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ABSTRACT

The expanding use of neurotechnologies in consumer products increases the risks to human rights such as autonomy and free thought. While potentially beneficial in clinical applications, technologies such as brain implants and EEG-enabled wearable devices pose serious concerns about mental and psychological manipulation of human beings. In the US in particular, law and policy are lagging behind technical developments, thereby increasing the risks of abuse and misuse from commercial neurotechnologies. This article focuses on commercial neurotechnologies, which are distinct from medical neurotechnologies for clinical diagnoses, and seeks to guard against human rights risks to users by overcoming that regulatory gap. The article contends that harm to users' free thought and autonomy from consumer neurotechnologies are foreseeable and known but obscured by market incentives and by the technologies' dual, therapeutic purpose, and it argues that preemptory regulation is both necessary and supported by precedent. To that end, an analysis of precedents from institutions of governance such as the precautionary principle, moral utility, and human rights, along with current initiatives in other jurisdictions (Chile, Spain, the UN), are provided. This analysis points to possible broad and narrow approaches for minimizing the risks from neurotechnologies. Specifically, the article stipulates that the expansion of patent law based on the moral utility doctrine, in combination

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with enhanced enforcement by FTC and lobbying by the neurorights community, might to be the most promising approach in the U.S.

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I. INTRODUCTION

By their nature, emergent technologies bring potential for human advancement, but they also carry risks that are often knowable and foreseeable to those developing them, while obscure or obscured to users. Dual or multiple use technologies—those that are utilized differently (and typically to different effect) in different contexts—present an additional complication that opens users to risks of harm by blurring the lines between what is helpful or threatening, depending on the circumstance. A critical example is neurotechnologies and other brain-computer interfacing technologies (BCIs), which show tremendous potential in clinical use to improve the lives of those with neurological disorders. However, when these same technologies are utilized in consumer products, such as extended reality (XR) headsets, the blurred line between medical/non-medical and healthy/non-healthy opens users to foreseeable harms. Legal liability is often avoided by hiding behind consumer consent in the small print of user agreements that few people ever read. This Article contends that harm to users' free thought and autonomy from consumer neurotechnologies is foreseeable and known but obscured by market incentives and the technologies' dual therapeutic and commercial uses. It argues that preemptory regulation is both necessary and supported by precedent. In the absence of regulation, consumer autonomy would almost certainly be subjugated to industry motives and interests.

To illustrate, on October 28, 2021, Facebook CEO Mark Zuckerberg announced a rebranding of the company as Meta, with a vision of life in a metaverse. Almost immediately, numerous Big Tech companies announced similar pledges. Billions of dollars poured into this speculative venture. Suddenly, as if by decree of the Big Tech industry, it became possible that humans will soon conduct work, shop, and engage in any manner of daily activities in extended reality with the aid of wearable, brain-computer interfacing devices. In Mr. Zuckerberg's lengthy 1hr17min VR presentation of Meta, he said just one sentence about Facebook's plan to utilize unused neural pathways in the user's brain to allow them to interact with objects in the Metaverse, but nothing of its potential implications for individual autonomy and social coherence.[1] While declarations of incredulousness over an endeavor to foster synthetic life among graphically simplistic avatars have been plenty,[2] United States (US) federal and state governments have expressed little concern, let alone pushback, about the introduction of neurotechnologies for non-therapeutic use, despite foreseeable risks and uncertainties about the consequences of their commercial use. Thus far, no proposal to regulate against the risk of future harm from neurotechnologies has come before Congress, state houses, or the courts, leaving open the practical

1. META, *The Metaverse and How We'll Build It Together—Connect 2021*, YOUTUBE, at 01:06 (2021), https://www.youtube.com/watch?v=Uvufun6xer8.

2. Sophie Thompson, *Meta Get Roasted for Announcing "legs" in the Metaverse*, INDY100 (Oct. 12, 2022), https://www.indy100.com/science-tech/meta-announces-legs-in-metaverse; Lauren Leffer, *Your Metaverse Memes Almost Made Mark Zuckerberg Feel Human Emotion*, GIZMODO (Oct. 27, 2022), https://gizmodo.com/metaverse-facebook-mark-zuckerberg-memes-1849708985; Paul Tassi, *Does Mark Zuckerberg Not Understand How Bad His Metaverse Looks?*, FORBES (Aug. 17, 2022), https://www.forbes.com/sites/paultassi/2022/08/17/does-mark-zuckerberg-not-understand-how-bad-his-metaverse-looks/?sh=1229a7f937d4; Stephen Moore, *The Metaverse Finally Has Some Legs to Stand On*, MEDIUM (Oct. 12, 2022), https://stephenmoore.medium.com/the-metaverse-finally-has-some-legs-to-stand-on- 69f344b2bcbe; Olivia Petter, *Why Is No One Taking Sexual Harassment In The Metaverse Seriously?*, BRITISH VOGUE (Mar. 20, 2022), https://www.vogue.co.uk/arts-and-lifestyle/article/sexual-assault-in-the-metaverse#:~:text=Similarly%2C%20when%20claims%20of%20sexual,In%20short%3A%20get%20a%20grip.

possibility of harm that might only be remediable by post-hoc adjudication, if it can be remediated at all.

This Article raises and challenges two underlying and reinforcing premises of inevitability (that any and all inventions are desirable and have a right to be made (while users have a choice over whether to use them))[3] and legal lag (that law cannot keep pace with technological development).[4] To address these challenges, the Article analyzes precedents to help understand present threats from the commercial use of neurotechnologies prior to the policy issue of how to preempt foreseeable harm from them. Since precedents link the present moment to the past, examining legal precedent can help identify and analyze possible policy mechanisms to avoid societal harm from neurotechnologies.

II. BCIs: Benefits and Ethical Concerns in Dual Use, Emergent Technologies

Emerging technologies are characteristically novel, have high social utility, and have impacts that are uncertain and ambiguous.[5] It is not uncommon for them to have dual or even multiple uses, making it necessary to weigh and account for their potential benefits and harms. Various approaches exist for doing this, including cost-benefit analysis (CBA), technology assessment (TA), ethical design, and the precautionary principle. Each of these approaches for weighing risks requires that potential harms and unintended consequences are recognized and made transparent before a technology is released, and not hidden behind corporate enthusiasm to realize profits.[6]

Recognition and disclosure of the risks of novel technologies are not uncommon. In fact, ethical concerns have often coemerged alongside novel

3. *See* SHEILA JASANOFF, THE ETHICS OF INVENTION 4-10 (2016) (challenging the misguided belief that technology is an unquestioned good, and so any regulation of invention would be tantamount to impeding the common good); *see* DONALD S. CHISUM ET. AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 6 (1st ed. 1998) (exemplifying by the deontological view in patent law that "one has a natural or moral right to one's creations regardless of the social or competitive consequences").

4. Berger v. State of New York, 388 U.S. 41, 49 (1967) (noting "[t]he law, though jealous of individual privacy, has not kept pace with these advances in scientific knowledge"); *Rosen v. Ciba-Geigy Corp.,* 78 F.3d 316, 319 (7th Cir. 1996) (noting "the court room is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it").

5. For discussions about the practical complications brought by emerging technologies, *see* Justine Pila, *Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies*, 38 NATURE BIOTECHNOLOGY 546, 555 (2020); Andrew Stirling & Josie Coburn, *From CBA to Precautionary Appraisal: Practical Responses to Intractable Problems*, 48 HASTINGS CTR. REP. 78, 78 (2018).

6. *See* Gregory E. Kaebnick & Michael K. Gusmano, *Making Policies about Emerging Technologies*, 48 HASTINGS CTR. REP. S2 (2018); Evie Kendal, *Ethical, Legal and Social Implications of Emerging Technology (ELSIET) Symposium*, 19 BIOETHICAL INQUIRY 363 (2022), for discussions about policy challenges associated with emerging technologies.

technological development. This was true of the development of artificial intelligence (AI), where Norbert Wiener recognized and warned of the potential for misapplications of AI and its dire consequences[7] and of the development of recombinant DNA, where researchers called for its regulation at the same time as they worked on its development.[8] Other emerging technologies like bioprinting technologies provide additional examples of the simultaneous pursuit of technological development alongside contemplation of regulation based on the risks associated with uncertainty about outcomes.[9] Neurotechnological development has inspired similar reactions, where, for at least six years, expert neuroscientists and bioethicists working in the field have warned of risks to human rights.[10] But, so far, their concerns have not affected policy.

The forethought of scientists is central to bringing these concerns to light, but the process of regulating emergent technologies additionally requires that policy analysts gather a contextual understanding of the problems that might emerge from the use of those technologies.[11] In dual or multiple use technologies such as neurotechnologies, which have both tremendously beneficial applications and potentially risky uses, contextual understanding is especially important because over-regulation of beneficial technologies can itself bring harm. This section lays out these ethical dilemmas by describing neurotechnologies and examining the potential risks they pose, in particular, the risks to autonomy and free thought.

A. What are BCIs?

Brain interfacing technologies, brain-computer interaction technologies, and brain-computer interfaces cover a range of technologies that utilize algorithms and/or machine learning (ML) to collect, analyze, and interpret information from neural activity in the brain, and through direct or indirect

7. NORBERT WEINER, CYBERNETICS OR CONTROL AND COMMUNICATION IN THE ANIMAL AND MACHINE 38 (1948).

8. *Recombinant DNA Technologies and Researchers' Responsibilities, 1973-1980*, NAT'L LIBR. OF MED., https://profiles.nlm.nih.gov/spotlight/cd/feature/dna (last visited Oct. 16, 2023).

9. Brooke Siegal, *The Emergence of "New" Organs: A Proposal to Regulate Bioprinting Technology Under the Medical Device Framework*, 24 N.C. J. OF L. & TECH. 117, 122 (2023), https://heinonline.org/HOL/P?h=hein.journals/ncjl24&i=666.

10. *See* Rafael Yuste et al., *Four Ethical Priorities for Neurotechnologies and AI*, 551 NATURE NEWS 159, 160 (Nov. 9, 2017); *see* Marcello Ienca & Roberto Andorno, *Towards New Human Rights in the Age of Neuroscience and Neurotechnology*, 13 LIFE SCI., SOC. POL'Y 1, 23 (2017) (discussing an interview where Rafael Yuste places his concern for neuroethics across his whole 33 year career as a neuroscientist); *see* Leigh Dayton, *Call for Human Rights Protections on Emerging Brain-Computer Interface Technologies*, NATURE INDEX (Mar. 2021), https://www.nature.com/nature-index/news/human-rights-protections-artificial-intelligence-neurorights-brain-computer-interface.

11. *See* Kaebnick & Gusmano, *supra* note 6.

stimulation, have the capacity to interfere with or modify brain activity. Other related brain-interfacing technologies are called BCIs. Neurotechnologies, for instance, are associated with methods to record and read the activity of brain tissue as well as rewrite neural activity. Neurotechnologies necessarily have a hardware component (sensors or microchips), while BCIs may also manipulate mental space through computational interaction (like affective computing methods), with or without a hardware component.[12] As science has evolved, different names have been used to describe these related sets of technologies. Though there are notable differences, references in literature can be found for the use of all terms interchangeably and the discourse on neuroethics is an expression of concern about BCIs and neurotechnologies as a collective body of technologies that affect neural activity.

