devices at first glance.[96] A number of direct-to-consumer ("DTC") neurotechnological products have already appeared on the market without going through the FDA due to this gap in FDA authority, since such products typically make "wellness" claims rather than express health claims.[97] Such non-invasive DTC products claiming to assist users with sleep, focus, or meditation can already be found on the market in multiple countries.[98] These could also include non-invasive, wearable BMIs such as those under development by Facebook, advertising the ability to type and send text by using only brain signals.[99]

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[91] *See id.* (noting some upcoming regulatory challenges in managing risk in BMI hardware and software).
[92] *Id.*
[93] *See* Baldwin, *supra* note 3, at 29–30 (discussing the trade-offs between invasive and noninvasive BMIs).
[94] *See generally* U.S. Food & Drug Admin., Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations: Draft Guidance for Industry and Food and Drug Administration Staff 1 (2019) (reviewing draft guidance for BMIs).
[95] *Id.*
[96] Dasgupta, *supra* note 18, at 200.
[97] *Id.*
[98] *See* Ienca et al., *supra* note 12, at 805–07 (highlighting certain direct-to-consumer neurotechnologies available in different countries).
[99] *See* Perry, *supra* note 13 (indicating Facebook has announced efforts towards developing a BMI).

### *B. FTC Adjudication*

The Federal Trade Commission Act grants the FTC authority to oversee consumer protection issues in the United States.[100] In comparison to the FDA, the FTC adopts a regulatory strategy primarily defined by adjudication rather than rulemaking.[101] The FTC wields the broad standard of "unfair or deceptive acts or practices,"[102] which it applies to actions by industry in a case-by-case basis through adjudication. This flexibility in enforcement provides the FTC with notable discretion and, along with a handful of new statutory authorities, has allowed it to expand its jurisdiction to include data privacy.[103] However, the agency has limited resources to use in pursuing consumer protection violations, restricting the practical scope of its oversight.[104] Over time, the FTC, through its adjudication and settlement activities, has incorporated data privacy and security within the scope of consumer protection issues that it regulates, and has built a healthy log of adjudicative "precedents" to draw from in addressing data protection violations.[105] Notably, the FTC has begun more recent efforts in enforcing companies' commitments to voluntary self-regulation in the area of data protection, expanding the agency's reach into privacy and consumer protection.[106] As such, the FTC's previously existing authorizations grant it the ability to adjudicate claims made by BMI developers, evaluating industry claims for "unfair or deceptive acts or practices."[107]

The FTC can review claims which may be false, incomplete, or misleading, including claims about the degree and type of data privacy and cybersecurity protections offered by a product or service.[108] This authority

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[100] Federal Trade Commission Act, 15 U.S.C. §§ 41–58 (2020).
[101] Daniel J. Solove & Woodrow Hartzog, *The FTC and the New Common Law of Privacy*, 114 COLUM. L. REV. 583, 620–21 (2014).
[102] Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (2020) ("Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.").
[103] *See* Solove & Hartzog, *supra* note 100, at 598–606 (depicting how the FTC has come to regulate privacy in the U.S.).
[104] *Id.* at 605 (noting "the FTC lacks general authority to issue civil penalties" and more often "is limited to fining companies under a contempt action for violating a settlement order").
[105] *See generally id.* (describing the breadth of FTC's adjudicative jurisprudence and its expansion over the past 15 years).
[106] Wendell Wallach & Gary Marchant, *Towards the Agile and Comprehensive International Governance of AI and Robotics*, 107 PROC. IEEE 505, 506 (2019).
[107] Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (2020).
[108] *See* Solove & Hartzog, *supra* note 101 at 627–48 (describing the agency's "jurisprudence" on deception, unfairness, and other statutory rules, including on matters of data security and improper use or collection of consumer data).

enables the FTC to go further than the FDA by allowing it to review nonmedical claims made by neurotechnological products, including DTC products.[109] Even if such claims are related to general "wellness," rather than making express health claims subject to FDA purview, they could still fall under the FTC's wide scope of authority.[110]

### *C. Federal Court Deference*

The federal courts play a significant role in the regulatory environment through their judicial review of administrative agency actions. In this context, judicial review includes determining whether an administrative agency acted beyond its statutory authority or complied with substantive and procedural requirements for taking regulatory action.[111] Beyond reviewing new rules, courts can also review agency efforts to extend the scope of their existing jurisdiction to new areas.[112] This can involve both reviewing new rules for products which the agency already regulates, or reviewing standards for new products that agencies have not regulated in the past. For example, in 2000 the Supreme Court reviewed and denied the FDA's moves to regulate tobacco under its authority to oversee drugs or devices.[113] The courts therefore could add to the regulatory environment for BMIs by placing an additional check on agency rulemaking authority.[114]

