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The Bionic Plaintiff and the Cyborg Defendant: Liability in the Age of Brain-to-Computer Interface

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ABSTRACT

Human-enhancing devices via machine-interface are rapidly approaching mass-marketability. These devices include hydraulically, mechanically, or electrically powered exoskeletons that allow functionality for the neurologically impaired. Newer devices, recently approved by the FDA, power such devices via brain waves transmuted into electrical signals. This Brain-to-Computer Interface (BCI) technology has been utilized in advanced designs, such as controlling a stylus or robotic arms, and more mundane contraptions, such as wheelchairs, via brain waves signaling intention. All are governed under Class II FDA designation for devices posing low and moderate risks.

Of concern are studies that have recorded the existence of a *readiness potential.* These are brainwaves recordable shortly before the intent to move – or even awareness of such intent – is acknowledged by the user. This raises the question regarding whether BCI technology can mobilize devices based on unconscious or subconscious thoughts – creating the possibility of "unintended" harm, and calling into question the legal definition of "intent" needed to prove assault and battery. The BCI devices also render it nearly impossible to divine relative contribution of fault in the event of an accident: was it due to the intent (conscious or not) of the user – or product malfunction, perhaps generating a product liability suit against the manufacturer? It appears this new technology is poised to throw the tort system into disarray.

Here, I postulate that FDA Class III regulation is warranted for BCI devices allowing remote movements engineered by pure thought. This would assure greater oversight and protection – not just for the user – but for bystanders and the public-at-large. I further suggest that enhanced testing is warranted – and that failure to pursue such testing might render the manufacturer liable in tort, allowing breach of pre-emption bars. This approach might possibly furnish double protection: deterrence via lawsuit, plus FDA oversight. This double protection, I suggest, is warranted in such potentially dangerous situations. Finally, I highlight the difficulties in assessing legal fault and recklessness when actions are committed without full awareness.

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I. INTRODUCTION

> *What if you could knock someone off merely by thinking about it? What if there was no way to trace your thoughts to the crime? And more horrendous still: what if you could harm someone because of some subconscious desire – and you weren't even aware of it? This isn't the stuff of science fiction. It might even be possible now.*[1]

It's been about a half a century since Martin Caiden wrote his science fiction novel *Cyborg* and Lee Majors played *The Six Million Dollar Man* on TV. Yet, real life today is poised to overtake science fiction. Workable – and commercially viable – prototypes of devices that confer on the user similar powers and abilities as *The Bionic Man* of TV are now available and approved by the FDA.[2]

At present, these devices have several major targets, including rehabilitating quadriplegics or amputees. In the medical arena, enhanced weight-lifting capacity helps nurses carry heavy patients and precision-guided arms facilitate micro-surgery. The armed forces, under DARPA, the Defense Advanced Research Projects Agency of the Department of Defense, is researching enhanced devices for wartime use. One sophisticated device designed for the military is called a powered exoskeleton, also known as powered armor, exoframe, or exosuit. Here, a system powered by motors or hydraulics energizes the device, facilitating limb movement, boosting the

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[1] *See* Barbara Pfeffer Billauer, *My Subconscious Made Me Do It: Legal Issues of Brain-To-Computer Interface*, AM. COUNCIL ON SCI. AND HEALTH (June 7, 2021), https://www.acsh.org/news/2021/06/07/my-subconscious-made-me-do-it-legal-issues-brain-computer-interface-15585; *see also* Barbara Pfeffer Billauer, *The Age of Mind-Control and the Cyborg*, AM. COUNCIL ON SCI. AND HEALTH (May 14, 2021), https://www.acsh.org/news/2021/05/14/age-mind-control-and-cyborg-15549.

[2] *See, e.g.*, Nicole Lou, *FDA OKs Brain-Computer Interface Device for Stroke Rehab:— IpsiHand System designed for individuals with upper-extremity disability*, MEDPAGE TODAY (Apr. 23, 2021), https://www.medpagetoday.com/neurology/strokes/92248.

wearer's strength and endurance. These are designed to help soldiers carry heavy loads both in and out of combat. In civilian areas, similar exoskeletons are being developed to help firefighters and rescue workers survive dangerous environments.

Novel uses of these devices are being designed to aid stroke victims or those suffering neurological diseases and paralysis who cannot move or control their appendages. Robotic arms are designed for remote-control. These devices are not powered by motor neurons or hydraulics- but by brain waves; a technology called Brain-to-Computer Interface or BCI.[3]

These newer devices, several of which recently received FDA approval[4] under its Breakthrough Device and the De Novo program,[5] have several components: mechanical, electrical, software, algorithmic – and human brain waves. Should any go wrong or misfire, accidents are sure to follow. I therefore suggest that thought be given to reclassifying these products as Class III devices. On one hand, imposing this doctrine might trigger the pre-emption doctrine, which has plusses and minuses, as described below. On the other hand, because independent human intentionality is also involved, perhaps tort law should supervene. If tort law does supervene, the brain-signaling technology involved raises thorny issues regarding the meaning of "intent" and "recklessness" as currently defined in tort law – rendering unknown exactly what aspect of tort law will be triggered, if, indeed, any.

Understanding the novel liability issues sure to arise requires understanding tort law, the FDA pre-emption doctrine, and the technology itself. The focus of this Article is to dissect out the relevant elements of each field, demonstrate the infirmities of current law in addressing anticipated BCI-related

[3] A corollary of this technology is called Brain to Brain (B2B) technology, still in the developmental stages.

[4] Lou, *supra* note 2.

[5] The De Novo program oversees novel low-to-moderate risk devices which are classified into Class I or II medical devices instead of automatically classifying them into Class III.

accidents, and determine the best means of regulating the technology, both to protect the user and society.

While the notion of a real-life bionic man or woman may seem difficult to apprehend, human functional adjuvants have been around in different forms for a long time. These include pacemakers and contact lenses, which are so ubiquitous that we've become inured to the paradigm shift they have wrought in terms of longevity and functionality. The law, too, has adjusted to the prospect of increased litigation – mostly by the pre-emption doctrine via the Medical Device Amendments of 1976[6] and later amendments,[7] along with the concept of risk-based classification for medical devices[8] and refinements in product liability law.

So, if externally enhanced humans and pre-emption have been around for such a long time, what's all the fuss with these new "bionic" units?

Three things: First, they augment human power to much more than ordinary human capacity. For example, contact lenses now give the wearer X-ray vision (apparently useful for cheating

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[6] Medical Device Amendments of 1976, 21 U.S.C. § 351; *see also* Riegel v. Medtronic Inc., 552 U.S. 312 (2008); 21 U.S.C. § 360K(A).

[7] *E.g.*, The FDA's Current Good Manufacturing Practice (CGMP) requirements for devices 21 C.F.R. part 820 were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act Federal Register of July 21, 1978 (43 FR 31 508) and became effective on December 18, 1978. The section prescribing CGMP requirements for medical devices was codified under part 820, which after lengthy revisions was published on October 7, 1996 (61 FR 52602), becoming effective June 1, 1997. *See Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, FDA, https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices (last updated Sept. 27, 2018). "The agency believed it would be beneficial . . . for the CGMP regulation to be consistent . . . with the requirements for quality systems contained in applicable international standards, primarily, the International Organization for Standards (ISO) 9001:1994 'Quality Systems--Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.'" *Id.*

[8] *A History of Medical Device Regulation and Oversight in the United States*, FDA, https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states (last updated June 24, 2019).

in cards)[9] and implanted cameras now can give "sight" to the sightless.[10] Exoskeletons can increase a runner's speed or augment the wearer's weight-bearing capacity, and armor enabling the wearer to withstand otherwise non-hospitable situations are all continually being refined and upgraded, meaning the potential for harm or damage or unfair competition is also upgraded, along with the enhanced gravity of such harm. Second, while older devices rely on external power sources, be they hydraulic, magnetic, or electrical, or even internal electrical impulses generated by motor nerves, new products are powered by brain waves – bypassing the sensory-motor nervous system entirely. These technologies confer on the bionically-enhanced 'super-human' powers that are 'self-powered' by mere thought, i.e., 'intentions' translated into electrical signals. And third, because these devices have mostly been classified as Breakthrough[11] and/or De Novo[12] – low to moderate risk[13] – products, they are not overseen under the more stringent Class III medical device protocol of the FDA,[14] thereby depriving society of the benefits more intense oversight confers.