Neurotechnologies and BCIs are multiple use tools that are employed in medical care as well as being utilized in commercial products and defense systems.[13] The ethics of using neurotechnologies is difficult to parse because different uses carry different ethical implications. As medical tools, neurotechnologies treat physical impairments by using impulses read from the brain to stimulate a machine—as when a disabled person is enabled the control of artificial limbs, wheelchairs, or objects in their environment via the direct reading of their brain activity.[14] There have been great successes in these areas, and neurotechnology research continues with the aim of finding treatment for poorly understood neurological and other chronic disorders such as Alzheimer's, Parkinson's, schizophrenia, depression, and acute brain damage.[15] These scientific advancements rely on research into reading,

12. *See* Leigh R. Hochberg & John P. Donoghue, *Sensors for brain-computer interfaces*, 25 IEEE ENG'G IN MED. AND BIOLOGY MAG. 32, 32 (Sept. - Oct. 2006); *see IEEE Brain Workshop: Future Directions in Consumer Neurotechnology*, https://brain.ieee.org/future-directions-in-consumer- neurotechnology-workshop/2021/ (last visited Oct. 3, 2023); *see* Stephen Rainey et al., *Brain Recording, Mind-Reading, and Neurotechnology: Ethical Issues from Consumer Devices to Brain-Based Speech Decoding*, 26 SCI. ENG. ETHICS 2295, 2295 (2020); A. Y. Paek et al., *Concerns in the Blurred Divisions Between Medical and Consumer Neurotechnology*, 15 IEEE SYS. J. 3069, 3069 (2021).

13. Tim Requarth, *This Is Your Brain. This Is Your Brain as a Weapon.*, FOREIGN POL'Y, https://foreignpolicy.com/2015/09/14/this-is-your-brain-this-is-your-brain-as-a-weapon-darpa-dual-use-neuroscience/ (last visited Oct. 20, 2023).

14. *See* Dayton, *supra* note 10; *see* Beata Jarosiewicz *et al., Virtual Typing by People with Tetraplegia Using a Self-Calibrating Intracortical Brain-Computer Interface*, 7 SCI. TRANSLATIONAL MED. 3, 3 (2015).

15. *See* Oliver Whang, *A Paralyzed Man Can Walk Naturally Again with Brain and Spine Implants*, N.Y. TIMES (May 24, 2023), https://www.nytimes.com/2023/05/24/science/paralysis-brain-implants-ai.html (discussing how scientists have shown the capacity to restore mobility and communication in paralyzed patients by decoding and relaying signals in the brain); *see also* '*Neuroprosthesis' Restores Words to Man with Paralysis*, WORLD ECON. F. (July 23, 2021), https://www.weforum.org/agenda/2021/07/neuroprosthesis-restores-words-to-man-with-paralysis/; *see* Knut Engedal *et al., The Power of EEG to Predict Conversion from Mild Cognitive*

writing, and re-writing neural signals. The neural signaling and the neural pathways they utilize in the brain are also expressly related to memory, thought, and emotion.[16]

For more than ten years, lab experiments to understand neural deficit and to improve mental manipulation have led to the successful creation of artificial and false memories in mice that were indistinguishable from real experience, and that prompt the feeling of fear in the mice by manipulating memory cells in the hippocampus.[17] To transfer false memories from one mouse to another, implant thoughts, and induce hallucinations using BCIs,[18] scientists have identified methods of sublimination by which false memory can be created through the presentation of associated concepts that enter the brain as perceptions, but ultimately become part of memory and recall.[19] They have also passed false information to a receiver mouse, and observed the receiver mouse using that information to make a decision.[20] It is not a big leap to infer that basic research such as this might also find a darker, commercial use for erasing memories, rewriting personal histories, and transcending pain in humans. Indeed, there is growing acceptance that "what can be done with mice today could be done with humans tomorrow."[21]

B. What are consumer BCI applications?

Consumer neurotechnologies like transcranial direct current stimulation (tDCS) and transcranial magnetic stimulation (TMS),[22] extended reality

Impairment and Subjective Cognitive Decline to Dementia, 49 DEMENTIA AND GERIATRIC COGNITIVE DISORDERS 38 (2020) (explaining how scientific discoveries have shown the ability to predict cognitive decline and epilepsy in order to begin treatment earlier); *see also* Xinzhong Zhu *et al.*, *Automated Epileptic Seizure Detection in Scalp EEG Based on Spatial-Temporal Complexity*, 2017 COMPLEXITY 1 (2017).

16. Pieter Roelfsema, Damiaan Denys & Chris Klink, *Mind Reading and Writing: The Future of Neurotechnology*, 22 TRENDS IN COGNITIVE SCIENCES 1, 1 (2018); Rainey et al., *supra* note 12.

17. *See* Steve Ramirez *et al*., *Creating a False Memory in the Hippocampus*, 341 SCI. 387, 387 (2013).

18. Rafael Yuste & Jared Genser, *It's Time for Neuro - Rights*, CIRSD, http://www.cirsd.org/en/horizons/horizons-winter-2021-issue-no-18/its-time-for-neuro—rights (last visited Oct. 20, 2023).

19. Henry L. Roediger & Kathleen B. McDermott, *Creating False Memories: Remembering Words Not Presented in Lists*, 21 J. OF EXPERIMENTAL PSYCH. 803, 803 (1995).

20. *See* Miguel Pais-Vieira et al.; *A Brain-to-Brain Interface for Real-Time Sharing of Sensorimotor Information*, 3 SCI. REP. 1319, 1319 (Feb. 28, 2013); *Workshop, "Neuroderechos en Chile: El Debate Filosófico*" - *17 de Marzo,* YOUTUBE at 47:48 (2021), https://www.youtube.com/watch?v=RcjxNRdY8A0.

21. Yuste & Genser, *supra* note 18.

22. *See* James Giordano et al., *Mechanisms and Effects of Transcranial Direct Current Stimulation*, 15 DOSE-RESPONSE 155932581668546 (2017); Vincent Walsh & Alan Cowey, *Transcranial Magnetic Stimulation and Cognitive Neuroscience*, 1 NATURE REV. NEUROSCIENCE 73, 73 (2000); Mascha van 't Wout-Frank et al., *Combined Transcranial Direct Current Stimulation with Virtual Reality Exposure for Posttraumatic Stress Disorder: Feasibility and Pilot Results*, 12 BRAIN STIMULATION 41, 41 (2019).

(XR) glasses and headsets,[23] and brain augmentation implants each promise superior command over practically all aspects of an individual's life. Thus, they are linked in purpose and form to medical neurotechnologies but are utilized in an array of non-clinical applications and, importantly, are not regulated by the Food and Drug Administration (FDA).

Research and development in extended reality glasses and headsets for everyday use in gaming and immersive environments has skyrocketed as the tech industry invests heavily in the metaverse and other XR worlds.[24] XR technologies are built upon the same fundamental research described above, since they need to be able to read and understand one's thoughts, emotions, and choice preferences in order for the immersive experience to be responsive and enthralling. Most commonly, the headsets utilize sensors to decode signals from the surface of the brain, but even the signals detected from a BCI wristband contain enough neural information to anticipate choices and sense emotional response to stimuli when navigating virtual worlds.[25] Coupled with machine learning techniques, the sensor-enabled technologies can decode emotions and thoughts from brain data to an increasing degree of accuracy.[26] For example, researchers have made strides in predicting

23. We use XR to refer to the collection of technologies that extend a user's view of physical reality. These include reality (VR), augmented reality (AR), mixed reality (MR), and neuroenhanced reality (NeR). As summarized in Floridi (2022) and Hilken et al. (2022), they differ as follows: A *virtual reality* experience is entirely digital. In *augmented reality*, digital and analog (synthetic and real) objects overlap. In *mixed realities*, digital and analogue objects coexist. *Neuroenhanced reality (*NeR) bypasses the sensory stages of perception and interfaces directly with the brain. Finally, as a grand category, all these realities are collectively labelled *extended reality* or XR. (In Luciano Floridi, *Metaverse: A Matter of Experience*, 35 PHIL. & TECH. (2022), https://link.springer.com/epdf/10.1007/s13347-022-00568-6; Tim Hilken et al., *Exploring the Frontiers in Reality-Enhanced Service Communication: From Augmented and Virtual Reality to Neuro-Enhanced Reality*, 33 J. OF SERV. MGMT. (2022)).

24. *See* Delphie Wahlstrom & Tony Sun, *Sensemaking and Decision Making in Uncertainty: A Case Study on How Tech Leaders´ Navigate the Metaverse,* UPPSALA UNIVERSITET 1, 8–9 (2022); *see* Sol Rogers, *Seven Reasons Why Eye-Tracking Will Fundamentally Change VR*, FORBES (2019), https://www.forbes.com/sites/solrogers/2019/02/05/seven-reasons-why-eye-tracking-will-fundamentally- change-vr/ (last visited Oct. 9, 2023).

25. According to Josh Duyan, the chief strategy officer of a company called CTRL-labs, (in NITA A. FARAHANY, THE BATTLE FOR YOUR BRAIN: DEFENDING THE RIGHT TO THINK FREELY IN THE AGE OF NEUROTECHNOLOGY 16 (2023)), brains constantly transmit signals to our peripheral nervous system—the parts of the nervous system outside of the brain and the spinal cord, and wristband can detect these signals using electromyography (EMG). *See also* Nick Statt, *Facebook Acquires Neural Interface Startup CTRL- Labs for Its Mind-Reading Wristband*, THE VERGE (2019), https://www.theverge.com/2019/9/23/20881032/facebook-ctrl-labs-acquisition-neural-interface-armband- ar-vr-deal.

26. The technologies are capable of decoding signals in the brain to various degrees based on the complexity of the system and number of sensors it has. The most advanced headsets, reports Hayden (2022) "include a suite of sensors including electroencephalogram (EEG), electrooculography (EOG) electromyography (EMG), electrodermal activity (EDA), and photoplethysmography

words/speech from brain data—going from an already impressive error rate as low as 3% with a 300-word vocabulary in 2020,[27] to an error rate as low as 2.25% (median of 6.13%) over a vocabulary of 1,152 words in 2022.[28] The same 2022 study also achieved word prediction at an error rate as low as 2.25% (median 8.23%) over a vocabulary of 9,000 words in offline simulations, which exceeds the estimated vocabulary considered necessary for basic fluency and general communication.[29] In a different 2022 study, using only a few seconds of brain activity data and zero-shot decoding (decoding without prior exposure to any similar information), researchers demonstrated a model that could identify the correct thought representation of what a person heard in its top 10 possibilities up to 72% of the time.[30]

Neuroenhanced reality (NeR) is a newer class of immersive devices which supports "neuro-to-digital and digital-to-neuro communication based on neuroimaging (e.g. controlling digital content through thought) and neurostimulation (e.g. eliciting brain responses based on digital content)".[31] NER is seen to be a promising tool in advertising (called neuroadvertising), because of its ability to bypass the sensory stages of perception and communicate messages directly to the brain. For example, NeR allows for simulating the smell of bread or perfume in one's mind, in the absence of any real product.[32] These technologies allow not only an accurate reading of a user's preferences, but the ability to directly shape the user's preferences, potentially undermining the very idea of individual choice.

Implanted neurotechnologies such as Elon Musk's much-hyped Neuralink is a microchip implant touted as a consumer product, and it promises everything from empowering telepathy and curing blindness to treating

(PPG) sensors, which are intended to measure data from the user's brain, eyes, heart, skin, and muscles," and reportedly cost as much as $22,500. Scott Hayden, *Varjo's Enthusiast Grade VR Headset is Getting a Brain- computer Interface*, ROAD TO VR (2022), https://www.roadtovr.com/varjos-aero-open-brain-computer- bci/.