Over decades, the Supreme Court has established a robust doctrinal method of interpreting agency rules and conduct.[115] The *Chevron* and *Auer* doctrines generally direct federal courts to uphold agency rules or an agency's interpretation of its rules, respectively, when such rules are based on a reasonable interpretation of the underlying, but ambiguous, legal

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[109] *See* Dasgupta, *supra* note 18, at 200–01 (highlighting the differences between FDA and FTC jurisdiction and noting two cases of the FTC taking enforcement action against neurotechnology developers).
[110] *Id.*
[111] Kent Barnett & Christopher J. Walker, *Chevron in the Circuit Courts*, 116 MICH. L. REV. 1, 1 (2017).
[112] *See, e.g.*, City of Arlington v. FCC, 133 S. Ct. 1863 (2013).
[113] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 1294 (2000).
[114] Further, regulatory policymakers are generally aware of judicial deference doctrines, which affects how new rules are constructed; *see generally* Christopher J. Walker, *Chevron Inside the Regulatory State: An Empirical Assessment*, 83 FORDHAM L. REV. 703, 703–04 (2014).
[115] Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837, 843 (1984); United States v. Mead Corp., 533 U.S. 218, 234 (2001); City of Arlington v. FCC, 569 U.S. 1863, 1874–75 (2013).

authority.[116] Judicial deference enables agencies such as the FDA to create new rules for novel and emerging issues or products without needing to receive additional delegations from Congress to handle them.[117] In the case of neurotechnological products, the FDA must interpret its existing medical device authority to justify oversight of both hardware and software, including cybersecurity issues.[118] The agency has already issued repeated guidance on software,[119] based on their medical device rules, yet these standards have not undergone rigorous judicial review and could be subject to *Auer* scrutiny in the future.[120] The FTC relies primarily on adjudication, which remains susceptible to judicial review.[121] However, empirical studies have shown that adjudications fare better in *Chevron* suits than notice and comment rulemaking,[122] suggesting that the FTC's regulatory decisions on neurotechnological products will be less contestable.

Given that the integrity of some of the FDA's standards on BMI products may rely on federal courts applying some form of *Auer* deference, as those standards have largely been issued as guidance rather than through classic rulemaking, the fate of the *Auer* doctrine becomes critical.[123] Both *Auer* and *Chevron* have faced increasing criticism from scholars and decisionmakers in the past decade, which has placed their durability on uncertain ground.[124] In *Kisor v. Wilke*, the Supreme Court recently left the *Auer* doctrine intact by a slim 5-4 majority, though qualified existing guardrails on the doctrine and affirmed that agencies should consider whether and how much stakeholders have relied on a particular interpretation of a rule.[125] Four justices would have formally overruled *Auer*, even though the Court unanimously supported the outcome in this particular case, because of the perceived bias in favor of

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[116] *See generally Chevron*, 467 U.S. at 843 (giving deference to agency interpretation of ambiguous laws); Auer v. Robbins, 519 U.S. 452, 461 (1997) (giving agencies a high level of deference in interpreting their own regulations).
[117] *Id.*
[118] *See generally* U.S. FOOD & DRUG ADMIN., *supra* note 94 (describing the FDA's current stance on and efforts at interpreting how it will aim to apply its statutory authority to BMIs).
[119] *Guidances with Digital Health Content,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/digital-health/guidances-digital-health-content (last visited Oct. 1, 2020).
[120] *Auer*, 519 U.S. at 461 (federal courts generally recognize an agency's interpretation of its own rules as "controlling unless plainly erroneous or inconsistent with the regulation").
[121] *See* Solove & Hartzog, *supra* note 101, at 613.
[122] Barnett & Walker, *supra* note 111, at 7.
[123] *See Auer*, 519 U.S. at 461.
[124] *See generally, e.g.*, Christopher J. Walker, *Attacking Auer and Chevron Deference: A Literature Review*, GEO. J.L. & PUB. POL'Y 103, 104–20 (2018).
[125] Kisor v. Wilke, 139 S. Ct. 2400, 2416–18, 2424 (2019).

regulatory agencies that the doctrine creates.[126] Chief Justice Roberts was the swing vote in upholding the *Auer* doctrine, though he emphasized the doctrine's limitations, suggesting an openness to upend *Auer* in the future.[127]

Efforts by the FDA to extend its medical device authority to BMIs with new rules and guidance will be reviewable by courts, but whether courts become involved will ultimately depend on whether litigants such as industry members challenge these efforts. Politically, the FDA enjoys relatively stable public support, though its reputation still fluctuates across constituencies and time.[128] Recently, however, the agency has come under fire for both overburdensome and lax responses to diagnostic testing and therapeutics during the COVID-19 pandemic.[129] Should public support for the FDA collapse, neurotechnology developers could become more prone to litigate FDA efforts to increase regulation of their industry. Unfavorable judicial review of the agency's decisions to increase regulatory scrutiny on emerging BMIs could then become more likely and lead to further destabilization of the regulatory environment for these innovative products.[130] Should courts limit the FDA's oversight of BMIs, the FTC could only fill in a small fraction of the gap left regarding medical devices, given the broad differences in the scope of the two agencies' respective authorities.[131] Instead, absent further legislation, this situation could see some safety and effectiveness regulation consigned to market forces and voluntary obligations, potentially jeopardizing the effectiveness of oversight.[132]