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[9] MARKED CARDS STORE, https://www.markedcardsstore.com/store/p37/x-ray-contact-lenses-for-marked-cards.html (last visited Sept. 15, 2021).

[10] *Bionic Eyes: A new device may restore vision to those whose sight is dwindling*, ECONOMIST, (FEB. 21, 2015) https://www.economist.com/science-and-technology/2015/02/19/bionic-eyes; *see also* DIEGO BARRETTINO, *Smart Contact Lenses and Eye Implants Will Give Doctors Medical Insights*, SPECTRUM (July 25, 2017), https://spectrum.ieee.org/smart-contact-lenses-and-eye-implants-will-give-doctors-medical-insights/particle-1.

[11] *Breakthrough Devices Program*, FDA, https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s1.

[12] *FDA Authorizes Marketing of Device to Facilitate Muscle Rehabilitation in Stroke Patients*, FDA, https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-device-facilitate-muscle-rehabilitation-stroke-patients ("The FDA reviewed the IpsiHand System device through the De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type.").

[13] *De Novo Classification Request*, FDA, https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request#What_is_a_De_Novo_Classification_Request_.

[14] 21 U.S.C. § 360c(a)(1)(A)-(C) (defining Class I devices as those that do not require special controls to ensure the device's safety and effectiveness, Class II devices as those that require special controls to

Generally, our ability to foresee future harm (a requirement of the negligence claim) can be derived from past experiences with similar products.[15] With these new devices, however, we are in an unchartered world.[16] The ability to turn women or men into "Wonder Women" and "hulking humans" brings new legal challenges, not to mention bio-ethical ones. As usual, new products herald the potential for new lawsuits, and while manufacturers may look askance at this possibility, litigation-preparation also enhances accident prevention. Thus, identifying potential problems in advance allows for solutions *prior* to marketing or even before manufacturing and testing are complete.

To begin the analysis, it is noted that one purpose of tort law is deterrence.[17] Fear of lawsuits sounding in negligence and strict liability in tort (SLT) for designing and producing defective products provides sound motivation for manufacturers to produce safer products.[18] Regarding certain medical devices, however, the FDA pre-emption doctrine, discussed below, generally shields the manufacturer from liability, if production is in accord with the data furnished and approved by that agency. The classification of a device triggering this pre-emption, the Class III designation, brings with it both advantages (enhanced FDA monitoring and review) and disadvantages to the consumer (protection from most lawsuits). Weighing and counterbalancing the pros and cons of such classification will be crucial in affording maximum safeguards to public health –

ensure safety and effectiveness, and Class III devices as those that require premarket approval to ensure safety and effectiveness).

[15] Although, as the 1982 experience with Tylenol demonstrates, even ordinary endeavors, like packaging, can challenge our ability to forecast things that can go wrong.

[16] The psychological impact of human-enhancing powers seemingly has yet to be investigated, other than in science-fiction. *See* MARTIN CAIDEN, CYBORG (1972).

[17] Mark A. Geistfeld, *The Coherence of Compensation-Deterrence Theory in Tort Law*, 61 DEPAUL L. REV. 383, 390 (2012).

[18] *See* Paul D. Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CAL. L. REV. 116 (1968), https://lawcat.berkeley.edu/record/1110167?ln=en.

while encouraging development of new products and protecting the user.[19]

The situation becomes more complicated when BCI is involved. This technology, involving implanting or attaching electrodes onto a user,[20] turns our potential litigant into a cyborg,[21] a human-machine complex. Here, even mundane devices or actions, such as the ability to push a button, wield a stylus, or control a wheelchair, can pose unanticipated dangers. While the concept of bio-assist units may not be new, the chimerical contraption, human-machine unit, hybrid apparatus, or cyborg – relying on BCI, until recently the stuff of science fiction, raises the specter of entirely new- or hybrid-problems which may require novel legal solutions. Perhaps the gap between legal protections and current technology is best illustrated by the most "frightening" of the devices we may soon encounter – those involving the potential for mind-control of other humans: Brain-to Brain-interface (B2B),[22] discussed in Part II, section D.

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[19] To put the classification picture in perspective: "Most Class I devices are exempt from the 510(k) process, while most Class III devices require Premarket Approval (PMA), which is a more rigorous regulatory pathway than a 510(k). A PMA requires clinical data, as well as performance data, to prove safety and effectiveness." Stuart Goldman, *Medical Device Testing Requirements for 510(k) Submissions*, IN COMPLIANCE (May 31, 2017), https://incompliancemag.com/article/medical-device-testing-requirements-for-510k-submissions/. Less stringent and often required of Class II products is the Premarketing Notification Process. "A 510(k) is a premarket submission made to FDA to demonstrate that the device . . . is . . . safe and effective . . . ." *Premarket Notification 510(k)*, FDA, https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (last updated Mar. 13, 2020).

[20] Thus, typically medical devices are used by people considered ill. They are prescribed by doctors for their 'patients.' In the case of the disabled, the trend is not to consider these people as sick, but as well, albeit functionally challenged. The consumer of an exoskeleton is called a 'user' not a 'patient.'

[21] A portmanteau of *cybernetic* and *organism*—is a being with both organic and biomechatronic body parts. The term was coined in 1960 by Manfred E. Clynes and Nathan S. Kline. Manfred E. Clynes & Nathan S. Kline, *Cyborgs and Space*, ASTRONAUTICS, Sept. 1960, at 26, 27.

[22] Even "headier" devices are in the offing than discussed here. *See, e.g.*, Anthony Cuthbertson, '*Brain-Like Device' Mimics Human Learning in Major Computing Breakthrough*, INDEPENDENT (Apr. 30, 2021),

Legally speaking, BCI devices raise pertinent questions regarding whether the current state of the law is appropriately configured to address the novel issues sure to be raised. Whether the FDA has the competence and capacity to properly inspect new devices and drugs is one such hot topic.[23] Whether the FDA has developed or determined proper procedures to evaluate the BCI technology is another. Whether the law has developed an appropriate and functional *modus operandi* to address AI-black box technology is a third. More pointedly, whether the FDA's current designation of these devices as presenting low to moderate risk, is proper – is a fourth. Finally, and crucially, whether concepts of *intent* and *recklessness* as currently conceived in tort law remain apt in view of the latest devices must be revisited.

In this article, I raise novel product safety concerns that arise by virtue of the newly created interface between mortal and machine – raising issues in legal protection by tort and scientific (FDA) review. I also highlight the deficits in assessing medical devices as a potentially dangerous device only to the user, rather than as a potential public health threat, as well.

In Part II, I provide an overview of the technology of bionic products on the market or near-ready for marketing. This section addresses two classes of devices: the external machine affixed to the human, and those with brain-directed interfaces (BCI) which are incorporated with or into the various devices. Part III postulates two hypotheticals setting forth in stark relief the legal problems generated by these devices and injuries they might cause to bystanders. Part IV reviews the current state of tort law. Part V discusses FDA pre-emption of medical device suits for the riskiest devices – which, for the time being, does not apply to BCI devices. On the assumption that the current classification (which does not trigger pre-emption) may change,

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https://www.independent.co.uk/life-style/gadgets-and-tech/brain-computer-interface-pavlov-b1839232.html (reporting on a device that can 'directly interface with living tissue' for next-generation bioelectronics).