27. Joseph G. Makin, David A. Moses & Edward F. Chang, *Machine Translation of Cortical Activity to Text with an Encoder–Decoder Framework*, 23 NATURE NEUROSCIENCE 575, 575 (2020) (no median error rate or confidence interval was reported).

28. *See* Sean L. Metzger et al., *Generalizable Spelling Using a Speech Neuroprosthesis in an Individual with Severe Limb and Vocal Paralysis*, 13 NAT. COMMUN. 1, 3 (2022).

29. *Id.* at 9.

30. *See* Alexandre Défossez et al., *Decoding speech from non-invasive brain recordings* (2022), http://arxiv.org/abs/2208.12266 (last visited Oct. 9, 2023).

31. Hilken et al., *supra* note 23 at 657.

32. *See, e.g.*, Maja Golf-Papez et al., *Embracing Falsity through the Metaverse: The Case of Synthetic Customer Experiences*, BUS. HORIZONS (2022), https://www.sciencedirect.com/science/article/pii/S0007681322000982 (last visited Oct. 8, 2023). *See also* Dan Ariely & Gregory S. Berns, *Neuromarketing: The Hope and Hype of Neuroimaging in Business*, 11 NATURE REVIEWS NEUROSCIENCE 284 (2010).

mental conditions including depression and anxiety.[33,34] Similarly, the SynChron BCI is implanted through a minimally invasive procedure and uses brain data to control digital devices and realize improvements in functional independence among patients with neurological disorders.[35] Researchers say that, if successful, BCIs like Neuralink would read and write between a brain and a smart phone device[36]–extending the capacity of the mind, but also opening it up to manipulation. Implanted neurotechnologies have been used in clinical treatment over the years (e.g. cochlear implants), but the introduction of AI and corporate algorithms,[37] as exemplified by Neuralink, blurs important lines between clinical/commercial/entertainment, diseased/healthy, and hardware/software. Importantly, the blurring of these lines may lead to harmful commercial technologies escaping meaningful regulation and legal liability hiding behind dubious consumer consent.[38]

C. What are the ethical concerns and imminent harms posed by BCIs?

Because of the hype and theatrics by celebrity salesmen like Musk and Zuckerberg, the immediacy of the potential risks from neurotechnologies is often discounted. Some put the actuality of what is commonly thought of as mind reading, thought manipulation, and military weaponization at least

33. *See* Elon Musk & Neuralink, *An integrated brain-machine interface platform with thousands of channels*, BIORXIV 703801 (2019); Antonio Regalado, *Elon Musk's Neuralink is neuroscience theater*, MIT TECH. REV. (2020), https://www.technologyreview.com/2020/08/30/1007786/elon-musks- neuralink-demo-update-neuroscience-theater/ (last visited Oct. 9, 2023); Daniela Fernandez, *Elon Musk Says Brain Implant Startup Neuralink Should Be Ready for Human Testing in Six Months - WSJ*, WALL ST. J. (Dec. 1, 2022), https://www.wsj.com/articles/elon-musks-neuralink-set-to-show-and-tell-latest-brain-computer-advances-at-event-11669785946.

34. In this category of neurotechnologies, many low-tech implantable devices would also fall. However, since this article is concerned with regulation, body hacking and DIY neurotechnologies are outside its scope.

35. *See* Sean Whooley, *Synchron Completes Its First U.S. Human Implant of Brain-Computer Interface Rivaling Elon Musk's Neuralink*, MASSDEVICE (2022), https://www.massdevice.com/synchron-brain- computer-interface-elon-musk-neuralink/ (last visited Oct. 9, 2023).

36. *See* Patrick O'Callaghan & Bethany Shiner, *The Right to Freedom of Thought in the European Convention of Human Rights*, 8 EUR. J. OF COMPAR. L. AND GOVERNANCE 112, 117-118 (2021).

37. *See*, *e.g.*, Ariely & Berns, *supra* note 33; Amelia Carrozzi et al., *What's Mine Is a Hologram? How Shared Augmented Reality Augments Psychological Ownership*, 48 J. OF INTERACTIVE MKTG. 71 (2019); Golf-Papez et al., *supra* note 33 (demonstrating how insight can be gained about the capacities of exploiting mental space by corporations from literature on neuromarketing).

38. The inadequacy of consent and terms of service is beyond the scope of this article and needs little validation. Also, because individuals have not entered into a social contract with technology companies over free thought and autonomy, such notions from contract theory cannot work for preemption from harm, which is also beyond the scope of this article.

[only] a decade away.[39] But the technological risks are in fact imminent, as evidenced by recent advances in machine learning by Meta;[40] by brain implantation hardware by SynChron Inc.;[41] by Musk's May 25, 2023 announcement on Twitter that Neuralink received FDA approval for human testing;[42] and as seen in patent applications. Recent patent filings on consumer technologies using EEG disclose methods for monitoring, recording, and stimulating/altering mood, attention, and preferences,[43] and research articles document the progress made in retrieving private information from the unconscious brain,[44] and detecting deep-held subconscious feelings and biases.[45] Both sets of documents provide windows into the capacities of BCIs and the intentions of their developers.

A document presented in support of the neurorights resolution adopted by the United Nations in 2022 cited reports that China is already using neurotechnologies for surveillance of workers as a means to assess and

39. *See* Jared Genser, Stephanie Herrmann & Rafael Yuste, INT'L HUMAN RIGHTS PROTECTION GAPS IN THE AGE OF NEUROTECHNOLOGY 11–12 (2022), https://static1.squarespace.com/static/60e5c0c4c4f37276f4d458cf/t/6275130256dd5e2e11d4bd1b /165183 9747023/Neurorights+Foundation+PUBLIC+Analysis+5.6.22.pdf.

40. *See* Défossez et al., *supra* note 30.

41. *See* SYNCHRON, https://synchron.com/https://synchron.com/ (last visited Jan. 24, 2024); *see* Fernandez, *supra* note 33.

42. *See* Daniel Gilbert & Faiz Siddiqui, *Elon Musk's Neuralink Says It Has FDA Approval for Human Trials: What to Know*, WASH. POST (May 26, 2023), https://www.washingtonpost.com/business/2023/05/25/elon-musk-neuralink-fda-approval/.

43. *See, e.g.*, Scott Burwell, *Assessing Motivated Attention with Cue Reactivity* (2021), https://patents.google.com/patent/US20210315508A1/en (demonstrating a headset configuration to assess motivated attention using EEG); Steve Denison et al., *Methods and devices for brain activity monitoring supporting mental state development and training* (2017), https://patents.google.com/patent/US9532748B2/en (demonstrating a system that supports mental state development and training, and brings capacity to monitor and record mental activity); Ranjan Kumar, *System for estimating a user's response to a stimulus* (2022), https://patents.google.com/patent/US20220248996A1/en; Hong Gu Lee & Song Sub Lee, *Method for determining preference, and device for determining preference using same* (2022), https://patents.google.com/patent/US20220273210A1/en (demonstrating a method and device for determining preferences through EEG sensors); Paola Telfer & Corey Julihn, *Method and apparatus for wearable device with eeg and biometric sensors* (2021), https://patents.google.com/patent/US20210353957A1/en. (demonstrating a method and device that uses "PBM stimulation combined with EEG sensors and neurofeedback, [where] neurofeedback may be used to assist users with stress, anxiety, fatigue, mood, creativity and mental focus and acuity").

44. Mario Frank et al., *Using EEG-Based BCI Devices to Subliminally Probe for Private Information*, PROC. OF THE 2017 ON WORKSHOP ON PRIV. IN THE ELEC. SOC'Y 133 (2017), https://doi.org/10.1145/3139550.3139559.

45. *See* Hayley K. Jach, Daniel Feuerriegel & Luke D. Smillie, *Decoding Personality Trait Measures from Resting EEG: An Exploratory Report*, 130 CORTEX 158 (2020) (showing that emotional states, subconscious biases, and political and sexual preferences can be estimated from neural data using EEG and can be shared without a person's awareness of what information has been extracted); *see also* Gillian Grennan et al., *Cognitive and Neural Correlates of Loneliness and Wisdom during Emotional Bias*, 31 CEREBRAL CORTEX 3311 (2021).

manipulate productivity and efficiency. "At a factory in Hangzhou, China, production line workers are allegedly being outfitted with hats and helmets which read brain signals to decode workers' emotions – and then this data is fed to artificial intelligence algorithms to detect changes in emotion which affect productivity levels".[46] Neurotechnologies for surveillance are also currently being used to monitor school children's attention in class,[47] and to conduct brain training games meant to enhance positivity and emotional resilience while decreasing stress among workers, all in the name of employee wellness.[48]

These developments have given rise to a set of fundamental questions about human identity, skills and capacities, agency, autonomy, and "free will." What does it mean to be an autonomous human agent if wearable technologies can supplant our thoughts and preferences, alter our beliefs, and recast or erase our memories? What if implantable technologies for enhancing attention and focus become accepted for professionals such as surgeons, pilots, or soldiers? If they become expected or mandatory, is human capacity insufficient? What does it mean to have free thought if our information environment is synthetic and controlled by corporate algorithms? For years, neuroethicists have been sounding an alarm over the potential of neurotechnologies to fundamentally disrupt human rights, particularly by altering personal identity, private mental life, self-determination or free will, and free and unbiased access to information.[49] Human autonomy and free thought rely on mental privacy—or one's ability to control one's own mental processes and the neural data gained from it[50]—and mental privacy is threatened when neurotechnologies that measure brain activity have the capacity to infer language, thought, beliefs, perceptions, desires, etc. Loss of autonomy and free thought are not simple unintended consequences of

46. Yuste & Genser, *supra* note 18; *see also* Erin Winick, *With Brain-Scanning Hats, China Signals It Has No Interest In Workers' Privacy*, MIT TECH. REV. (Apr. 30, 2018), https://www.technologyreview.com/2018/04/30/143155/with-brain-scanning-hatschina-signals-it-has-no- interest-in-workers-privacy/; Samantha Cole, *China Claims It's Scanning Workers' Brainwaves to Increase Efficiency and Profits*, VICE NEWS (May 1, 2018), https://www.vice.com/en/article/8xkymg/china-brain-wave-hats-helmets-productivity.

47. *See* Jane Li, *A "Brain-Reading" Headband for Students Is Too Much Even for Chinese Parents*, QUARTZ (2019), https://qz.com/1742279/a-mind-reading-headband-is-facing-backlash-in-china; Yifan Wang, Shen Hong & Crystal Tai, *China's Efforts to Lead the Way in AI Start in Its Classrooms*, WALL ST. J. (Oct. 24, 2019), https://www.wsj.com/articles/chinas-efforts-to-lead-the-way-in-ai-start-in-its- classrooms-11571958181.

48. *See* Farahany, *supra* note 25, at 55.

49. *See* Yuste et al., *supra* note 10; Abel Wajnerman Paz, *Is Your Neural Data Part of Your Mind? Exploring the Conceptual Basis of Mental Privacy*, MINDS & MACHINES (2021), https://doi.org/10.1007/s11023- 021-09574-7; Dayton, *supra* note 10.

50. *See* Ienca & Andorno, *supra* note 10; Yuste & Genser, *supra* note 18.

neurotechnologies because gauging likes and preferences and revealing other mental content is often what consumer technologies are designed for.[51]

When mental privacy is threatened, people are not free to think their own thoughts.[52] Likewise, mediation of thoughts, ideas, and deliberations also mediates autonomous agency and self-representation.[53] Yet, despite warnings from neuroethicists about the threats to autonomy and free though, work has proceeded, leading to improvements in accuracy and greater degree of control which threaten the very capacities of intentional action and thought at the heart of human autonomy.