### *D. Fragmented Regulatory Governance for BMIs*

The presence of multiple administrative agencies and types of substantive regulation for BMIs creates the risk of fragmented and duplicative regulation,

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[126] *See id.* (Gorsuch, J., concurring; Kavanaugh, J., concurring).
[127] *Id.* at 2024 (Roberts, J., concurrence).
[128] *See* CARPENTER, *supra* note 77, at 11–15 (illustrating how the FDA relies on pharmaceutical companies and physicians for support).
[129] The Editorial Board, *The Epic Failure of Coronavirus Testing in America*, N.Y. TIMES (Mar. 19, 2020), https://www.nytimes.com/2020/03/19/opinion/coronavirus-testing.html; Laurie McGinley, *FDA Steps Up Scrutiny of Coronavirus Antibody Tests to Ensure Accuracy*, WASH. POST. (May 4, 2020), https://www.washingtonpost.com/health/2020/05/04/fda-steps-up-scrutiny-coronavirus-antibody-tests-ensure-accuracy/.
[130] James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 939–40 (2008).
[131] This FDA-FTC overlap may include, for instance, cybersecurity; *see*, *Cybersecurity*, U.S. FOOD & DRUG ADMIN. (Oct. 13, 2020), https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity.
[132] *See* O'Reilly, *supra* note 130, at 940.

if not properly coordinated.[133] Not only are administrative agencies such as the FDA and FTC involved, but also state and federal courts and lawmakers.[134] Other public entities, including the U.S. Patent and Trademark Office ("USPTO") or Consumer Products Safety Commission ("CPSC"), could contribute to this fragmentation in the future as well, although USPTO oversight may be less direct and CPSC regulation appears unlikely to trigger.[135] Fragmentation results from the involvement of multiple decisionmakers with each having only partial authority, expertise, and information to address a regulatory problem, rather than one centralized decisionmaker with a comprehensive mandate and high capacity.[136]

The resulting fragmentation from these gaps could create three types of problems in the regulatory governance of neurotechnologies like BMIs. First, overlap between agencies reviewing the same products could create additional costs on industry actors from inconsistent or duplicative norms, increasing both the financial costs and amount of time required for private actors to pass regulatory approval and remain on the market.[137] The FDA and FTC both have authority over health- and safety-related claims of BMIs and will both have capacity to review the cybersecurity protections, creating potentially costly regulatory overlap.[138] Second, and similarly, bifurcated jurisdiction could lead to different and inconsistent regulatory standards applied to the same problem.[139] The FDA wields a standard of "safety and effectiveness" for medical device performance while the FTC applies an "unfair or deceptive acts or practices" standard to business activities such as communication and marketing,[140] which could create two different sets of regulatory norms that must be met. Not only can this place costs on

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[133] Scott, *supra* note 76, at 330–31.

[134] Of course, lawmakers and courts at the state level cannot create rules conflicting with federal ones, such as FDA regulations, although defining the scope of federal preemption can be contentious. *See generally* Catherine M. Sharkey, *Federalism in Action: FDA Regulation Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013 (2007).

[135] *See* Dasgupta, *supra* note 74, at 249–50; Christi J. Guerrini et al., *The Rise of the Ethical License*, 35 NATURE BIOTECHNOLOGY 22, 22–23 (2017) (discussing how and why the U.S. Patent and Trademark Office is getting involved in the oversight of emerging neurological products).

[136] Julia Black, *Critical Reflections on Regulation*, 27 AUSTL. J.L. PHIL. 1, 5 (2002).

[137] Jason Marisam, *Duplicative Delegations*, 63 ADMIN. L. REV. 181, 182–84 (2014).

[138] *See generally* Dasgupta, *supra* note 18 (describing the regulatory approaches and providing examples of how the FDA and FTC could each regulate neurotechnologies like BMIs).

[139] Marisam, *supra* note 137.