[23] Tia Powell, *What A Bad Day Science Had*, HASTINGS REP. (June 8, 2021), https://www.thehastingscenter.org/what-a-bad-day-science-had/; *see also* Josh Bloom, *A Victory Over Alzheimer's? Not So Fast*, ACSH J. (June 7, 2021), https://www.acsh.org/news/2021/06/07/victory-over-alzheimers-not-so-fast-15589.

an overview regarding the suitability of pre-emption in light of these technological advances is undertaken.

Finally, in Part VI, I suggest a different legal paradigm that may better address the needs of the cyborg and those with whom it interfaces, along with addressing the societal need for safe and effective BCI powered products, namely by reclassifying these devices as Class III and allowing a limited window for tort lawsuits for failure to test bystander impact in real world circumstances.[24] This approach incorporates a public-health oriented focus, mimicking the traditional health-centric view vested in the states. I end by reminding the reader that current developments in BCI may turn time-worn tort concepts of intentionality and recklessness on their heads.

II. TECHNOLOGICAL REVIEW

A. What's an Exoskeleton? What's a Cyborg?[25]

A cyborg is generally defined as a human-machine interface contrivance. According to Cyborg lore[26] there are four

[24] FDA Class II categorization does include requirements for clinical testing although the bystander impact is not specifically identified. Bobby Marinov, *FDA Classifies Exoskeletons as Class II*, EXOSKELETON REPORT (Mar. 7, 2015), https://exoskeletonreport.com/2015/03/fda-classifies-exoskeletons-as-class-ii/; *see also* Medical Devices; Physical Medicine Devices; Classification of the Powered Exoskeleton 21 C.F.R. § 890 U.S. GOV'T PUBLISHING OFFICE (2015) https://www.govinfo.gov/content/pkg/FR-2015-02-24/html/2015-03692.htm.

[25] "An interesting 11-minute PBS News Hour video demonstrates several bionics projects that use state-of-the-art robotics technology to create artificial body parts capable of assisting people with disabilities. The video demonstrates a robotic exoskeleton called eLegs . . . and glasses that provide 'bionic eyesight.'" *Bionic body parts offer hope to the disabled*, DEVICE GURU (July 3, 2015), https://deviceguru.com/bionic-body-parts-offer-hope-to-the-disabled/. It includes an artificial arm that gets wired into up to the user's nerves, a robotic arm operated by a monkey, special glasses that provide bionic eyesight for the visually impaired, and a runner with prosthetic legs who hopes to compete in the 2012 Olympics. *Id.*

[26] There are presently two certified cyborgs along with a cyborg foundation. *See* CYBORG FOUNDATION, https://www.cyborgfoundation.com/; there are also lots of far-future science fiction depicting their place in society. *See, e.g.*, SAMUEL DELANEY, NOVA (1986).

classes of cyborg which describe the technology we are about to encounter.

> Cyborg technologies can be:
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> - ☐ 1. restorative, in that they restore lost functions and replace lost organs and limbs;
> - ☐ 2. normalizing, in that they restore some creature to indistinguishable normality;
> - ☐ 3. reconfiguring, creating posthuman creatures equal to but different from humans . . . ; and,
> - ☐ 4. enhancing, the aim of most military and industrial research, or what those with cyborg-envy or cyborgphilia fantasize. Th[is] . . . category seeks to construct everything from factories controlled by a handful of 'worker-pilots' and infantrymen in mind-controlled exoskeletons to the dream many computer scientists have—downloading their consciousnesses into immortal computers . . . reconfiguring . . . in science-fiction-land . . . posthuman creatures equal to, but different from, humans . . . .[27]

Technically, humans with artificial cardiac pacemakers or implantable cardioverter-defibrillators are cyborgs. These devices measure voltage potentials in the body or on the skin, perform signal processing, and keep the user alive by delivering electrical stimuli using a synthetic feedback mechanism.

[27] *What is a Cyborg?* CYBORG ANTHROPOLOGY (quoting THE CYBORG HANDBOOK 3 (Chris Hables Gray et al. eds., 1st ed. 1995)), http://cyborganthropology.com/What_is_a_Cyborg%3F (last modified Dec. 24, 2010); "Cyborg translators are currently thought of almost exclusively as enhancing: improving existing translation processes by speeding them up, making them more reliable and cost-effective." *Id.* (quoting Doug Robinson, *Cyborg Translation,* UNIV. OF MISS., http://home.olemiss.edu/~djr/pages/writer/articles/html/cyborg.html).

Another such device is the cochlear implant.[28] Interestingly, cochlear implants are regulated by the FDA under Class III designation, reserved for devices considered to pose a high degree of risk to the user.[29] Perhaps as a harbinger of things to come, in addition to allowing the deaf to hear, cochlear implants have forged cracks in the previously inviolate pre-emption doctrine which generally provides manufacturers safe passage through the liability arena for suits sounding in strict liability in tort (SLT) and negligence.

On February 24, 2015, the FDA designated exoskeletons and similar devices, even those powered by brain waves or thoughts, as Class II devices,[30] regulated much the same as condoms.[31] For now, these exoskeleton-type Class II devices, including powered wheelchairs[32] or other cyborg enhancement devices, fly under the FDA-pre-emption radar screen.

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[28] *See infra* pp. 102-04.

[29] *Cochlear Implants: A Different Kind of 'Hearing'*, FDA (Nov. 10, 2017), https://www.fda.gov/consumers/consumer-updates/cochlear-implants-different-kind-hearing.

[30] "Class II medical devices are those devices that have a moderate to high risk to the patient and/or user. 43% of medical devices fall under this category. Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits." *What's the Difference Between the FDA Medical Device Classes?*, FDA (Feb. 2, 2018), https://www.bmpmedical.com/blog/whats-difference-fda-medical-device-classes- 2/#:~:text=Class%20II%20medical%20devices%20are,and%20some%20pregnancy%20test%20kits.

[31] Bobby Marinov, *FDA Classifies Exoskeletons as Class II*, EXOSKELETON REPORT (Mar. 7, 2015), https://exoskeletonreport.com/2015/03/fda-classifies-exoskeletons-as-class-ii/.

[32] To date one powered wheelchair, the iBOT, had received FDA Class III designation. The company manufacturing them, however, has recalled them and is not marketing them. *Putting Powerchairs to the Test*, MOBILITY MGMT. (Feb. 1, 2009), https://mobilitymgmt.com/Articles/2009/02/01/Putting-Powerchairs-to-the-Test.aspx. Currently, stair-climbing and motorized (powered) wheelchairs have been downgraded to Class II, although special requirements are enacted, including clearance through the 510(k) premarketing approval pathway prior to being allowed on the market. Alexander Gaffney, *FDA Loosens Regulatory Controls on Stair-Climbing Wheelchairs*, REGUL. FOCUS (Apr. 14, 2014), https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2014/4/fda-loosens-regulatory-controls-on-stair-climbing-wheelchairs.