Those who oppose any regulation on neurotechnologies believe it may foreclose life- altering medical discovery; they contend that not enough is known yet about the human brain to implement measures which could impede innovation in neurotechnologies. However, we do know enough to be able to discern potential harms and risks from these interventions: it *is* known that: neurotechnologies expose users to new means of behavioral "nudging;"[54] neuromarketing can make trickery and misrepresentation cognitively imperceptible;[55] the enactment of real daily tasks as an avatar in a synthetic world can be both physically and psychologically disorienting.[56]Also, critically important is that people cannot control which thoughts and emotions they expose to systems processors. This leaves them vulnerable and would fundamentally change how they interact in a world where they are not the only knower and controller of their thoughts.

Chile and Spain have recognized these risks and have advanced "neurorights" legislation. Furthermore, in October 2022, the United Nations Human Rights Council (HRC or UNHRC) adopted a resolution that mandates further studies and a subsequent report on human rights and neurotechnologies.[57] On the other hand, in the United States, law often lags sciences, and it is definitely so with neurotechnologies. In contrast to Chile, Spain, and the United Nations (UN), American policy makers have paid scant attention to the issue.

51. *See* Farahany, *supra* note 26.

52. *See* Rainey et al., *supra* note 12, at 2301.

53. *Id.* at 2301–02.

54. Erick Jose Ramirez, Miles Elliott & Per-Erik Milam, *What It's like to Be a ____: Why It's (Often) Unethical to Use VR as an Empathy Nudging Tool*, 23 ETHICS & INFO. TECH. 527 (2021), https://philpapers.org/archive/RAMWIL.pdf.

55. *See* Ariely & Berns, *supra* note 32; Anna Wexler & Robert Thibault, *Mind-Reading or Misleading? Assessing Direct-to-Consumer Electroencephalography (EEG) Devices Marketed for Wellness and Their Ethical and Regulatory Implications*, 3 J. COGNITIVE ENHANCEMENT 131 (2019), https://link.springer.com/article/10.1007/s41465-018-0091-2.

56. *See* Carrozzi et al., *supra* note 38.

57. G.A. RES. 51/3, ¶2 (Oct. 6, 2022).

While technologies are imminent that could compromise human autonomy and imperil free thought, what policies might allow an open gate for medical innovation but a high level of scrutiny over commercial and other uses of neurotechnologies that could pose real harm? What can be learned from the precedent of Chile and Spain, and from the United Nations' initiative? What can be learned from past efforts in the US to control potentially dangerous technologies? If patent applications expose capabilities and intentions behind the innovation, is there precedent for the US Patent Office to act as an institutional gatekeeper? Precedent from these diverse institutional settings represent different models of regulation, and the next section explores the connection between present or imminent problems, policy interventions, and possible futures.

III. PRECEDENT FOR PRECAUTIONARY REGULATION AGAINST FORESEEABLE HARM

Whether it be to protect human rights, bodily harm, the environment, or any type of injustice, incentives to preempt harm exist in common law and negative rights, but this can only occur upon a showing of legal justification. Even before the age of statutes, common law required individuals to engage in reasonable precautions to avoid harms. What constituted reasonable precaution depended on the likelihood and magnitude of harm from some activity. The highest level of precaution is required for activities that are considered abnormally dangerous or ultra-hazardous (typically involving hazardous substances). The person or firm carrying out such an activity is obligated to exercise the "highest possible degree of skill, care, caution, diligence, and foresight" with respect to the technical, mechanical, and scientific aspects of the undertaking, to avoid liability for even unintentional subsequent harm.[58]

In the age of statutes, efforts to prevent harm have often taken the form of precautionary regulation – regulation not to prevent something completely but to take precautions against foreseen harms stemming from it. Precaution has been a guiding principle of environmental law since the early 1970s, regulating (but hardly ever prohibiting completely) pollution primarily to reduce risks of harm to public health. In the 1980s, the preemptive strategy against foreseeable harm manifest when international treaties applied precautionary measures when enacting bans on the dumping of toxic substances in the

58. Ronald M. Sandgrund, *Inherently Dangerous and Ultrahazardous Activities*, 47 COLO. LAW. 50, 51 (Feb. 2018), https://www.burgsimpson.com/wp-content/uploads/2015/03/InhDang-UltraHazard-TortAndInsuranceLaw-clean.pdf.

North Sea.[59] In 1992, the "precautionary principle" was formalized in the UN's Rio Declaration to require that, if there is a strong suspicion that a certain activity may have environmentally harmful consequences, a state should control that activity, even if full scientific certainty over the harm or causality is lacking.[60] In the US itself, a form of precautionary principle was used as early as 1973 in the drafting of the Endangered Species Act. The precautionary principle's "don't wait to act" approach seeks to preempt or minimize risk of future harm. Though intended for environmental harms, the principle has occasionally been invoked in other domains to justify regulation of consumer products like e-cigarettes.[61]

Human rights obligations and first amendment speech protections also establish some precautionary boundaries around autonomy and free thought, mostly through the use of negative rights. In fact, the discourse around the need for the regulation of neurotechnologies largely leans on human rights. Importantly, this perspective views the brain and mind as fundamental to humanness, and therefore posits that the brain requires specific human rights protections. *Neurorights*, a term used to refer to human rights-based protections against neurotechnologies, is forward-thinking with respect to emergent technologies because it sets the boundaries of what should be preserved, rather than battling the rapidly evolving specifications of technologies.Three of the four cases discussed next provide precedents for precautionary regulation of foreseeable harms rooted in human rights law.

A. Precedent for preempting harm by institutional approach

The view of the mind/brain as exceptional and fundamental to humanness is a motivating force behind neurotechnology research and also neurorights.[62] The neurorights perspective on governance is that safeguarding

59. *See* James Cameron & Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, 14 B. C. INT'L & COMP. L. REV. 1, 4-5 (1991), https://lira.bc.edu/work/ns/f06efb0b-19f6-4b96-b64c-276e8548c8c4; *Precautionary Principle*, SCIENCEDIRECT https://www.sciencedirect.com/topics/earth-and-planetary-sciences/precautionary-principle (last visited Oct. 8, 2023).

60. U.N. District-General, *Report of the United Nations Conference on Environment and Development*, ¶ 3, U.N. Doc. A/CONF.151/26 (Vol. I) (Aug. 12, 1992), www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_CONF.151_26_Vol.I_Declaration.pdf.

61. Competitive Enter. Inst. v. United States DOT, 863 F.3d 911, 917–18 (D.C. Cir. July 21, 2017) (the DOT applied the "precautionary principle" when seeking regulation on electronic cigarettes).

62. *See* Meghan C. Mott, Joshua A. Gordon & Walter J. Koroshetz, *The NIH BRAIN Initiative: Advancing Neurotechnologies, Integrating Disciplines*, 16 PLOS BIOLOGY 1, 1–2, (2018), https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000066; Henry T. Greely et al., *Neuroethics Guiding Principles for the NIH BRAIN Initiative*, 38 J. NEUROSCIENCE 10586–10588 (2018), https://www.jneurosci.org/content/38/50/10586; Universidad Alberto Hurtado,

the privacy, integrity, and autonomy of mental activity should "transcend state law."[63] Proponents of neurorights call for:

> a multi-level approach to governance, starting with an international framework, or convention, pulling together the fundamental ethical and human rights arguments for the protection of mental privacy, mental integrity and personal identity. [They] argue that the principles must then be enforced with national legislation and regulation.[64]

Compared with more narrow approaches examined later, the examples of Chile, Spain, and the United Nations Human Rights Council require a reframing of human rights to incorporate novel threats along with protections that are instituted throughout government.

1. The case of Chile

To date, the Republic of Chile is the only state to constitutionalize neurorights. Marking an important moment in the protection of neurorights, on October 25, 2021, the National Congress of Chile amended the constitution to recognize the risks of neurotechnologies and mandate responsible development in the field, saying:

> Scientific and technological development will be at the same time, at the service of people and will be carried out with respect for life and physical and mental integrity. The law shall regulate the requirements, conditions, and restrictions for its use in people, having to safeguard especially brain activity, as well as information coming from it.[65]

An accompanying bill was also passed establishing the legal parameters of protection in terms of human rights.[66] Chile's decision to take action simultaneously at both the constitutional and policy levels of governance is both strong and institutionally broad. The benefit of a constitutional approach is that it sets at a high level, a principled, pro-human stance towards brain-computer interactions, but leaves implementation to relevant lower-level agencies where they may apply the principle, as specified, to

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Workshop: Neuroderechos en Chile. El Debate Filosófico, YOUTUBE at 41:17 (Mar. 17, 2021), https://www.youtube.com/watch?v=RcjxNRdY8A0.

63. Marcello Ienca, *Towards Neurorights: An Interview with Neurorights Advocate Marcello Ienca, PhD*, NEUROETHICS TODAY (2022), https://www.neuroethicstoday.com/post/towards-neurorights-an-interview-with-neurorights-advocate-marcello-ienca-phd [https://perma.cc/4EZ4-Q95K].

64. Dayton, *supra* note 10.

65. Law No. 21.383, Octubre 25, 2021, DIARIO OFFICIAL [D.O.] (Chile).

66. Lorena Guzman, *Chile: Pioneering the protection of neurorights*, THE UNESCO COURIER (2022), https://courier.unesco.org/en/articles/chile-pioneering-protection-neurorights; Dayton, *supra* note 10.

neurotechnologies. The combination of a general constitutional rule with a more specific precautionary statute underscores both the urgency of the risks of evolving neurotechnologies and Chile's determination to deal with those risks.

Chile's achievement has been widely regarded amongst neuroethicists, human rights communities, and the media.[67] It provides insight and political hope for other countries that several countries have already followed. In July 2023, Mexico announced it would be following Chile's example and drafting an amendment to article four of their Constitution to adapt the article's guarantees for the protection of health and a dignified life, "to the needs and challenges of the 21st Century [that the neurorights] initiative raises."[68] Brazil has also expressed the intent to do the same.[69]

While Chile's ongoing efforts to draft an entirely new constitution could potentially put neurorights in peril in Chile, currently support remains strong, and the momentum is spreading across Latin America. The precedent, however, may be difficult to replicate and apply in the US. This is because the Chilean response was inspired largely by the "country's history of human rights abuse" and is reflective of an oversized influence of neurorights advocacy by the renowned Columbia University neuroscientist Rafael Yuste and others in the international NeuroRights Network (NRN) that he founded.[70] Inspired by Yuste's advocacy, Senate Committee-chair Guido Girardi enlisted Yuste to advocate before the legislature and the president on the issue. The resulting amendment and legislation passed with significant bipartisan and popular support and received robust backing from the academic and scientific world.[71] In the US, a similar constitutional amendment is scarcely worth contemplating, especially given the extreme partisanship in Congress. Even getting ordinary, precautionary legislation through a hyper-partisan Congress will be difficult enough.

2. The case of Spain

While Chile is the only state so far to have constitutionalized human rights protections against the novel risks from neurotechnologies, Spain and the United Nations have taken other approaches similarly using Human Rights law to justify protections against the risks created by developing neurotechologies. Instead of amending the constitution to protect novel neurorights, Spain issued a charter protecting rights in the broader digital world.

67. *Id.*; Universidad Alberto Hurtado, *supra* note 62.

68. Canal del Congreso, *Virtual Forum: Neurotechnología Humanos Desafíos Para Las Américas*, YOUTUBE (July 31, 2023), https://www.youtube.com/watch?v=hUwUtcMsFaQ.