[140] Dasgupta, *supra* note 74, at 246–47, 249.

industry,[141] but federal agencies may waste resources by developing similar expertise independent from each other, rather than by collaboratively sharing experiences. Third, the partial authority of each regulator in the neurotechnological landscape will likely result in governance gaps, as some risks and problems may fall outside of each entity's perceived or actual scope of authority.[142] In particular, using BMIs to enhance cognitive or physical performance presents novel regulatory challenges which neither the FDA nor the FTC have meaningfully addressed in the past and may lack authority over entirely.[143]

Significant fragmentation risks raising the costs of regulation for public and private actors, lowering the effectiveness of oversight, and losing public legitimacy by presenting duplicative requirements and slowing access to potentially valuable innovation.[144] Resolving or mitigating fragmentation of oversight for BMIs will require strategies to bring regulators together, potentially alongside private and civil society actors, to ensure that regulation can achieve its goals to protect the public without imposing unacceptable costs.

## III. STRATEGIES FOR MANAGING FRAGMENTATION FROM CONVERGENCE

The fragmented regulatory governance scheme for BMIs in the United States could result in both inhibiting innovation or market access for these promising new products and overlooking critical risks, while using scarce regulatory resources inefficiently. Alleviating these oversight issues will require thoughtfully engaging legal and political tools to stimulate and coordinate activity by the FDA, FTC, and other public bodies without rendering judicial resolution necessary. Successful coordination will be critical to generating robust, responsive, and efficient regulation for this site of technological convergence. Part III will proceed by considering tools and institutions that can be leveraged to promote greater regulatory effectiveness and efficiency through early action and collaboration.

### *A. Interagency Coordination: Tools and Institutions*

Multiple federal agencies can hold regulatory authority which overlaps, creating potential inefficiencies and gaps in the governance of a shared

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[141] *Id.* at 252.
[142] *See generally* Marisam, *supra* note 137 (discussing the problems of duplicative delegation).
[143] *See* Wexler & Reiner, *supra* note 5, at 235.
[144] *See* Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1209–10 (2012).

regulatory space.[145] Consolidating different agencies or subagencies into a larger department or other administrative unit provides one way to address fragmentation issues.[146] Perhaps the most notable recent example is the Bush Administration crafting the Department of Homeland Security in 2002 by fusing multiple agencies that were previously housed in other departments.[147] However, legal and social scholars have illustrated how consolidation cannot guarantee that fragmentation will not continue within the new agency, undermining the rationale for consolidation.[148] Instead, recent literature suggests that coordinating various federal agencies with similar jurisdiction offers the most effective solution to fragmentation.[149]

Coordinating agencies requires understanding the "toolbox" of available coordination solutions and which particular institutions can most effectively wield those tools.[150] These tools can involve (1) interagency consultation, whether voluntarily initiated by agencies or externally required, (2) memoranda of understanding ("MOU") or other agreements between agencies on how to manage a shared space, and (3) joint policymaking, such as co-creating and issuing rules.[151] For BMIs, each of these tools could provide value in coordinating the FDA and FTC in their endeavors. First, interagency consultation should provide opportunities for regulators at each agency to communicate with each other about their priorities, data collected,

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[145] *See generally* Gersen, *supra* note 20 (discussing problems that arise with overlapping and underlapping authority).

[146] For example, Congress has previously requested reports illustrating where federal programs overlap and recommendations on whether and how to consolidate those programs. *See generally* U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-318SP, OPPORTUNITIES TO REDUCE POTENTIAL DUPLICATION IN GOVERNMENT PROGRAMS, SAVE TAX DOLLARS, AND ENHANCE REVENUE (2011), https://www.gao.gov/assets/320/315920.pdf.

[147] *See Who Joined DHS*, DEP'T HOMELAND SEC. (Sept. 15, 2015), https://www.dhs.gov/who-joined-dhs (outlining the history of the DHS and why it was created).

[148] *See* Freeman & Rossi, *supra* note 144, at 1133, 1151–55 (reviewing legal and political barriers to consolidation and arguing that consolidation can "convert an *inter*agency coordination problem into an *intra*-agency problem."); *see generally* Jennifer Nou, *Intra-Agency Coordination*, 129 HARV. L. REV. 421, 424–27 (2015) (illustrating how coordination issues can arise even within a single agency).

[149] *See generally, e.g.*, Keith Bradley, *The Design of Agency Interactions*, 111 COLUM. L. REV. 745, 745 (2011) (exploring how interagency cooperation can lead to positive policy outcomes, especially in the context of complex "orthogonal-interests" problems); Freeman & Rossi, *supra* note 144 at 1133 (arguing the strengths of coordination outweigh those of consolidation and providing a set of tools for effective coordination); Marisam, *supra* note 137 (discussing duplicative delegation and how to leverage it towards beneficial policy outcomes).

[150] Freeman & Rossi, *supra* note 144, at 1209–11.

[151] *See id.* at 1155–73 (taxonomizing and describing several legal and organizational instruments available to coordinate multiple agencies within a shared regulatory space).

and lessons learned to form a more robust and coordinated agenda.[152] Simply by consulting each other, the FDA and FTC could share experiences and technical expertise in regulating BMIs, especially on the most complex issues arising from technological convergence. By discussing successes and failures in handling BMIs, the two agencies could collaboratively develop regulatory capacity for BMIs rather than each independently spending their own resources, and taxpayer dollars, to develop similar expertise.