B. An Overview of Available "Cyborg-Enhancements"

Any implant combining mechanical modification with a feedback response that augments human capacity would be considered a "cyborg enhancement," be it exo-skeleton or cochlear implant, regardless of FDA class designation. Take the exoskeleton. Like its animal namesake, this device is an external skeleton that supports and protects a person's body. In its current incarnation, coupled with a power source, sensor, and bio-feedback unit, it enables the non-walking to stand and ambulate.[33] In conventional usage, larger animal exoskeletons are sometimes called "shells" while the human variants are called "armor", which, like their animal counterparts, contain rigid and resistant components that fulfill a set of functional roles. So far, these include walking, sensing, support, weightlifting, protection, and acting as barriers in hostile environments using sensory signals.[34]

Exoskeletons have also been used for military purposes – giving soldiers the ability to move faster while carrying more weight; the Defense Department research arm, DARPA, has been experimenting with them for over a decade.[35] These

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[33] Dennis R. Louie et al., *Gait Speed Using Powered Robotic Exoskeletons After Spinal Cord Injury: A Systematic Review and Correlational Study*, J. NEUROENGINEERING & REHAB. (Oct. 14, 2015), https://pubmed.ncbi.nlm.nih.gov/26463355/. *See also* Ashraf S. Gorgey, *Robotic Exoskeletons: The Current Pros and Cons*, 9 WORLD J. ORTHOPEDICS 112, 112 (2018).

[34] *See* Giacomo Valle et al., *Mechanisms of Neuro-Robotic Prosthesis Operation in Leg Amputees*, *SCI. ADVANCES* (Apr. 21, 2021) ("Restoring intraneural sensory feedback results in functional and cognitive benefits. It is unknown how this artificial feedback, restored through a neuro-robotic leg, influences users' sensorimotor strategies and its implications for future wearable robotics. . . . Commercially available lower-limb prostheses do not provide voluntary active control nor sensory feedback to the user. Consequently, amputees . . . rely on visual cues during everyday prosthesis use . . . [and] there are no commercially available leg prostheses that provide sensory feedback to the users (i.e., real-time information about the movement of the prosthesis itself or about the interaction with the ground).").

[35] *See* Charles E. Gannon, *Imag(in)ing Tomorrow's Wars and Weapons*, 21 PEACE REV. 198, 201 (2009) (noting DARPA's "Exoskeletons for Human Performance Augmentation" program has the goal "to develop

military exoskeletons create super-soldiers that can lift hundreds of pounds as easily as lifting ten pounds while running at twice normal speed, and with greater endurance. For the civilian, uses currently focus on helping paraplegics regain mobility.[36] Among the major players are ReWalk's exoskeleton, Cyberdyne's HAL, and Ekso, (formerly E-legs, "Exoskeleton Lower Extremity Gait System") made by Ekso Bionics.[37] The EKSO system, a hydraulically powered exoskeleton system, helps paraplegics and persons with lower extremity weakness to stand and walk with crutches or a walker.[38] Originally developed for DARPA as the Ekso Bionic's GT™ Human Universal Load Carrier, the device was eventually repurposed for civilian use, including in traumatic brain injury. Force and motion sensors monitor the user's gestures and motion and translates it into action via its computer interface. According to the company's website, "Ekso Bionics offers a wearable suit, called EksoNR, which was developed exclusively for use in rehabilitation centers and clinical settings to help patients gain back their mobility sooner."[39] The EksoNR is the "first powered exoskeleton

devices and machines that will increase the speed, strength, and endurance of soldiers in combat environments.").

[36] *ReWalk™ Personal Exoskeleton System Cleared by FDA for Home Use*, REWALK (June 26, 2014), https://ir.rewalk.com/news-releases/news-release-details/rewalktm-personal-exoskeleton-system-cleared-fda-home-use; David Shamah, *ReWalk, Which Helps the Paralyzed Walk, Goes Public*, TIMES ISRAEL (Aug. 27, 2014), https://www.timesofisrael.com/rewalk-which-helps-the-paralyzed-walk-goes-public/. *See also* ReWalk Robotics, *ReWalk – Walk Again: Argo's Exoskeleton Technology*, YOUTUBE (Jan. 7, 2014), https://www.youtube.com/watch?v=2Xd27c-pz4Y.

[37] *See Ekso Bionics*, WIKIPEDIA, https://en.wikipedia.org/wiki/Ekso_Bionics (describing a product marketed as a Class I device) (as of Oct. 3, 2021, 1:39 GMT); *see also* Ashraf S. Gorgey, *Robotic Exoskeletons: The Current Pros and Cons*, 9 WORLD J. ORTHOPEDICS 112, 112 (2018).

[38] Ashraf S. Gorgey et al., *Exoskeletal Assisted Rehabilitation After Spinal Cord Injury*, 5 ATLAS OF ORTHOSES AND ASSISTIVE DEVICES, 440 (2019) https://www.sciencedirect.com/topics/nursing-and-health-professions/exoskeleton-rehabilitation; *see also* Sarah R. Chang et al., *Powered Lower-Limb Exoskeletons to Restore Gait for Individuals with Paraplegia – a Review*, NIH, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5166705/ (2015).

[39] *How an Exoskeleton Helps With Mobility Therapy*, EKSO BIONICS, https://eksobionics.com/how-an-exoskeleton-helps-with-mobility-therapy/ (last visited Sept. 15, 2021).

cleared by the FDA for ABI [Acquired Brain Injury]."[40] EksoNR was also an early contender for use with stroke paralysis and spinal cord injury and is "designed to ensure the most natural gait by re-teaching the brain and muscles how to properly walk again."[41] In addition, EksoNR can also help patients with injuries from aneurysms, hypoxia/anoxia, ischemia, and brain tumors.[42] Regardless, the product specifications are quite precise:

> Users can "put on and take off the device by themselves as well as walk, turn, sit down, and stand up unaided." . . . [The device] weighs 45 pounds (20 kg), has a maximum speed of 2 mph (3.2 kph) and a battery life of 6 hours. It is suitable for users weighing up to 220 pounds, who are between 5 ft 2in and 6 ft 4in tall and can transfer themselves from a wheelchair to a chair.[43]

The Israeli ReWalk system is a wearable robotic exoskeleton targeted to individuals with Spinal Cord Injury (SCI). It is the first exoskeleton to receive FDA clearance for use with SCI.[44] It provides powered hip and knee motion enabling them to sit, stand upright, and walk. With proper training, the wearer can also master the capacity to ascend and descend stairs. According to the company's website:

> ReWalk exoskeleton is a light, wearable brace support suit featuring DC motors at the joints, rechargeable batteries, an array of sensors, and a

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[40] *EksoNR – Description*, EXOSKELETON REPORT, https://exoskeletonreport.com/product/eksonr/ (last visited Oct. 17, 2021).

[41] *How an Exoskeleton Helps With Mobility Therapy*, *supra* note 39. *See also EksoNR – Description*, *supra* note 40.

[42] *How an Exoskeleton Helps With Mobility Therapy*, *supra* note 39.

[43] eLEGS *Berkeley Robotics and Human Engineering Laboratory*, BERKELEY BIONICS, https://www.wikiwand.com/en/Ekso_Bionics#:~:text=In%202011%20eLEGS%20was%20renamed,a%20wheelchair%20to%20a%20chair (last visited Sept. 15, 2021).

[44] Francie Diep, *First Exoskeleton Gets FDA Approval For U.S. Sales*, POPULAR SCIENCE (June 27, 2014, 7:30 PM), https://www.popsci.com/article/science/first-exoskeleton-gets-fda-approval-us-sales/.