69. *Id.*

70. Dayton, *supra* note 10.

71. *Id.*

Adopted in July 2021, the *Spanish Charter of Digital Rights* outlines twenty-five rights. These rights are intended to be used by public authorities to "boost the benefits of digital technology, guide regulation, and minimize risks,"[72] and to provide a framework to ensure that subsequent legislation "promot[es] equality in the digital ecosystem" for individuals and collectives.[73] This means the charter is not itself a mechanism for regulation, but instead is meant to serve as a unifying framework for all Spanish authorities to inform future, rights-based action.[74]

Among the various rights to freedom, equality, participation in public spaces, labor and business-related rights, and digital rights in specific environments, right number twenty-four outlines digital rights in the use of neurotechnologies. These include, for example, preserving individual identity, self-determination and freedom in decision-making, including freedom from incomplete, undesirable, unknown, or biased decisions or processes caused by neurotechnologies. Although the charter itself is non-regulatory and non-binding,[75] it provides authority for regulation of brain augmentation or brain stimulation technologies when used beyond therapeutic applications.[76]

The Charter functions as part of a larger plan called "Digital Spain 2025," which has ideological, commercial, and regulatory aims. Pursuant to an electoral promise made in the 2018 elections by Prime Minister Pedro Sánchez, the Charter is one of the projects of the Digital Spain 2025 plan, along with a National AI Strategy (ENIA) (issued in December 2020) and a newly adopted Neurotech initiative (December 2022).[77] Alongside an ideological goal of instigating a "humanistic transformation" of digital development, Spain is working to boost economic development through the

72. *Id.*

73. *Charter of Digital Rights*, DERECHOS DIGITALES 1, 9 (2022), https://portal.mineco.gob.es/RecursosNoticia/mineco/prensa/noticias/2021/SPAIN_Charter-of-Digital-Rights.pdf; s*ee also The Government Adopts the Digital Rights Charter to Articulate a Reference Framework to Guarantee Citizens Rights in the New Digital Age [Government/News]*, LA MONCLOA (July 14, 2021), https://www.lamoncloa.gob.es/lang/en/gobierno/news/Paginas/2021/20210713_rights-charter.aspx.

74. *See* Joshua Nelson, *Spain President Proposes Digital Rights Charter, Outlining Fundamental Rights of Individuals Online*, JURIST (2021), https://www.jurist.org/news/2021/07/spain-president-proposes-digital- rights-charter-outlining-fundamental-rights-of-individuals-online/.

75. *See* Dayton, *supra* note 10; *see* La Moncloa, *supra* note 73.

76. *See* Charter of Digital Rights, *supra* note 73.

77. *Pedro Sánchez Presents National Artificial Intelligence Strategy with Public Investment of 600 Million Euros for Period 2021-2023 [President/News]*, LA MONCLOA (Dec. 12, 2020), https://www.lamoncloa.gob.es/lang/en/presidente/news/Paginas/2020/20201202_enia.aspx; Dayton, *supra* note 10; *The Government of Spain Launches the National Neurotechnology Centre, Spain Neurotech, a Pioneer in Europe [Government/News]*, LA MONCLOA (Dec. 12, 2022), https://www.lamoncloa.gob.es/lang/en/gobierno/news/Paginas/2022/20221222_spain-neurotech.aspx; *Charter of Digital Rights for Consultation in Spain*, FIND YOUR DIGITAL SELF (Nov. 26, 2020), https://blog.fyself.com/charter-of-digital-rights-for-consultation-in-spain/.

country's tech sector. At the same time, Spain is positioning itself as an international leader and active contributor in European and global efforts to promote and guarantee citizens' updated human rights for the new digital era.[78] Neurotechnologies are one area targeted for potential regulation in the Charter and targeted for growth in the Neurotech Initiative. Specifically, the objectives of the Spain Neurotech Initiative are:

> advancing the understanding of the human brain; developing diagnostic methods and therapies for diseases of the nervous system; fostering an innovation and entrepreneurship ecosystem; developing the ethical and legal rules necessary …; and attracting talent and training new generations of leaders in neurotechnology.[79]

Spain has formatively provided an update of human rights for the digital age that is rooted in (and compliant with) international and regional treaties, while being receptive to novel digital concerns. Having those concerns managed through specialized efforts like the Neurotech initiative creates scaffolding to which "prospective" or preemptory safeguards can later be attached. [80] At the time of writing, the regulatory rungs remain to be built.

The model that Spain sets for the preemption of harms from neurotechnologies is perhaps more instructive as precedent than the Chilean model as it is more consistent with legislative processes in the US. After P.M. Sanchez set the broad, executive mission, the "drafting [of] the Digital Rights Charter followed a participatory process, with contributions from experts in the field and advocacy associations, as well as from citizens, together with input from the private sector, service providers, and the public sector with relevant competences."[81] In addition to being more easily replicable, the Spanish model may also be more desirable, as discussed below in section IVA.

3. The case of the United Nations Human Rights Council

Since 2021, the United Nations Human Rights Council has been on a similar trajectory as Spain with respect to neurotechnologies, achieving, in October 2022, the adoption of Resolution A/HRC/51/L.3, *Neurotechnology and Human Rights,* which mandates further studies on human rights related to neurotechnologies.[82] The resolution grew out of a draft resolution written by neurorights advocates within the Council. The final resolution was adopted by consensus (without a vote) after the Council examined

78. *See* La Moncloa, *supra* note 73.
79. *See* La Moncloa, *supra* note 77.
80. *See* La Moncloa, *supra* note 75.
81. *Id.*
82. *See* G.A. Res. 51/3 A (Oct. 13, 2022).

preliminary reports[83] and held discussions with experts on the imminent risks posed by neurotechnologies.[84] The next step, not yet completed, is for the HRC Advisory Committee to prepare an "easy to read and accessible" study on the "impact, opportunities and challenges of neurotechnology with regard to the promotion and protection of all human rights," to be presented at the next session of the HRC in September 2024.[85]

Though the organization, processes, and regulatory powers of the UNHRC are different from those of the Spanish government, the UN and Spain have both taken the view that neurotechnologies are not the sole and primary cause of the novel human rights concerns they create, but they are part and parcel of digitization. The interdependency between the neurotechnology resolution with other emergent human rights concerns supports that view.

Specifically, the UNHRC's neurotechnology resolution was conceived in the context of the Secretary-General's 2021 report entitled "Our Common Agenda," which states that "consideration should be given to updating or clarifying the application of human rights frameworks and standards to address frontier issues and prevent harms in the digital or technology spaces, including in neuro-technology . . . ."[86] Like the Digital Spain 2025 plan, "Our Common Agenda" recognizes the need to revise and expand human rights and update frameworks to identify and adjudicate new rights violations in future encounters. According to the UNHRC's neurotechnology resolution, neurorights should also be conceived within the context of other relevant HRC resolutions, including resolutions on 'human rights on the Internet' (July 2021), 'human rights in new and emerging digital technologies' (July 2021), 'privacy in the digital age' (October 2021), and 'freedom of opinion and expression' (July 2022).[87]

Compared to both Chile and Spain, UNHCR is at an exploratory stage, but the UN approach of contextualizing neurorights *within* human rights at a high level and *among* related and overlapping novel concerns on the same level, is similar to the approach of Spain. It is still unknown whether or how far neurorights will proceed in the UN, but, thus far, the advancements set a positive precedent for at least recognizing neurorights. While replicating the

83. *See* Genser et al., *supra* note 39 (a report prepared by Raphael Yuste, Jared Genser, and Stephanie Herrmann that highlighted the regulatory gap in traditional human rights in the face of novel threats from neurotechnologies, was key evidence submitted to the Human Rights Council).

84. *See* Lenca, *supra* note 63 (describing the process of advancing the resolution through the HRC and demonstrating the role of advocacy by neurorights experts).

85. *See* G.A. Res. 51/3 A, *supra* note 82.

86. U.N. Secretary General, *Our Common Agenda-Report of the Secretary General*, 33, U.N. DOC. A/75/982 (2021), https://www.un.org/en/content/common-agenda-report/assets/pdf/Common_Agenda_Report_English.pdf.

87. *See* G.A. Res. 51/3 A, *supra* note 82.

UN path, with its draft resolutions and committee reports, has little value outside its idiosyncratic context, recognizing the role of the relevant actors can be instructive. In all three cases, longstanding, internationally recognized neurorights advocates have played a major role in petitioning the legislative bodies, submitting reports, and providing expertise to policymakers. In the case of the United Nations, instigation to raise the issue to the committee came from HRC Advisory Council member Milena Costas Trascasas who, by her own account, simply read a critical report on neurotechnologies in the popular media which called for a universal framework on neurorights, and was compelled to investigate and ultimately draft the resolution on neurotechnologies for the UNHCR.[88] Thus, part of what can be learned from the cases of Chile, Spain, and the UNHCR is the need for neurorights advocacy and high-level institutions converging on a kairotic moment.

B. Precedent for preempting harm by sectoral approach

Beyond the human rights regime or constitutional reform, there are numerous agencies with varying degrees of oversight and influence over the development and deployment of neurotechnologies. Potential exists for specific agencies like the FTC or FDA to bound technological potential in narrow and particular ways which nevertheless can have far-reaching impacts. For example, the FTC might block mergers that could combine neurotechnology and computer hardware, metaverse software, and social media companies. The US Patent Office has a statutory role as gatekeeper, which historically included normative considerations in patent review. In addition to government agencies, the common law courts have historically taken decisions to preempt harm from dangerous activities.

1. The case of the US patent system

Established in 1790 during the first meeting of Congress, pursuant to Article I, Sec. 8 of the US constitution, the US Patent Office issues patents, a legal protection in the form of a limited term monopoly, for any "new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof" that it deems nonobvious and novel.[89] To obtain a patent, an inventor must meet these criteria and be the first to file for a patent on the invention.[90] Patenting offers inventors desirable rights

88. *Conference on Neurotechnology and Human Rights: Issues and Progress 2022*, THE NEUROTECHNOLOGY CTR. AT COLUM. UNIV., at 4:46:00 (2022), https://ntc.columbia.edu/neurotechnology-and-human-rights-issues-and-progress-2022/.

89. 35 U.S.C. § 101 (1952).

90. *See* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 757-58 (2012) (detailing how the "first to file" requirement was added to address the progressive and

akin to property rights on their invention—allowing them to capture market share and charge a competitive price by excluding others from making, using, or selling the invention in the US or importing the invention into the US for 20 years. The patent holder also has discretion to license their technology or sell the patent right.[91] In return for the time-limited monopoly grant on their invention, the patentee must disclose details of their invention to the public. The overall goal of the patent system is to create positive incentives for invention and innovation.

The Patent Office, though tasked with enabling invention and promoting social progress, has mainly been agnostic with respect to the social consequences of those inventions. It has been guided mainly by two considerations, one deontological and the other consequential. The deontological consideration is that "one has a natural or moral right to one's creations regardless of the social or competitive consequences."[92] The consequentialist consideration is that "property right[s] in one's intellectual creation [are] necessary as a means to a greater end."[93] Each ethical consideration, however, presumes that innovation is always socially beneficial and manifests an indifference to future harm.