Second, interagency agreements such as MOUs can bring agencies together to negotiate the scope of each of their authorities and activities in a shared regulatory space, which can reduce overlapping activity and administrative costs.[153] Agreements between the FDA and FTC on how to collectively regulate BMIs could provide significant clarity and predictability, both to regulators and to private industry, leading to a more stable environment for innovation and well-balanced oversight.[154] Such MOUs would not be unprecedented.[155] The FDA's subunit for drugs and the FTC have an existing MOU on prescription drug labeling oversight,[156] so creating another specialized agreement between the FDA's medical device authority and the FTC has clear precedent. The existing, working MOU between the agencies could lower transaction costs in establishing a new one,[157] as some of the same staff may be involved in establishing a new MOU over BMIs, particularly on the FTC side.

Third, joint policymaking sees agencies come together to collectively issue rules or guidance to assist regulated entities with compliance in a complex area.[158] Agencies may organically decide to make policy together or Congress may require this through legislation.[159] However, joint rulemaking may prove less effective in the particular case of regulating BMIs, because the FDA generally favors rulemaking while the FTC generally prefers adjudication in policymaking.[160] Yet, providing predictable and effective BMI regulation could still involve the FDA closely consulting

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[152] *Id.* at 1157, 1184, 1192.
[153] *Id.* at 1161–65.
[154] *See, e.g.*, Marisam *supra* note 137, at 212–13.
[155] *Id.*
[156] Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration Concerning Exchange of Information, U.S. FOOD & DRUG ADMIN. (Dec. 15, 2017) https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003.
[157] *See* Freeman & Rossi, *supra* note 144, at 1192 ("MOUs are easier to negotiate, and more likely to be implemented, in situations where the agencies recognize the need for coordination and possess the resources to devote to it").
[158] *Id.* at 1165–69.
[159] *Id.*
[160] *See* Solove & Hartzog, *supra* note 101, at 620–21.

with the FTC before issuing rules or guidance and the FTC closely consulting the FDA during or prior to adjudication.

To be sure, interagency coordination and collaboration efforts can pose normative and statutory overreach issues when these activities empower agencies beyond what Congress may have intended when delegating power to individual agencies.[161] However, adopting a functionalist point of view, agencies "pooling powers" may be effective and normatively desirable for responding to emerging technologies, such as BMIs, when Congress fails to appropriately direct regulatory policy.[162] This strategy can even include agencies transferring their authority to adjudicate certain subject matters between each other.[163] Technological convergence will spark issues that no one agency can oversee with their current jurisdiction and expertise, such as cognitive enhancement or sensitive neuroprivacy matters.[164] Accordingly, the FDA and FTC working to expand their collective regulatory power may be desirable in both resolving fragmented governance for BMIs and working to close governance gaps to protect the public health and wellbeing.[165]

Different government institutions can apply these coordination tools, including the agencies themselves, Congress using their political or lawmaking power to facilitate coordination, or the Executive Office of the President ("EOP") convening different federal agencies.[166] Each institution has strengths and weaknesses in how well and when they can perform coordination functions.[167] In resolving fragmented regulatory governance of BMIs, however, Congress and interagency engagements have significant advantages over the EOP.[168] The Office of Budget and Management ("OMB"), an EOP subagency, has made efforts to encourage agency coordination in the governance of AI,[169] which neurotechnologies including

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[161] Daphna Renan, *Pooling Powers*, 115 COLUM. L. REV. 211, 275–85 (2015).
[162] *Id.*
[163] *See generally* Bijal Shah, *Interagency Transfers of Adjudicative Authority*, 34 YALE J. REG. 279, 281–91 (2017) (describing how, at times, "agencies make agreements in order to transfer their entire jurisdiction to adjudicate administrative decisions to other agencies").
[164] *See generally* Garden et al., *supra* note 8, at 18–19 (identifying multiple risks and regulatory concerns raised by BMIs).
[165] *See* Renan, *supra* note 161, at 239–40.
[166] *See* Walter G. Johnson, *Conflict Over Cell-Based Meat: Who Should Coordinate Agencies in U.S. Biotechnology Regulation?*, 74 FOOD & DRUG L.J. 478, 489–92, 499–500 (2019) (analyzing "the strengths and weaknesses of varying public institutions in resolving jurisdictional disputes over novel biotechnologies").
[167] *Id.*
[168] *Id.*
[169] *Technology & Science*, OFF. BUDGET & MGMT. (2020), https://www.gao.gov/technology_and_science [hereinafter *Technology*].