> computer-based control system. Users wear a backpack device and braces on their legs and select the activity they want from a remote control. A sensor on the chest determines the torso's angle and guides the legs to move forward or backward to maintain balance.[45]

Again, the specifications are clearly enumerated:

> ReWalk's robotic legs, which support their own weight, weigh 46 pounds, while its backpack, which houses the system's computer and battery, weighs five pounds.
>
> . . . ReWalk's computer runs Windows, and delivers control signals to the exoskeleton. The signals are first transmitted by a wrist device that has physical buttons, and allows the wearer to engage three exoskeleton modes: standing, sitting and walking. Currently, the battery is designed to support a full day of intermittent walking, but if the wearer walks non-stop, the battery will last three to four hours. . . . [A] physical restriction limits the use of the ReWalk to those between 5-foot-3 and 6-foot-3, along with a top weight limit of 220 pounds.[46]

The HAL (Hybrid Assistive Limb**)** exoskeleton, the first unit to receive global safety certification, is made by Cyberdine in Japan. Its robotic limbs also strap to the user's arms and legs, and its backpack, battery, and control computer are strapped around the waist of the wearer, but it only weighs 22 pounds –

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[45] Design World Staff, *ReWalk Exoskeleton Helps Paraplegics Walk*, MEDICAL DESIGN AND OUTSOURCING (May 19, 2008), https://www.medicaldesignandoutsourcing.com/rewalk-exoskeleton-helps-paraplegics-walk/; *see also* David Shamah, *ReWalk, Which Helps the Paralyzed Walk, Goes Public*, TIMES ISRAEL (Aug. 27, 2014), http://www.timesofisrael.com/rewalk-which-helps-the-paralyzed-walk-goes-public/#ixzz3SlW2NXOq.

[46] Adario Strange*, FDA Approves First Robotic Exoskeleton for Paralyzed Users*, MASHABLE (June 30, 2014), http://mashable.com/2014/06/30/fda-approves-robotic-exoskeleton-paralyzed-rewalk/.

providing greater mobility than a wheelchair. The suit's backpack contains a battery and computer controller. HAL was originally targeted to help elderly patients who are not paraplegics with their daily tasks.[47] The newer Leggs-only HAL version has been modified to assist the walking-disabled. In addition to its rehabilitation uses, it has been used in disaster response work, including cleanup at the Fukushima nuclear accident site.[48]

The mechanism of HAL's operation is different from the EKSO or ReWalk version: Generally, when a person attempts to move, the brain sends electrical signals via motor neurons to the muscles. In the HAL system, weak traces of these signals, called biosignals, are detected on the skin surface via an attached sensor. The HAL exoskeleton identifies these signals, then amplifies them and sends them to the suit's power unit, which then "commands" the suit to move in sync with the wearer's own limbs. The HAL suit is controlled by both a user-activated "voluntary control system" known as Cybernic Voluntary Control (CVC) and a "robotic autonomous control system" known as Cybernic Autonomous Control (CAC) for automatic motion support.[49]

Additional devices include the "body extender" full body exoskeleton, invented with Italian technology whose primary purpose is to assist in heavy weight-lifting (50kg per each hand).

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[47] Tim Hornyak, *Smart Walkers Lead the Way for Japanese Elder-Care Robots*, COMPUTERWORLD (Oct. 16, 2014), https://www.computerworld.com/article/2835074/smart-walkers-lead-the-way-for-japanese-eldercare-robots.html.

[48] Teo, *New HAL Exoskeleton: Brain-Controlled Full Body Suit to Be Used in Fukushima Cleanup*, 18 NEUROGADGET (Oct. 18, 2012), https://www.bibliotecapleyades.net/ciencia/cienciatranshumanism15.htm.

[49] *See generally* Kenta Suzuki et al., *Intention-based walking support for paraplegia patients with Robot Suit HAL*, 21 ADVANCED ROBOTICS 1441 (2007); Hiroaki Kawamoto et al., *Pilot Study of Locomotion Improvement Using Hybrid Assistive Limb in Chronic Stroke Patients*, BMC NEUROLOGY (Oct. 7, 2013), https://bmcneurol.biomedcentral.com/articles/10.1186/1471-2377-13-141; Research Program Cybernics University of Tsukuba, GLOBAL COE PROGRAM, CYBERNICS, University of Tsukuba, (Apr. 1, 2007).

Sagawa Electronics in Japan has also invented a full body robotic suit.

While these devices may seem fabulous enough,[50] even more audacious inventions have moved off the planning stages and are in preparation. These include robotic leg prostheses, which are powered robotic prostheses that sense a person's next move using sensorimotor strategies to provide powered assistance,[51] and prosthetic control devices with implantable myoelectric sensors that detect nerve signals above a missing limb, using these signals to help the user move more naturally. Another such device is the *Tongue Drive System*, which helps individuals with severe paralysis navigate their environment using only tongue movements. Additionally, artificial electroactive polymers are now being incorporated in design. These electrically contractive fibers supposedly increase the strength-to-weight ratio of movement.[52]

C. Future Shock: Brain-to-Computer Interface

These products are tame, however, compared to what's just come off the drawing-board: instead of sensory-motor signals directing movement that might be targeted to amputees, wireless Brain-Computer Interface (BCI) allows a greater range of the neurologically impaired to use their thoughts to control external devices for mobility or communication by recording and transmitting brain activity wirelessly. Thus, BCI can restore

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[50] There are, however, those who voice concerns of the propriety of their usefulness. *See* Ashraf S. Gorgey, *Robotic Exoskeletons: The Current Pros and Cons*, 9 WORLD J. ORTHOPEDICS 112 (2018).

[51] Anil K. Ra et al., *Mina: A Sensorimotor Robotic Orthosis for Mobility Assistance*, 2011 J. ROBOTICS (Dec. 14, 2011), https://www.hindawi.com/journals/jr/2011/284352/. *See generally* Giacomo Valle, et al., *Mechanisms of Neuro-robotic Prosthesis Operation in Leg Amputees*, 7 SCI. ADVANCES 1, 1 (2016), https://www.science.org/doi/10.1126/sciadv.abd8354.

[52] *See* Pinhas Ben-Tzvi, Novel Field Robots and Robotic Exoskeletons: Design, Integration, and Applications, Conference Presentation at SPIE Smart Structures + Nondestructive Evaluation 2020 (Apr. 24, 2020), *in* 11375 SPIE ELECTROACTIVE POLYMER ACTUATORS AND DEVICES (2020), https://www.spiedigitallibrary.org/conference-proceedings-of-spie/11375/1137503/Novel-field-robots-and-robotic-exoskeletons--design-integration-and/10.1117/12.2539157.full?SSO=1.

functionality to those disabled by neuromuscular disorders such as amyotrophic lateral sclerosis, cerebral palsy, stroke, or spinal cord injury, as well as paralysis. The external devices to which they are connected might be exoskeletons or cursors, robotic arms or prostheses, even wheelchairs or drones. In principle, any type of brain signal could empower a BCI; the ones currently explored are those signaling intentions.[53] These devices, recently authorized by the FDA,[54] can make profound differences in people's lives – allowing movement of a bionic arm in someone previously paralyzed[55] – merely by reading their thoughts,[56] or allowing someone "locked in" to communicate by writing with a stylus.[57] The devices, however, also have the potential to cause severe and unanticipated damage on a grand scale.

The novel BCI technology involved in these inventions employs electrodes to detect brain signals involved in the intention to move, and translates them into commands

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[53] Jerry J. Shih, *Brain-Computer Interfaces in Medicine*, 87 MAYO CLIN. PROC. 268, 269 (2012).

[54] On April 23, 2021, the FDA announced its authorization of the Neurolutions IpsiHand Upper Extremity Rehabilitation System for stroke survivors trying to regain hand, wrist, or arm function as part of their rehabilitation therapy. Press Release, Food and Drug Admin., FDA Authorizes Marketing of Device to Facilitate Muscle Rehabilitation in Stroke Patients (Apr. 23, 2021).