In addition to this indifference, and between the early 1920's and 1982, the scope of patentability grew significantly. In 1920, instead of a patentee necessarily being the individual inventor, companies came to claim ownership of all the technology innovated by its employees,[94] and in 1982, the centralization of patent appeals cases in the Court of Appeals of the Federal Circuit led to dismantling exclusions to patentability for inventions like math algorithms and mental steps.[95] As a consequence to these changes, the doors to patentability swung wide open to all novel and nonobvious inventions, and ideologically, patenting evolved to reflect "corporate-capitalism."[96]

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simultaneous nature of invention, where numerous inventors often work separately to innovate upon previous work, and then race to receive exclusive patent rights).

91. *See id.* (Discussing that coupled with the first to file rule, the monopoly provisions encourage a rush to patent and a strategy of patenting components of inventions so that inventors may claim exclusive rights. Consequences include that the incentive to rush serves to handicap forethought, and the incentive to patent components of inventions, by disaggregating the technology, serves to obfuscate the broad impact a technology may have).

92. Chisum et al., *supra* note 3 at 6.

93. *Id.*

94. *See* Coriat & Weinstein, *Patent Regimes, Firms and the Commodification of Knowledge*, 10 SOCIO- ECON. REV. 267, 275 (2012).

95. *Id*. at 267–282.

96. Coriat & Weinstein, *supra* note 95. (Providing an elaborate telling of the "corporate-capitalism" evolution in the patent system).

The influence of these historical inflection points played out in cases like *Diamond v. Chakrabarty* (1980),[97] in which the U.S. Supreme Court ruled that the framers of the U.S. constitution intended that anything manmade could be patented. The Court cited a 1952 congressional report on Title 35, which recognized patentable subject matter as "anything under the sun that is made by man." This ruling on patentable subject matter created a pathway for patenting higher life forms among plants and animals and other ethically controversial innovations that had previously been unpatentable.[98,99] Such an expansive perspective on patentable subject matter ignores considerations of moral utility, which had held sway earlier in the U.S.

a. Moral utility doctrine in the US, Europe and beyond

Belying the instances of patenting deceptive and potentially reckless innovations, there is historical precedent in patent theory, in the U.S., Europe, and elsewhere, to require that innovations be not only novel and nonobvious but also useful. Since the late 1700's, the 1790 Patent Act described an eligible patentee as one who "invented or discovered any *useful* art, manufacture, engine, machine, or device, or any improvement therein not before known or used."[100] The interpretation of utility came to be assessed in terms of morality a few years later, with the interpretation in *Lowell v. Lewis* (1817).[101] In the case, the plaintiff claimed that the defendant's pump had to be "a better pump than the common pump" to be considered "useful."[102] Setting a baseline for utility, Justice Story indicated that utility would be lacking if an invention was "frivolous or injurious to the well-being, good policy, or sound morals of society," and he gave as contraindications inventions "to

97. Diamond v. Chakrabarty, 447 U.S. 303 (1980) (the court held that "A live, man-made microorganism is a non-naturally occurring composition and therefore may be patented. The micro-organisms [new species of bacterium capable of metabolizing hydrocarbons] exhibited great promise in the treatment of oil spills").

98. *See* Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003), https://scholarship.law.wm.edu/wmlr/vol45/iss2/3/; *see also* David O. Taylor, *Immoral Patents*,(2021), https://papers.ssrn.com/abstract=3937640.

99. *See* ex parte Allen, 2 USPQ 2d 1425 (1987) (ruling that non-naturally occurring, non-human multicellular living organisms, including animals, are to be patentable subject matter within the scope of the Statute); *see also* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (1999) (upholding patentability on a drink dispenser, the only novelty of which was in being deceptive).

100. Patent Act of 1790, Ch. 7, § 1, 1 Stat. 109, 110 (1790) (emphasis added).

101. *Id*.

102. *Id.*

poison people, or to promote debauchery, or to facilitate private assassination."[103]

A judicially created *moral utility doctrine* emerged from *Lowell v. Lewis,* and "served as a type of gatekeeper of patent subject matter eligibility" for many years—allowing both the US Patent and Trademark Office and courts to judge innovations according to their potential to bring harm to the well-being or sound morals of society. Moral utility guarded against the risk of future harm across cases which covered patentability,[104] such as addictive products,[105] deceptive products,[106] and products which did not have social value.[107] The guiding force of moral utility on patent decisions eventually waned as judicial decisions chipped away at it in cases like *Chakrabarty* and *Juicy Whip*; however, the precedent remains.

The US Supreme Court's decision in *Chakrabarty* led to a deluge of patent claims on controversial biotechnologies in the United States. The situation in Europe was very different.[108] Article 53 of the European Patent Convention (EPC) includes a morality clause that requires the European Patent Office (EPO) to weigh the claimed benefits of an invention against the potential harm it may cause to living beings, the environment, or public moral unease.[109] The article states that "European patents shall not be granted in

103. *Id.; see also* Bagley, *supra* note 98; Paul Spiel, *Deceptive Patents: Deconstructing Juicy Whip*, BYU L. REV. 37, 747–48 (2017), https://digitalcommons.law.byu.edu/cgi/viewcontent.cgi?article=3104&context=lawreview.

104. Bagley, *supra* note 99 at 269. *Also see* Margo A. Bagley, *Illegal, Immoral, Unethical . . . Patentable? Issues in the Early Lives of Inventions*, https://web.stanford.edu/dept/law/ipsc/2008/pdf/bagley-margo-ab.pdf; Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685 (2004); Kevin Ruane, *Can Moral Utility Deter American Tech's Complicity in Human Rights Abuses?*, FORDHAM INTELL. PROP., MEDIA & ENT. L. J. (2021), http://www.fordhamiplj.org/2021/12/11/can-moral-utility-deter-american-techs-complicity-in-human-rights-abuses/; Julien Crockett, *Morality: An Important Consideration at the Patent Office*, 108 CAL. L. REV. 267 (2020).

105. *See* Schultze v. Holtz, 82 F. 448 (N.D. Cal. 1897) (denied coin-controlled apparatus used for gambling purposes); Nat'l Automatic Device Co. v. Lloyd, 40 F. 89 (N.D. lll. 1889) (denied patent on toy horse racecourse because it was used in bar-rooms and saloons and "no [other] such use has been as yet made"); *see generally* Spiel, *supra* note 103.

106. *See* Klein v. Russell, 86 US 433 (1874) (denied patent because the process of tanning sheep skin to look like dog skin leather was not "useful for any honest purpose, and can be useful only for perpetrating a fraud upon the public").

107. *See* Rickard v. Du Bon, 103 F. 868 (2d Cir. 1900) (denied because the innovated process for artificially producing spots on tobacco leaves was deemed to have "no other benefit upon the public than the opportunity of profiting by deception").

108. *See generally* Kathleen Liddell, *Immorality and patents: The exclusion of inventions contrary to ordre public and morality*, *in* NEW FRONTIERS IN THE PHIL OF INTELL. PROP. 140, 140 (Annabelle Lever ed., 2012), https://www.cambridge.org/core/books/new-frontiers-in-the-philosophy-of-intellectual-property/immorality-and-patents/369CA0C11E2D48EAF2D4759114D869D2.

109. Jasanoff, *supra* note 3 at 194.

respect of . . . inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."[110,111]

The European Union is one of many governments around the world that apply a moral utility threshold to patentability. According to the World Intellectual Property Organization's (WIPO) 2010 report *Exclusions from Patentability and Exceptions and Limitations to Patentee's Rights*, 84 countries have exclusions on "inventions contrary to law, public order, public policy, public interest and/or morality."[112] The report identified 27 categories of this type of exemption, including the exemption from patentability on "inventions contrary to social order or morality," "inventions contrary to public health or environmental protection," and "inventions use or commercial exploitation of which is contrary to law or morality." These 27 categories and 84 countries represent those with exceptions against 'immoral' inventions alone. There are also 41 other types of exceptions including "inventions detrimental to human, animal or plant life or health and/or the environment." Under this type of exclusion, Uruguay has a notable exception on "inventions the commercial exploitation of which shall be prevented in order to preserve health or life of persons, animals, plants or the environment."[113] The United States does not have any such exemptions on patenting, however. Although many of the countries that utilize the moral utility doctrine are repressive—using patentability as a mechanism of state-control— plenty of democracies, including all European member states, apply the utility requirement of patent eligibility to protect against harms to social order.

2. Other narrow approaches

In bits and pieces across legal domains, examples exist of regulations that constrain harms. For one, environmental law, which is guided by a principle of precaution, protects public health against hazardous and dangerous substances. For example, before a new chemical can go on the market, the US Environmental Protection Agency (EPA) must make an affirmative

110. *Article 53, Exceptions to patentability*, EUR. PAT. OFF. (2000), https://new.epo.org/en/legal/epc/2020/a53.html.

111. *See also* Crockett, *supra* note 104; NEW FRONTIERS IN THE PHIL OF INTELL. PROP. (Annabelle Lever ed., 2012); Ruane, *supra* note 104.

112. Lionel Bently, Brad Sherman & Denis Borges Barbosa, *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights* 64 OXFORD ACAD. 315, 320 (2011), doi:10.1093/clp/cur011.

113. Bently, Sherman & Barbosa, *supra* note 113.

finding that a chemical is safe.[114] The agency also requires that companies register new chemicals with the EPA and undergo safety testing before marketing them or using them in products and industrial processes. And, if the same chemical is marketed for a new use, it must receive reapproval. Chemical companies must maintain records on the use and any disclosed health effects, and report regularly to the federal agency. If a serious risk to health and safety is identified, the EPA can ban the substance. If the substance poses an existential but reasonable degree of risk, the EPA can further regulate its sale and use.[115] But EPA has only held this level of authority since 2016, long after evidence of harm from many chemical substances was well known.

As Sheila Jasanoff narrates across numerous examples of environmental catastrophe, regulation typically comes only after harms pile up, and risk assessment typically follows after a technology is fully developed and too far down the pipeline for any "unintended" consequences to be contained.[116] The case of the Lautenberg Act, however, shows that Congress is sometimes capable of responding, if only belatedly, to empower regulatory agencies to preempt further harm. The precedent from environmental law is instructive in what it tells us about the function and power of administrative orders to protect against public harm.

In privacy law, too, initial promise and precedent exist in the foundational principle that people have "the *right* to be let alone."[117] Intrusion upon seclusion, public disclosure of private facts, and placing a person in a false light are among tortious acts in privacy law.[118] Such principles speak to the possibilities for protecting the right to free thought, autonomy, and mental privacy from technological systems that can undermine them. Unfortunately, much of the hope contained in these principles has been lost or abandoned in a digital world that demands the sacrifice of personal data in exchange for goods and services. At the very least, rights of privacy, or simply to be left alone, have been hollowed out in the US by constitutional standing requirements that focus exclusively on whether harm is actualized versus imminent. Nonetheless, as with the moral utility doctrine in patenting, some hope persists from decisions like Rowan v. US Post Office, which held that individuals have authority over the types of informational content from commercial

114. Frank R. Lautenberg Chemical Safety for the 21st Century Act, 130 Stat. 448 (2016), https://www.congress.gov/114/statute/STATUTE-130/STATUTE-130-Pg448.pdf. *Also see* Alyssa S. Rosen, *The Lautenberg Act: Chemical Safety Overhaul of the Toxic Substances Control Act*, L. LINES (Aug. 5, 2016), http://digitalcommons.pace.edu/lawfaculty/1040.

115. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, 130 Stat. 448, *supra* note 114.

116. Jasanoff, *supra* note 3, at chapter 2.

117. Samuel D. Warren & Loius Brandeis, *Warren & Brandeis, The Right to Privacy,* 4 HARV. L. REV. 193 (1890). (Influentially established a right to privacy (Emphasis added)).