BMIs use.[170] However, the federal regulation of BMIs involves an independent agency, the FTC, which may limit the utility and legitimacy of the EOP and the President to coordinate oversight here.[171] Instead, voluntary FDA-FTC engagement or Congressional nudges or mandates to collaborate may instead provide more pragmatic and less politically fraught institutions for coordination, as Presidential attempts to direct an independent agency could generate controversy.[172]

### *B. Technology Assessment for Policymakers*

A second and complementary strategy for managing the fragmentation from convergent BMI technologies involves equipping policymakers with the information and tools to understand and respond to BMIs. Technology assessment ("TA") programs are designed to inform policymakers about various dimensions of technology policy issues by synthesizing research in social science, policy, natural science, and engineering.[173] Both interagency and Congressionally led coordination will require policymakers to anticipate the potential value of BMIs and the hazards of fragmented regulation and take proactive measures to use coordination tools described above. Given that BMIs are still emerging, and that agencies and Congress have finite time and resources when setting an agenda, successful coordination may necessitate conveying the urgency of early action to policymakers.

The first step toward policymakers having the information they need is providing expert advice directly to political decisionmakers in Congress

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[170] *See* THE U.K. ROYAL SOC'Y, *supra* note 1, at 49 (discussing the advantages AI may bring to neurotechnologies).

[171] *See* Bijal Shah, *Executive (Agency) Administration*, 72 STAN. L. REV. 641, 685–89 (2020) (explaining the Trump Administration has indicated some interest in attempting to extend OMB oversight of agency rulemaking to independent agencies, though independent agency adjudication, favored by the FTC, has received relatively little attention); *see also* OFF. BUDGET & MGMT., *supra* note 169 (describing the guidance to all federal agencies to inform and coordinate the development of regulatory approaches to artificial intelligence).

[172] *See, e.g.*, Elena Kagan, *Presidential Administration*, 114 Harv. L. Rev. 2245, 2327–28 (2001) ("In then delegating power to [an independent] agency (rather than to a counterpart in the executive branch), Congress must be thought to intend the exercise of that power to be independent [from the Executive].").

[173] *See* David H. Guston & Daniel Sarewitz, *Real-Time Technology Assessment*, 24 TECH. SOC. 93, 93–95 (2002) (proposing a research program integrating science and policy research utilizing real-time technology assessment ("TA") For the purpose of this article, TA is used as a general term also incorporating newer frameworks for assessing technologies and policy options such as ethical, social, and legal implications (ELSI) or, more recently, responsible innovation); *see, e.g.*, Daniel Sarewitz et al., *This Won't Hurt a Bit: Assessing and Governing Rapidly Advancing Technologies in a Democracy*, WOODROW WILSON INT'L CTR. SCHOLARS (Dec. 2005).

through dedicated Congressional agencies, whether providing services to specific committees or the full body of Congress. Unfortunately, Congress has limited its own TA resources in past decades.[174] The Office of Technology Assessment ("OTA") was a Congressional agency that sought to provide unbiased reviews of how novel technologies function and the social and economic policy issues they might trigger.[175] Beginning in 1972,[176] the OTA produced forward-looking TA reports for Congress on issues ranging from genetic testing to the value of nurse practitioners,[177] long before these issues became significant policy concerns in the Genetic Information Nondiscrimination Act ("GINA") or Affordable Care Act ("ACA"). Though the OTA provides one model for building lawmakers' technical capacity, the agency was defunded in 1995 when Congressional leaders sought to limit their budget.[178] Since the mid-1990s, Congressional technical expertise has consolidated in the offices of individual leaders in Congress, rather than being readily accessible to Congress as a whole.[179] The lack of reliable and authoritative technical policy resources to most lawmakers has undermined Congress' knowledge of and capacity to address issues of science and technology, including BMIs, and likely weakened Congress' role in responding to COVID-19.[180] While many proposals to create a new OTA

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[174] *See* Grant Tudor & Justin Warner, *Congress Should Revive the Office of Technology Assessment. Here's How to Do It*, BROOKINGS (Dec. 18, 2019), https://www.brookings.edu/blog/fixgov/2019/12/18/congress-should-revive-the-office-of-technology-assessment-heres-how-to-do-it/.

[175] Technology Assessment Act, Pub. L. No. 92-484, 86 Stat. 797 (1972).

[176] *Id.*

[177] *See Office of Technology Assessment Reports Collection*, GEORGETOWN UNIV., https://repository.library.georgetown.edu/handle/10822/707927 (last visited Oct. 1, 2020) (containing a repository of these works).

[178] Tudor & Warner, *supra* note 174.