[55] Press Release, *Prosthetic Arm Can Move and Feel*, UNIV. OF UTAH (July 24, 2019), https://healthcare.utah.edu/publicaffairs/news/2019/07/prosthetic-arm.php. *See also Motorized prosthetic arm can sense touch, move with your thoughts*, SCI. NEWS (July 24, 2019), https://www.sciencedaily.com/releases/2019/07/190724144150.htm.

[56] Francis R. Willet et al., *High-performance brain-to-text communication via handwriting*, 593 NATURE 249, 249-54 (May 12, 2021); *see also Brain Computer Interface Turns Mental Handwriting into Text on Screen*, HOWARD HUGHES MED. INST. (May 12, 2021), https://www.hhmi.org/news/brain-computer-interface-turns-mental-handwriting-into-text-on-screen.

[57] Alan Johnston, *Paralysed Man Moves Arm for First Time Since Accident Using Brain Implant that Reads His Thoughts,* THE INDEPENDENT (Mar. 28, 2017, 11:45 PM), https://www.independent.co.uk/news/science/paralysed-man-moves-arm-for-first-time-in-years-using-brain-implant-that-can-read-his-thoughts-a7654761.html; *see also* A. Bolu Ajboye et al., *Restoration of Reach and Grasping Movements Through Brain-Controlled Muscle Stimulation in a Person with Tetraplegia: A Proof-Of-Concept Demonstration*, 389 THE LANCET 1821 (2017).

that bypass neuro-muscular pathways to activate increasingly complex control of external devices.[58] The electrodes can be implanted on the scalp, on the cortical surface (intracortical monitoring), or inserted within the brain to access and retrieve brain waves.[59] "The resulting signal features are then passed to the feature translation algorithm, which converts the features into the appropriate commands for the output device (i.e., commands that accomplish the user's intent)."[60] In an advanced iteration, the process of neuro information is reversed: the computer sends feedback back to the brain, or computer to brain interface (CBI).[61] This continuous dance between computer and brain allows the user to refine his or her motions – it is a form of ultimate learning, enhanced by AI. Added to the medical uses of BCI are drones used for recreational[62] or military purposes. These introduce yet another layer of legal considerations.

D. Future Super-Shock: Brain-to-Brain Interface

While mind-machine interface is an astounding concept with which we may not be prepared to deal – at least legally and ethically – mind-to-mind communication using voluntary control of alpha waves[63] portends the greatest challenges.[64] It is also much closer to actuality than might be expected.

Brain-computer interfaces (BCI) and computer-brain interfaces (CBI) "can be combined to realize the vision of non-

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[58] *Id.*

[59] Shih, *supra* note 53, at 269-73. *See also Billauer*, *The Age Of Mind-Control And The Cyborg*, *supra* note 1.

[60] Shih, *supra* note 53, at 272.

[61] *See* Carles Grau, et al., *Conscious Brain-to-Brain Communication in Humans Using Non-Invasive Technologies*, 9 PLoS ONE e105225 (2014), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0105225.

[62] Jason Dearen, *Drones Fly Controlled by Nothing More Than People's Thoughts*, THE INDEPENDENT (Apr. 22, 2016, 4:27 PM), https://www.independent.co.uk/news/science/drones-brain-thoughts-controlled-bci-brain-computer-interface-brain-controlled-interface-a6996781.html.

[63] *See* Grau et al., *supra* note 61 (noting "Pioneering research in the 60's using non-invasive means already demonstrated the voluntary control of alpha rhythm de-synchronization to send messages based on Morse code.").

[64] *See, e.g.*, Eric Kandel, *The New Science of Mind and the Future of Knowledge*, 80 NEURON 546 (Oct. 30, 2013).

invasive, computer-mediated brain-to-brain (B2B) communication between subjects (hyperinteraction)."[65] Also known as BTBI or B2B, brain-to-brain interfacing is "a novel means of information transfer which bypasses the customary sensory means for the brain to apprehend information from another individual."[66] In one iteration, researchers demonstrated "the conscious transmission of information between human brains through the intact scalp and without intervention of motor or peripheral sensory systems." This is accomplished by linking two human minds directly via integrating two neurotechnologies – BCI and CBI – and thereby effectuating a non-invasive, cortically based, and consciously driven information transfer system.[67] After achieving non-invasive direct communication between human minds, the authors concluded:

> [W]e anticipate that computers in the not-so-distant future will interact directly with the human brain in a fluent manner, supporting both computer- and brain-to-brain communication routinely. The widespread use of human brain-to-brain technologically mediated communication will create novel possibilities for human interrelation with broad social implications . . . .[68]

Current research and available products readily demonstrate the possibility for abuse and the need for legal safeguards:

> The very act of linking two brains together to transfer information raises a variety of ethical and safety concerns. Though born of two approaches, extraction and delivery of information . . . BTBIs are a novel means of information transfer which bypasses the customary sensory means for the brain to

[65] Grau et al., *supra* note 61.

[66] John B. Trimper et al., *When "I" Become "We": Ethical Implications of Emerging Brain-to-Brain Interfacing Technologies*, FRONTIERS IN NEUROENGINEERING (2014), https://www.frontiersin.org/articles/10.3389/fneng.2014.00004/full.

[67] Grau et al., *supra* note 61.

[68] *Id.*

> apprehend information from another individual.[69]

It is also anticipated that brain wave transmission could also be mined surreptitiously via "epidermal electronics," which are "extremely thin grids of electrical sensors applied directly to the outside of the skin, similar to a temporary tattoo – placed on the forehead under hair, for instance."[70] Through wireless BTBI transmissions, soldiers, police, or criminals could communicate silently and covertly during operations – as could a lawyer and client during a trial.[71] Researchers anticipate the ability to be able to transfer emotion and false memories recently achieved experimentally in both mice and humans,[72] thereby taxing the limits of even the most impressive cross-examiner. BTBI-related neural information also can be transferred over the internet.[73] Hence concern that the neural device could be hacked, as has been done with heart pacemakers, is warranted.[74]

B2B could also be used to control the limbs of the receiving subject via the encoder's neural activity, causing another person to act in unintended ways. "For example, a recent article reports experiments in which EEG was used to control a Brain-Machine Interface (BMI) suit worn by the user, allowing

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[69] Trimper et al., *supra* note 66.

[70] *Id.* (citing Dae-Hyeong Kim et al., *Epidermal Electronics*, 333 SCIENCE 838 (Aug. 12, 2011)).

[71] Trimper et al., *supra* note 66.

[72] *Compare* Ying Li, et al., *The influence of positive emotion and negative emotion on false memory based on EEG signal analysis*, BIORXIV (Jan. 14, 2021), https://www.biorxiv.org/content/10.1101/2021.01.12.426168v1.full (n.b., the article cited is a pre-print, and has not yet been peer-reviewed), *with* Trimper et al., *supra* note 66, *and* Sarah Gibbens, *Memories Can Be Altered in Mice. Are Humans Next?*, NATIONAL GEOGRAPHIC (July 13, 2018), https://www.nationalgeographic.com/science/article/news-memory-manipulation-research-neuroscience (citing Steve Ramirez et al., *Creating a False Memory in the Hippocampus*, 341 SCIENCE 387 (July 26, 2013)).

[73] *See* Miguel Pais-Vieira et al., *A Brain-to-Brain Interface for Real-Time Sharing of Sensorimotor Information*, 3 SCI. REP. 1319 (Feb. 28, 2013).

[74] *See* Daniel Halperin et al., *Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses*, 2008 IEEE SYMPOSIUM ON SECURITY AND PRIVACY 129 (2008).

the suit to grasp a ball and subsequently drop the ball in a target location,"[75] rendering the now-objectionable defense, "He made me do it," now quite plausible.