118. William Prosser, *Privacy*, 48 CAL. L. REV. 383 (1960) (divided privacy into four torts).

actors that reaches their mailbox or the threshold into their homes.[119] The case of Valentine v Chrestensen outlined limits to the bombardment of commercial advertising.[120] Such scattered precedents provide limited reason to hope that courts eventually will deal with the more serious issues of the manipulation and/or overwriting of ideas, desires, and preferences in the mind through the manipulation of informational content by corporate actors using BCIs.

Can anything be salvaged or learned from all these precedents, however broad or narrow? For example, can presently moribund principles of utility in patent determinations be revived? The next section proceeds by combining actors with action situations to consider the lessons of the lone instigator, the committed and tireless advocates, and the administrative order within the present kairotic moment, where the need for neurorights is well documented and increasingly justified by acts of law.

IV. CONFRONTING THE DISCOURSE OF INEVITABILITY AND LEGAL LAG

Especially in free societies, law often lags social problems. The risk of overregulation is emphasized to avoid the excessive shackling of liberty. This conservatism with respect to regulation lends itself to technological inevitability, propelling unencumbered innovation, which, in turn, may ironically reduce individual freedom and autonomy, as in the case of BCIs.

When the law lags behind risk-creating technological developments, subsequent regulatory efforts may be ad hoc, rather than systematic. Christopher Pace observes that causation requirements in torts law demand that plaintiffs demonstrate that a product *could* produce a harm, in addition to showing *that* it has caused harm, make it difficult, if not impossible, for plaintiffs to prevail even when they rely on unrefuted scientific evidence and expert opinion to substantiate their claims.[121] Many jurors are ill-equipped to make judgements about cutting-edge science. They tend to be awestruck by the mystique of experts,[122] and exhibit technochauvanism in their

119. Rowan v. Post Office Dept., 397 U.S. 728 1970 (Holding that that in their homes, people should not be forced to receive materials they do not want and are sensitive in nature (such as pornographic content), when it is easy to request and be removed from a mailing list. The ruling established that commercial advertising may be reasonably regulated without offending the First Amendment).

120. Valentine v. Chrestensen, 316 U.S. 52 (1942)(Supreme Court held that speech that was purely for commercial purposes, such as handing out sales flyers and advertisements in the streets, could be regulated; the First Amendment does not protect purely commercial speech acts. The interpretation is that there must be some public good in the messaging).

121. Christopher Pace, *Admitting and Excluding General Causation Expert Testimony: The Eleventh Circuit Construct*, 37 AM. J. TRIAL ADVOC. 47, 62 (2013).

122. *Id.*; Allison v. McGhan Med. Corp., 184 F.3d 1300, 1310 (11th Cir. 1999).

determinations. Additionally, even judges seem reluctant to accept animal studies as evidence of adverse effects on humans, even when presented with proof of harm by scientific experts, further heightening the causation hurdle.[123] These biases are difficult to counter because of the prevailing attitude that "[t]he courtroom is not the place for scientific guesswork, even of the inspired sort."[124]

Before they protect against foreseeable harm from neurotechnologies, governance units, including courts, legislatures, and administrative agencies must first be convinced that such harm is not only foreseeable but practically inevitable, in the absence of regulatory intervention. In section three, different modes of legal precedents were considered that might jumpstart and guide precautionary regulation of neurotechnologies in the US. At this point, we can only speculate on how neurorights advocates might move the policy needle in the United States. These lessons are confounded by the dual use and ambivalent character of modern technologies.[125] For that reason, any recommended policies will have to balanced and judicious. We need to figure out how to avoid the harms from commercial exploitation of neurotechnologies without creating obstacles to their development and application for medical and therapeutic purposes.

A. Confronting inevitability by broad measure

The heavy hand of regulation is the underlying concern of critiques that contend that outlining negative rights to mental privacy and integrity—writing them into the constitution or the framing of human rights—institutionalizes our conception of mental space and humanness forevermore and that this is premature given the uncertainty over the full capabilities of the human mind. Joseph Fins writes that the Chilean neurorights effort is cautionary to the point that it may be prohibitory; it may prohibit *any* manipulation of cerebral activity, and therefore any medical advancements.[126] This is not necessarily the case because clinical uses can be separated from non-clinical uses. In fact, in the US, the Food and Drug Administration (FDA) already regulates neurotechnologies for treating diagnosed conditions to protect medical

123. Kristen Ranges & Jessica Owley, *Vermin of Proof: Arguments for the Admissibility of Animal Model Studies as Proof of Causation in Toxic Tort Litigation*, 34 GEO. ENV'T L. REV. 303 (2021).

124. This prevailing view is a residual from Rosen v. CibaGeigy Corp., *supra* note 4. *Rosen* supported the earlier ruling in Berger v. New York, *supra* note 4 that articulated that "[t]he law, though jealous of individual privacy, has not kept pace with these advances in scientific knowledge."

125. HAMID R. EKBIA & BONNIE A. NARDI, HETEROMATION, AND OTHER STORIES OF COMPUTING AND CAPITALISM (2017).

126. Joseph J. Fins, *The Unintended Consequences of Chile's Neurorights Constitutional Reform: Moving Beyond Negative Rights to Capabilities*, 15 NEUROETHICS 26 (2022). *See* Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003 (2002).

patients. Meanwhile, consumer neurotechnologies, which create serious risks of harm to the entire population, are not regulated. Second, the critique that neurorights policy is premature dismisses the alternative perspective that we also do not know enough about the potential for technology to benefit or threaten society, and dismissing the corollary perspective may resultantly serve to protect science more than humanness. Plus, based on the view that policy should not be pursued because of the paucity of information about brains, the uncertainty about the potential of neurotechnologies should logically leave open the possibility of total prohibition. But since neither absolute is true in reality (there *is a* growing understanding of mind and brain, and foreseeable harms *can* be identified), policy should take a systematic approach based on the risks posed. In this case, institutionalizing the boundaries according to desired protections (for example, protecting autonomy and free thought) is an essential part of a preemptive measure.

Autonomy and free thought have been sources of extensive contemplation in the fields of philosophy and human rights law and have been variously defined. Following the Kantian tradition that links autonomy to self-determination, a definition used in Neuroethics sees autonomy as "*the ability to act or think with intention, in the absence of coercion or manipulation, with sufficient information to make rational choices in decisions regarding one's mind and body*."[127] The boundaries of free thought are best outlined in terms of human rights, where freedom of thought can be defined as *one's unimpeded internal mental capacity to hold and change ideas and beliefs*.[128]

127. Sara Berger & Francesca Rossi, *The Future of AI Ethics and the Role of Neurotechnology*, 2942 CEUR WORKSHOP PROC. 87, 92 (2021), https://ceur-ws.org/Vol-2942/invited1.pdf. Although there is no single definition of autonomy used in neuroscience, this definition from Berger and Rossi captures the standard conception across the field and is also aligned with a range of philosophical conceptualizations. *See* IMMANUEL KANT GROUNDING FOR THE METAPHYSICS OF MORALS (James Wellington trans., Hackett Publishing Co. 3rd ed. 1993) (1785) (envisioning autonomy as an entitlement to free will and self-determination, where one has the capacity to live according to one's own reasons and motives without manipulation from external forces); ALEXANDER PFANDER, PHENOMENOLOGY OF WILLING AND MOTIVATION (Herbert Spiegelberg trans., NW. Univ. Press 1967) (presenting a phenomenological account that defines autonomy as self-determined acts that originate as ego-centered and abide by one's values and interests); (John Stuart Mill, ON LIBERTY (David Spitz ed., 1975) (1859) (valuing individual agency and held that societal welfare hinges on individuals having freedom to hold and express beliefs and values).

128. *See Universal Declaration of Human Rights (UDHR) Article 18 and the International Covenant on Civil and Political Rights (ICCPR*), U.N. (1948), https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-civil-and-political-rights (guaranteeing that "Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance"); It is also compatible with U.N. Special Rapporteur on freedom of religion or belief, Ahmed Shaheed's articulation of freedom of thought (*see* Ahmed Shaheed (Special Rapporteur on Freedom of Religion or Belief), *Interim report of the Special Rapporteur on freedom of religion or*

All three neurorights protection efforts from Chile, Spain, and the UN use the language of existing rights, but as a model, the Spanish path appears to hold more promise for making progress on neurorights in the US. One important feature of the Spanish model is that beyond delineating possible harms and benefits from neurotechnologies, it has further contextualized them within digital rights. Contextualizing neurotechnologies within the realm of digital technologies puts the emphasis on *constraining harms* that might emerge from digitization processes, rather than *constraining technological development* on neurotechnologies as an isolated regulatory endeavor. The difference is that digitization opens and closes far more possibilities than neurotechnologies alone, and there should be broad governance (such as rules of understanding) at those openings/fissures; however, applications such as neurotechnologies that rely on digitization can only really be governed more narrowly. Specifically, processes, methods, and products of digitization (like algorithms in their varied uses) can be controlled in more specific ways and by a larger group of stakeholders. Thus, both practically and organizationally, the Spanish model is promising compared to constitutional reform.

The global domain and relative lack of governance authority of the UNHCR makes it challenging to compare to national efforts. However, the UN may possess greater authority to set definitions and boundaries of rights, given that the concepts largely exist in international human rights laws, to which most states are signatories. This makes the UN effort necessary, though by no means sufficient since there is an insufficient intersection between international human rights principles and basement-tinkerers developing tools for mental manipulation and recreational weaponry.[129] Thus, to make things happen on the ground, a channel would still be needed to administer of those principles. Such principles can be administered sectorally, but the high-level boundaries must first be in place. This is the model that Spain is establishing through the trifecta of Digital Spain, the National AI

belief, U.N. Doc. A/76/380 (Oct. 5, 2021), https://www.ohchr.org/en/documents/thematic-reports/a76380-interim-report-special-rapporteur-freedom-religion-or-belief#:~:text=Summary,Political%20Rights%3A%20freedom%20of%20thought (identifying four attributes of freedom of thought, as conceived in international jurisprudence, to include the freedom not to disclose one's thoughts and the freedom from impermissible alteration of one's thoughts); *see* Loukis G. Loucaides, *The Right to Freedom of Thought as Protected by the European Convention on Human Rights Case Notes and Analysis*, 1 CYPRUS HUM. RTS. L. REV. 79, 80 (2012), https://heinonline.org/HOL/LandingPage?handle=hein.journals/cyphumr1&div=10&id=&page= (drawing on American Judge Benjamin Cardozo's understanding of freedom of thought as "the indispensable condition, of nearly every other form of freedom," with expression and speech being the outward countenance of one's thought).

129. *See* Matthew Gault, *Palmer Luckey Made a VR Headset That Kills the User if They Die in the Game*, VICE (Nov. 7, 2022), https://www.vice.com/en/article/dy7kbq/palmer-luckey-made-a- vr-headset-that-kills-the-user-if-they-die-in-the-game.

Strategy, and the Neurotech initiative. But, as discussed, the regulatory rungs are still to be built.

1. The trajectory of precedent in the present, kairotic moment

In 2013, the Obama White House issued the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative to "measure every action potential for each neuron in brain circuits; manipulate the activity of every neuron in this circuit; and computationally analyze and model these circuits," according to scientists working on it.[130] Since that time, it has incentivized research and development, and directly and indirectly influenced advancements in neurotechnologies. While Rafael Yuste has been a key advisor on the initiative and is committed to neuroethics, the BRAIN Initiative has not yet adopted an explicit stance toward ethical impacts or regulatory reforms.