[179] *See* M. Anthony Mills & Robert Cook-Deegan, *Where's Congress? Don't Just Blame Trump for the Coronavirus Catastrophe*, ISSUES SCI. & TECH. (Apr. 16, 2020), https://issues.org/congress-pandemic-response/ (noting the "staff reductions—especially in [Congressional] agencies and committees with science and technology jurisdiction" as well as that "staffing has increased elsewhere, including the 'leadership' offices of the House." Instead Congress receives much information on scientific and technical issues "exactly the same way it gets all its information: from a cacophony of competing voices in the forms of lobbyists, think tanks, policy shops, advocacy groups, media reports, agency officials, interested parties and even, from time to time, the public"); Michael Rodemeyer, *Back to the Future: Revisiting OTA Ten Years Later*, WOODROW WILSON INT'L CTR. FOR SCHOLARS (Dec. 2005).

[180] *See id.* (depicting some shortcomings of the current state of technical expertise of Congress).

have surfaced since its demise, opinions diverge on how to reconstruct the institution.[181]

By informing lawmakers of the different issues and interests at stake with an emerging technology, Congress may become more involved in proactively taking steps to resolve potential issues. In BMIs, timely and nonpartisan TA could enable and empower Congress to make decisions about the fragmentation in BMI regulatory governance, thereby striking a democratically backed balance between innovation and risk management. Instead of aiming to reconstruct an old Congressional agency or create a new one for TA services, an existing Congressional agency could be used to provide reliable and authoritative TA to lawmakers. In recent years, the Government Accountability Office ("GAO") has begun to build their TA capacity and resources to fill the void of nonpartisan technical advice for policymakers.[182] The GAO has offered TA services on a range of timely issues from "deepfakes" to COVID-19.[183]

The Congressional Research Service ("CRS") also holds significant technical expertise and provides brief or in-depth reports to lawmakers upon their request.[184] Only two CRS reports to date mention BMIs, and this merely occurs within broader reports on export controls.[185] While the CRS contains significant technical expertise and access to the resources of the Library of Congress, lawmakers must request reports from the agency.[186] The potential for the CRS to successfully advise Congress on matters of BMI regulation and governance therefore depends on lawmakers' own interests in learning about new neurotechnologies and their policy dimensions as CRS only researches as directed by members of Congress.

Similarly, the National Academies of Sciences, Engineering, and Medicine ("NASEM") represents a quasi-government institution of technical experts from whom Congress or agencies can request reports on emerging

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[181] *See, e.g.*, Tudor & Warner, *supra* note 174 (recounting the defunding of the OTA).
[182] *Technology*, *supra* note 169.
[183] *Id.*
[184] *See About CRS*, U.S. CONG., RES. SERV. (Apr. 16, 2019), https://www.loc.gov/crsinfo/about/ (describing the services offered by CRS to Congress).
[185] *Export Controls: Key Challenges*, U.S. CONG. RES. SERV. (Jan. 14, 2021), https://crsreports.congress.gov/product/pdf/IF/IF11154; *Export Controls: New Challenges*, U.S. CONG. RES. SERV., (Mar. 22, 2019), https://crsreports.congress.gov/product/pdf/IF/IF11154 (listing "brain-computer interfaces," a virtually synonymous term for BMIs, as one of several emerging technologies "essential to U.S. national security").
[186] *About CRS*, *supra* note 184.

issues.[187] While NASEM has some capacity to set its own agenda, producing a report on BMIs and the issues of fragmented regulation may gain the most traction with lawmakers if they themselves prioritized this policy challenge and responded by requesting the report from NASEM.

Attracting the attention of political actors may in turn require public awareness or advocacy about the importance of striking the right balance in BMI regulation. Political science scholar John Kingdon's theory of "policy windows" argues that political interest in any given policy issue waxes and wanes, and meaningful legislative action on an issue often requires an event or significant effort to open a window of opportunity.[188] However, waiting until a notable event such as a regulatory failure or national security concern arises would not provide ideal conditions for resolving the complex fragmented regulatory environment surrounding BMIs.[189] Enacting statutes in the wake of a crisis may present risks such as overreacting to the event or drafting regulation which does not adequately balance the complex interests and issues involved.[190]

In the absence of a scandal or government failure, gaining the attention of political decisionmakers will require other strategies, potentially including building a more general public awareness of the important benefits and risks of BMIs through science communication. The field of science communication aims to provide the public with easily digestible information, consistent with their values, to inform individual decision-making and political stances.[191] Research and policy initiatives on how to propel accessible information on BMIs and how its governance aligns with public values may inspire public support for resolving fragmented regulatory issues early.[192] Efforts at public engagement, which educate lay members of the public about a technical policy issue and then solicit their opinions and

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[187] *About Us*, U.S. NAT'L ACAD. SCI. ENG'G & MED., https://www.nationalacademies.org/about (last visited Oct. 1, 2020) ("many of our activities are requested and funded by Congress and federal agencies").

[188] JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES 166–94 (2d ed. 1995).