As one group of scientists working on B2B science noted:

> Human sensory and motor systems provide the natural means for the exchange of information between individuals, and, hence, the basis for human civilization. . . . Our results provide a critical proof-of-principle demonstration for the development of conscious B2B communication technologies. . . . We envision that hyperinteraction technologies will eventually have a profound impact on the social structure of our civilization and raise important ethical issues. . . . However, there is now the possibility of a new era in which brains will dialogue in a more direct way. Previous attempts to realize this vision include demonstrations of bidirectional computer-brain communication and cortical-spinal communication in animals.[76]

Along with transcranial direct current stimulation (TDCS), B2B interface also has the potential to enhance human cognition, a tempting product for students to artificially boost grades and scores on standardized tests. And creating home-made brain-interface devices to achieve these results is not

[75] Trimper et al., *supra* note 66 (citing Takeshi Sakurada et al., *A BMI-Based Occupational Therapy Assist Suit: Asynchronous Control by SSVEP*, 7 FRONTIERS IN NEUROSCI. 172 (Sept. 23, 2013).

[76] Grau et al., *supra* note 61.

unforeseeable – it has already been done with TDCS[77] where do-it-yourself kits are pre-selling on the internet.[78]

Akin to the "Vulcan mind-meld," the direct transfer of information introduced to a receiving brain, without the ability of that brain to refuse or inhibit the impulse, portends gross abuse including coercive information transfer. This ability raises two concerns: the planting of false knowledge and the ability to extract guarded information, which, of course, raises privacy concerns.

E. The Readiness Potential Raises Legal Concerns

The older, currently available BCI technology portends to be impressive in terms of helping the disabled, but the potential for abuse is commensurately impressive.[79] Astounding as BCI must seem, the prevalent notion of movement must be re-examined when the object of the movement is far stronger, quicker, and more precise than the normal hand, arm, or finger, such as using brain signaling to empower an exoskeleton with bionic potential.[80]

But there are more concerns. Nobel Laureate and physicist Roger Penrose opines that pre-cognition

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[77] Trimper et al., *supra* note 66; *see also* Nicholas S. Fitz and Peter B. Reiner, *The challenge of crafting policy for do-it-yourself brain stimulation*, J. MED. ETHICS 41, 410 (2015) (noting "Transcranial direct current stimulation (tDCS), a simple means of brain stimulation, possesses a trifecta of appealing features: it is relatively safe, relatively inexpensive and relatively effective. It is also relatively easy to obtain a device and the do-it-yourself (DIY) community has become galvanized by reports that tDCS can be used as an all-purpose cognitive enhancer. . . . The range of indications for which tDCS has been explored is substantial. In the clinical realm, investigators are evaluating its use as a treatment for stroke, pain and depression."). *But see* Jane Horvath et al., *Evidence that transcranial direct current stimulation (tDCS) generates little-to-no reliable neurophysiologic effect beyond MEP amplitude modulation in healthy human subjects: A systematic review*, NEUROPSYCHOLOGIA 66, 213 (2015).

[78] FOC.US, https://foc.us (last visited Sep. 7, 2021).

[79] *See* Trimper et al., *supra* note 66.

[80] J. Fingas, *Israel reportedly used a remote-controlled gun to assassinate an Iranian scientist – It could change the nature of espionage*, ENGADGET (Sept. 18, 2021), https://www.engadget.com/israel-remote-control-iran-scientist-assassination-144746205.html.

"consciousness" is involved in voluntary activity. He bases his views on studies by Benjamin Libet[81] and Hans Helmut Kornhuber,[82] who explored the biological role of the unconscious in decision making. According to their work, when you initiate a voluntary movement, such as moving your hand, you produce a "readiness potential" (RP), an electrical signal that can be detected on the surface of your skull. This early electrical signal, the RP[83] or *Bereitschaftspotential*, suggests the brain prepares for movement even before we become aware of it. The signal itself begins one second or more before the movement is even initiated, and reflects not a conscious decision to initiate movement, but a neural decision to do so.[84]

In his work, Libet asked people to consciously "will" a movement and to note exactly when that willing occurred and measured electrical impulses at various stages in the process.[85] Surprisingly, the *conscious* "willing" occurred substantially *after* the readiness potential was detected. By averaging several trials, Libet could tell the subjects were about to move *before* they were even aware of it. This astonishing result suggests that we unconsciously or subconsciously decide to move before being aware of having made the decision. In fact, Libet recorded that the brain activity precedes the *decision* to move, not the movement itself, by milliseconds before consciousness of the

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[81] Patrick Haggard and Benjamin Libet, *Conscious Intention and Brain Activity*, 8 J. OF CONSCIOUSNESS STUD. 47 (2001).

[82] ROGER PENROSE ET AL., THE LARGE, THE SMALL AND THE HUMAN MIND 135 (Malcom Longair ed., 1997) 135.

[83] Neysan Donnelly, *Free Will: all in our Heads?*, LINDAU NOBEL LAUREATE MEETINGS (Apr. 16, 2020), https://www.lindau-nobel.org/blog-free-will-all-in-our-heads/.

[84] Aaron Schurger, et al., *An accumulator model for spontaneous neural activity prior to self-initiated movement*, PNAS (Oct. 16, 2012), https://www.pnas.org/content/109/42/E2904/1 ("RP has since been linked to changes in neuronal firing rates in the supplementary motor area . . . and is widely assumed to reflect an intentional sequence of neural operations directed at producing a movement . . . This assumption has become a source of controversy because human subjects appear to be unaware of their intention until only ~200 ms before the onset of the movement . . . .").

[85] Chad Vance, *Free Will and Neuroscience*, COLL. OF WM. & MARY, available at https://wmpeople.wm.edu/asset/index/cvance/libet; *see also* BBC Radio 4, *The Libet Experiment: Is Free Will Just an Illusion*?, YOUTUBE (Nov. 7, 2014), https://www.youtube.com/watch?v=OjCt-L0Ph5o.

decision to move was reached, concluding that initiation of the activity precedes awareness in every action we take.[86] In effect, "the brain's wheels start turning before the person even consciously intends to do something. Suddenly, people's choices – even a basic finger tap – appeared to be determined by something outside of their own perceived volition."[87]

While the readiness potential begins milliseconds before actual awareness of the decision to move, it lasts a full second (in Libet's experiments it was a half-second), a fairly long time. Perhaps not so coincidentally the time delay is the same as a driver's reaction-time for braking.[88]

To be sure, recent research has cast doubt on the interpretation of Libet's conclusion[89] (although not the existence of the readiness potential itself). "[S]imply because the *Bereitschaftspotential* can be measured before the conscious decision to move does not mean that this process is responsible for that movement, and decisions are not made when a *Bereitschaftspotential* starts, but rather when it crosses a threshold which triggers movement."[90]

One 2012 study says that Libet's study just measured artifactual noise.[91] A more recent study argues that the *readiness potential* is an artifact of breathing.[92] Whether the readiness

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[86] Eric Kandel, *Neuron Perspective The New Science of Mind and the Future of Knowledge*, 80 NEURON 546, 551 (2013).

[87] Bahar Gholipour, *A Famous Argument Against Free Will Has Been Debunked*, THE ATLANTIC (Sept. 10, 2019), https://www.theatlantic.com/health/archive/2019/09/free-will-bereitschaftspotential/597736/.

[88] *What is the average driver's reaction time?*, DMV WRITTEN TEST, https://www.dmv-written-test.com/question/cdl/what-is-the-average-driver-s-reaction-time_VyvVklyG.html (last visited Sept. 10, 2021) (noting "The average driver has a reaction time between three-quarters of a second and one second.").

[89] *See, e.g.*, Gholipour, *supra* note 87; Donnelly, *supra* note 83.