In October 2022, President Biden issued an executive order that could instigate such efforts. Similar to a combination of Spain's Digital Spain and their National AI Strategy, the US AI Bill of Rights guides the development of guardrails on artificial intelligence.[131] The AI Bill of Rights delivers practical guidance to government agencies and places responsibility on tech companies, researchers, and civil society to design and build AI that, essentially, does no harm. The bill identifies five non-binding principles (safe and effective systems; algorithmic discrimination protections; data privacy; notice and explanation; and human alternatives, consideration, and fallback), and explains why they are each important and how they could be implemented. For example, under 'safe and effective systems,' it calls on actors to design systems that "proactively protect [people] from harms stemming from unintended, yet foreseeable, uses or impacts of automated systems."[132] The government has enforced the guidelines on government agencies, as is the president's prerogative, but it is not enforceable against commercial applications or actors.

No executive order can mandate acts by private commercial actors. That requires legislation. However, Biden's AI Bill of Rights could be an impetus for legislative action. It could even lead to the resurrection of the patent system's utility test (discussed in section IIIB). For example, an amendment to the patent laws could provide grounds for rejecting a patent application for a

130. WORKSHOP: NEURORIGHTS A PHILOSOPHICAL DEBATE, *supra* note 20 at 11:33.

131. *Blueprint for an AI Bill of Rights,* THE WHITE HOUSE (2022), https://www.whitehouse.gov/wp- content/uploads/2022/10/Blueprint-for-an-AI-Bill-of-Rights.pdf (last visited Oct. 8, 2023); *see Unpacking the White House Blueprint for an AI Bill of Rights*, THE BROOKINGS INST. (2022), https://www.brookings.edu/events/unpacking-the-white-house-blueprint-for-an-ai-bill-of-rights/.

132. THE WHITE HOUSE, *supra* note 131 at 15.

new neurotechnology-based game that can kill a player who loses.[133] In addition, a statute recognizing neurorights might include measures such as blocking mergers of neurotechnology hardware companies and social media companies.

In all three cases examined herein, there was a prime mover, and the AI Bill of Rights could serve as one in the US, but individuals within governmental agencies will need to be key players. So too, will legislators from both sides of the aisle. For that to happen, neurorights advocates must provide them with a great deal of credible information about the threats to individual autonomy from commercial uses of neurotechnologies. They could take advantage of widespread agreement in Congress that protecting individual rights – predominantly *negative* individual rights – is a primary goal of government. Still, only an extreme optimist would bet that any such legislation could pass Congress in the next few years.

B. Confronting inevitability by narrow measure

A sectoral approach also has considerable promise, and while the dual nature of neurotechnologies will naturally require that protection from harm will rely on multiple sectors, the patent system can play a central role because its right-granting function is already positioned in proximity to the consumer marketplace. What this means is that patent law offers a proximal gate through which basement tinkerers and tech companies alike must pass to gain monopoly rights on their inventions. Like a guard at the gate, an extra level of patent review could be implemented in dual use technologies, and, if additional information were to be required, the existing disclosure mechanism could alert patent examiners and the public about the risk of harm.

1. Manning the gate through disclosure

Amanda Levendowski emphasizes disclosure's critical role in rooting out and exposing dystopian technologies.[134] She found that if civil society organizations are looking for it, evidence of dystopian motives could be found in disclosures in trademark filings well before them affecting society. Exposure in trademark findings may be helpful to confront harm, but it is seemingly less forceful in confronting the inevitability of harm.[135] On the other hand, facing the damage and the incentives to invention can be helped

133. *See* Gault, *supra* note 130, at 1.

134. Amanda Levendowski, *Trademarks as Surveillance Transparency*, 36 BERKELEY TECH. L.J. 439 (2021).

135. Though trademark disclosures require transparency, the technologies are still present in societyunless or until an agent finds it, reports on it, and some action is taken (all post-hoc). The recommendation that patenting has more power to preempt, of course, assumes that the guarantees of patenting and the decision of patent eligibility weigh stronger on an inventor's decision to exercise their technology than the guarantees provided by trademarking.

by patent law, where disclosure is also vital—deemed unquestionably necessary across judicial decisions and legal scholarship and central to sustaining innovation.[136] The dual notice/dissemination function, whereby the specification of the metes and bounds of the invention wards off infringement and furthers knowledge and technological progress, is foundational to the terms of the monopoly granted by patenting.[137]

Since patents are granted in exchange for disclosure, disclosure is a bargaining tool that can be utilized to encourage, for example, more forethought in both innovation and the granting of patents. The patent system provides precedent for forethought beyond the often toothless invocations for forethought.[138] Its disclosure requirement provides a necessary mechanism. However, as it exists now, the disclosure requirement does not require all of the necessary information that would allow a patent examiner to fully assess an invention's risk and/or moral utility. To serve this role, disclosure must include more than the information needed to determine nonobviousness.

To assist in determining the risk of future harm, the filing process could require applicants to disclose known alternative or coterminous uses of their technology, and in fact, the patent system *should* be given enough information to analyze the impact of technology on individuals and the social order. Examiners would need to have the capacity to do this analysis based on the information disclosed. Additionally, the patent system could formalize the process of considering the disclosures in trademark filings (along with patent disclosures) in patent determination, when such filings exist. Finally, as with ethics statements in research, it can expect applicants to provide the intended use of their technology and how they intend to ensure their technology is not used for purposes that have negative consequences.

2. Adding more gates to account for dual use technologies and iterative development

Dual use and iterative development add considerable complexity to the idea of considering moral utility/risk of future harm in determining patent eligibility. This is certainly true for neurotechnologies, which are tremendously important for people with neurological disorders, but, as elaborated

136. Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539 (2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1116020.

137. *See* Chisum et al., *supra* note 3, at 155.

138. *See* Luke Munn, *The Uselessness of AI Ethics*, 3 AI AND ETHICS, 869 (2022), https://link.springer.com/article/10.1007/s43681-022-00209-w; Anaïs Rességuier & Rowena Rodrigues, *AI Ethics Should not Remain Toothless! A Call to Bring Back the Teeth of Ethics*, 7 BIG DATA & SOC'Y, 1 (2020), https://www.diva-portal.org/smash/get/diva2:1458636/FULLTEXT01.pdf; Charlotte Stix, *Actionable Principles for Artificial Intelligence Policy: Three Pathways*, 27 SCI. AND ENGINEERING ETHICS 15 (2021), https://link.springer.com/article/10.1007/s11948-020-00277-3.

upon above, they introduce risks to autonomy and free thought that are presently unregulated in the consumer neurotechnology space. The review process could be a critical way to fill that regulatory gap by managing the risks put upon society. This would mean that dual-use technologies and improvements to previous technologies not specific to neurotechnologies, would undergo an added level of review.

The invention of complex technologies like neurotechnologies is typically iterative and uses many parts.[139] Additional review is essential in these cases because, when inventors build upon previously patented inventions, they may use things in ways not originally intended. This is part of the novelty, but it could introduce new places where risk should be assessed. An example is NeR technologies, which adapt medical discoveries in transplanting memories and ideas for non-medical or recreational use, or the case where a low-tech neurotechnology seems to be low-risk and patent-eligible, but it can accept additional, separate software, which would increase the capabilities and risks of the device. If the hardware and software are sold separately, the potential harm may escape a patent reviewer's notice. Thus, an additional level of patent review may be necessary when a patented technology is being reused for a different purpose. Or, if a company is using their patented technology in different ways, they could be required to apply for separate patents that state their purpose accurately, as is done in chemical manufacturing.

Given that neurotechnologies may be used for medical treatment, military operations, and entertainment, multiple government agencies would have regulatory roles to play. If the device is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, … [or is] intended to affect the structure or any function of the body of man …",[140] it would pass through the Food and Drug Administration (FDA), which would scrutinize its risks before making a determination about its use for those purposes. However, many consumer neurotechnologies, in spite of claims about treating depression, anxiety, and attention deficit, will not need FDA approval pursuant to Section 520(o), which excludes software functions that are intended to help make decisions for work and home and maintain and encourage a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a

139. Steven Dow, Blair MacIntyre, Jaemin Lee, Christopher Oezbek, Jay David Bolter & Maribeth Gandy, *Wizard of Oz Support Throughout an Iterative Design Process*, 4 IEEE PERVASIVE COMPUTING 18 (2005), https://www.cs.cmu.edu/~spdow/files/AEL-IEEEPervasive05.pdf; JAMES A. HIGHSMITH, ADAPTIVE SOFTWARE DEV.: A COLLABORATIVE APPROACH TO MANAGING COMPLEX SYSTEMS (2013).

140. 21 U.S.C. § 321(h).

disease or condition,[141] since they do not claim to treat *diagnosed* conditions. It is through this opening that technologies such as those used to monitor the productivity of workers and schoolchildren by reading their brain wave patterns (as described in section IIB) come to be marketed and used.

Although the FTC is reactive, responding to consumer safety issues post-hoc, it could act preemptively if, in conjunction with the added notice from patent disclosure (proposed above), a system of product labeling could be developed and shared between the patent system and FTC. This could expose risk ex ante. To do this, the patent system could use the new information from disclosure to screen for harmful products and require warning labels on certain products as a stipulation of a patent award. If required at the stage of patenting, it could limit harm and its inevitability. Applying warning labels earlier would be in line with disclosure's notice function. They could serve as an effective way to limit harm that is foreseeable.

Adding new disclosure requirements and additional scrutiny to the patent process would require an act of Congress to extend the duties under the Patent Act. The instigation to do this could originate from a lone supporter in Congress, could result as an application of the AI Bill of Rights, or could come through lobbying by the neurorights community—all precedents that have been seen. The chief concerns are that disclosure and added scrutiny will lead companies that do not want to disclose the capacities and motives of their products, to either disclose disingenuously or resort to trade secrecy, and that some patent examiners will need extra training to evaluate the social consequences of technology. Neither concern seems insurmountable, and both will require thoughtful and strategic additions that supplement the existing disclosure requirements with only questions that would be needed to assess social consequences. At some point, the requisite line-drawing will need to be motivated by a commitment to protect human autonomy and free thought in brain-intervening technologies.

V. CONCLUSION

It is now well recognized that BCIs and neurotechnologies pose a risk to human autonomy and freedom of thought, among other potential harms. This Article has outlined the nature of those harms and the foreseeable nature of the threat. It has raised the question of why society must be subject to technologies with known risks (which makes the risk of future harm inevitable). While government is reluctant to play its regulatory hand (for reasons largely beyond the scope of this Article), at its core, governance is a tool for public good and social order. This is evidenced by institutions including private property and freedom of contract, but not only those. Other institutions

141. *See* 21 U.S.C. § 360(j).

such as the precautionary principle, duty of care, human rights, and moral utility, all of which were discussed in section three, are important tools for good governance. They provide legal precedents and justification for precautionary regulation. For example, in Chile, Spain, and the United Nations, human rights law has been an important driver of their prophylactic policies on neurotechnologies, even at these early stages in the commercial neurotechnology industry. The moral utility doctrine, which previously guided patent determinations in the US and continues to do so in countries across the world, amounts to a precedent of a different kind. The final section analyzed the various precedents and speculated on the practicability of each one as a model for the US. Finally, the Article proposes that that the patent system and FTC have potentially important roles to play in preempting foreseeable harms from BCIs and neurotechnologies, and speculated about sources that could instigate necessary legislation, including the AI bill of rights, perhaps combined with lobbying by the neurorights community. There would be nothing unprecedented about a statute regulating the potentially very serious harms from commercial exploitation of biotechnologies.