[189] *See* Walter G. Johnson & Gary E. Marchant, *Legislating in the Time of a Pandemic: Window of Opportunity or Invitation for Recklessness?*, 7 J.L. & BIOSCIENCES at 1, 2 (2020) (outlining the U.S. regulatory failure in the COVID-19 pandemic over diagnostic testing to show the challenges of enacting regulatory reform during times of crisis).

[190] *Id.*

[191] *See* U.S. NAT'L ACAD. OF SCI. ENG'G & MED., COMMUNICATING SCIENCE EFFECTIVELY: A RESEARCH AGENDA 1, 3, 5–7 (2017) (exploring issues in communicating science effectively).

[192] *Id.*

stances,[193] could assist in both communicating BMI related-issues to the public and in bringing public interest on BMIs to the attention of policymakers in Congress and administrative agencies.[194]

Civil society and interest groups can also play a role in educating the public and in bringing public concerns to lawmakers.[195] Interest groups striving to advance BMI policy, such as patient advocacy organizations, will benefit from calling both lawmakers and regulators' attention to statements from authoritative national or global institutions which have called for policy action on BMIs. Notably, the OECD issued a recommendation to its member states, which includes the Unites States, to take proactive steps toward ensuring that neurotechnologies such as BMIs have appropriate governance.[196] The OECD recommendation and any similar statements may help in legitimizing civil society organizations' calls to lawmakers to address the fragmentation in BMI regulatory governance.[197] Further, while regulatory agencies typically have internal capacity to build expertise on new technologies such as BMIs, they still might choose not to prioritize BMIs or interagency coordination for more comprehensive, effective policy. Especially with the potential coordination challenges the FDA and FTC may face given their overlapping mandates and divergent expertise, action from nonstate actors could help place coordination activities for BMIs on regulatory and legislative agendas. Both civil society organizations and the neurotechnology industry could play a role in advocating for the importance of addressing BMIs as a collective priority to the FDA and FTC.

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[193] See Lisa M. PytlikZillig & Alan J. Tomkins, *Public Engagement for Informing Science and Technology Policy: What Do We Know, What Do We Need to Know, and How Will We Get There?*, 28 REV. PUB. POL'Y RES. 197, 197–201 (2011) (describing how public engagement can be critical for general education and knowledge about impacts of scientific research and technological development).

[194] *Id.*

[195] *Id.*

[196] *See* ORG. FOR ECON. CO-OPERATION & DEV., *supra* note 70, at 6–9 (recommending "Members and non-Members . . . promote and implement . . . principles for responsible innovation in neurotechnology," including by promoting safety in, privacy around, and access to innovation in neurotechnologies).

[197] *See, e.g.*, Kenneth W. Abbott et al., *Soft Law Oversight Mechanisms for Nanotechnology*, 52 JURIMETRICS J. 279, 290 (2012) (describing how civil society activities have influenced government approaches to other emerging technologies, such as with nanotechnologies); *see also* BRIDGET M. HUTTER & JOAN O'MAHONY, THE ROLE OF CIVIL SOCIETY ORGANIZATIONS IN REGULATING BUSINESS 8, 12 (Ctr. Analysis Risk & Reg. London Sch. Econ. & Pol. Sci. 2006) (discussing the role of civil society organizations as regulators).

## CONCLUSION

The realities of technological convergence, and the new risks it can create, challenge the notion that policymakers and regulatory frameworks can treat convergent emerging technologies in isolation.[198] This article anticipates the ways in which combining the power and potential of neuroscience, big data, AI, and engineering to create BMIs can have a multiplicative effect on both social benefits and risks, ultimately compounding the "pacing problem."[199] Furthermore, convergence can create or exacerbate already existing regulatory fragmentation problems by forcing two or more agencies into a novel, shared regulatory space.

The complexities of convergence in BMIs will require a policy response defined by collaboration and early action. Lawmakers and regulators will need to coordinate activities at the FDA and FTC to expedite expertise building by both agencies, prevent the creation of duplicative standards hostile to responsible BMI development, and manage novel risks that neither agency could address alone. Successful coordination will rely not only on favorable political conditions and support from the judiciary, but also on policymaker and public awareness of the importance of neurotechnological governance. Efforts to provide TA to decisionmakers and communicate science and risk to a diverse public will, in turn, bolster Congressional efforts to take early and informed action on coordinated BMI policy. Although fragmented regulatory governance in the United States may initially struggle to manage convergence in BMIs, these strategies offer a first step towards constructing a more robust policy approach to promote responsible development and use of BMIs.

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[198] *See* Park, *supra* note 34, at 1 (describing how regulation of converging technologies can be difficult because "delineating which policy authorizes which government agency to apply which standards to regulate which industry is no longer simple and straightforward."); *see also* MAYNARD, *supra* note 9 (arguing that converging technologies can lead to unanticipated problems and unintended consequences).

[199] *See* MARCHANT, *supra* note 63 (defining "the pacing problem").