[90] Donnelly, *supra* note 83.

[91] Schurger, *supra* note 84.

[92] Hyeong-Dong Park et al., *Breathing is coupled with voluntary action and the cortical readiness potential*, 11 NATURE COMMUNICATIONS 1 (2020), https://www.nature.com/articles/s41467-019-13967-9#auth-Hyeong_Dong-Park ("The readiness potential (RP), a slow drift of neural activity preceding self-initiated movement, has been suggested to reflect

signal is an artifact or directly associated with the motion itself, we don't know what impact it will have on the BCI sensors. And if Libet is correct, we also don't know if our better natures can override this preparatory signal – should its design be untoward.

F. If It Can Go Wrong, It Probably Will: The Software Problem

Given all these interconnected pieces and parts incident to devices powered by BCI technology (as well as the more remote B2B), something is bound to go wrong – and this makes for the stuff of litigation.[93] In addition to hardware issues, computer software has been a notorious safety and security problem,[94] and that is even before considering machine-learning or AI and algorithmic technology.

Almost a decade ago the Government Accountability Office (GAO) warned that computerized medical devices could be vulnerable to hacking, posing a safety threat, and asked the FDA to address the issue.[95] The GAO report focused mostly on

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neural processes underlying the preparation of voluntary action; yet more than fifty years after its introduction, interpretation of the RP remains controversial . . . our findings demonstrate that voluntary action is coupled with the respiratory system and further suggest that the RP is associated with fluctuations of ongoing neural activity that are driven by the involuntary and cyclic motor act of breathing."). *See also Breathing may change your mind about free will*, SCIENCE DAILY (Feb. 6, 2020), https://www.sciencedaily.com/releases/2020/02/200206080449.htm. *Cf.* Bahar Gholipour, *A Famous Argument Against Free Will Has Been Debunked*, THE ATLANTIC (Sept. 10, 2019), https://www.theatlantic.com/health/archive/2019/09/free-will-bereitschaftspotential/597736/.

[93] Such as products liability suits. Given that, for example, the RE-Walk system is manufactured in Israel, conflict of laws in products liability will also complicate resolution. *See* Barbara Pfeffer Billauer, *Primacy in Products Liability: A comparison of Israeli and American Law*, 51 TORT, TRIAL & INS. PRAC. J. 943 (2016). *See also* Tim Retter, *Exoskeleton Safety*, EXOSKELETON REPORT (Sep. 20, 2016), https://exoskeletonreport.com/2016/09/exoskeleton-safety.

[94] Kevin Fu. *Trustworthy medical device software*, *in* PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS: MEASURING POSTMARKET PERFORMANCE AND OTHER SELECT TOPICS: WORKSHOP REPORT 97 (National Academies Press, 2011).

[95] U.S. Gov't Accountability Off., GAO-12-816, Medical Devices: FDA Should Expand Its Consideration of Information Security for Certain

the threat to two kinds of wireless implanted devices: implanted defibrillators and insulin pumps whose vulnerability had received widespread press attention.[96] Guidance for medical devices containing software now exists,[97] and standard-bodies are taking additional actions to improve medical device cybersecurity.[98] Nevertheless, software glitch issues of all kinds are common in the medical arena and should be assumed to persist, and there is no reason to suppose this laxity won't continue in BCI and B2B Interface technologies.

To put this in context, between 2006 and 2011, 5,294 recalls and approximately 1.2 million adverse events of medical devices were reported to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.[99] Almost 23% of these recalls were due to computer-related failures, of which approximately 94% presented medium to high risk of severe health consequences.[100] While it is known that computer-related failures play a significant role in medical device-related deaths and injuries due to software problems, no reporting system exists that captures security-related failures – such as cyber hacking.[101]

Types of Devices, (2012).

[96] *Id. See also* Dennis Fisher, *Medical Device Security in Need of Major Upgrade*, THREATPOST (Oct. 17, 2012), http://threatpost.com/en_us/blogs/medical-device-security-need-major-upgrade-101712.

[97] U.S. FOOD AND DRUG ADMIN., GUIDANCE FOR THE CONTENT OF PREMARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN MEDICAL DEVICES (May 11, 2005), https://www.fda.gov/media/73065/download.

[98] Kevin Fu & James Blum, *Inside Risk: Controlling for Cybersecurity Risks of Medical Device Software*, 56 Commc'ns of the ACM 21, 23 (2013). ("The Association for the Advancement of Medical Instrumentation (AAMI) recently formed a working group on medical device security and has released standards specific to network-related cybersecurity risks (ANSI/AAMI/IEC-80001). International harmonization of cybersecurity guidance is also likely on the horizon, given that phrases such as "security patches" appear in proposals from the International Medical Device Regulators Forum.").

[99] Alemzadeh, H. et al. *Analysis of Safety-Critical Computer Failures in Medical Devices*, IEEE SEC. AND PRIV. 14, 14 (2013).

[100] Fu & Blum, *supra* note 98, at 21.

[101] Kramer, D.B. et al. *Security and Privacy Qualities of Medical Devices: An Analysis of FDA Postmarket Surveillance*, 7 PLOS ONE, July 2012, at 1.

Hence we have no way of knowing the extent of this issue as a separate problem.

It is believed that individual hospitals know of hundreds of unreported computer-related security related incidents regarding medical devices.[102] Computerized devices, including BCI interface, are usually connected to an internal network which is, in turn, connected to the internet. Hence, we can expect them to be rendered vulnerable to cyber-infection via that route. Indeed, "the FDA MAUDE does not capture adverse events such as lack of or impaired availability of function when malware infects a medical device's operating system. The FDA's own disclaimer explains that the MAUDE database is qualitative rather than quantitative."[103] Old malware – with known issues and mitigation strategies (perhaps the basis of a regular tort suit in ordinary devices) – still persist in existing medical devices, the same with generic virus infiltration.[104] Medical devices use outdated software, some still relying on the original versions of Windows XP (circa 2001), even though security support no longer exists for this version. Often a medical device manufacturer fails to provide an effective way for hospitals to upgrade to supported versions of operating systems, and even where they do, there is reluctance to implement the technology for fear of triggering a new FDA review.[105] Further, while

> anti-virus software can help mitigate certain cybersecurity risks, [it] . . . can also introduce its own risks. On April 21, 2010, one-third of the hospitals in Rhode Island were forced to "postpone elective surgeries and stop treating patients without traumas in emergency rooms" because an automated anti-virus software update

[102] Christopher Weaver, *Patients Put at Risk By Computer Viruses*, WALL ST. J., June 13, 2013, at 1.

[103] Fu & Blum, *supra* note 98, at 22.

[104] David Talbot, *Computer Viruses Are "Rampant" on Medical Devices in Hospitals*, MIT TECH. REV., (Oct. 17, 2012), http://www.technologyreview.com/news/429616/computer-viruses-are-rampant-on-medical-devices-in-hospitals (finding that a meeting of government officials reveals that medical equipment is becoming riddled with malware).

[105] Fu & Blum, *supra* note 98, at 23.

> had accidentally misclassified a critical Windows DLL as malicious.[106]

Another example of computer vulnerability is the 2012 experience at Boston's Beth Israel Deaconess Medical Center. There, 664 pieces of medical equipment

> are running on older Windows operating systems that manufacturers will not modify or allow the hospital to change – even to add antivirus software – because of disagreements over whether modifications could run afoul of U.S. Food and Drug Administration regulatory reviews.[107]

The problem is exacerbated by the fact that manufacturers often will not allow their equipment to be modified, even to add security features, again, for fear of triggering another FDA review.[108]

While the FDA mission statement accepts responsibility for protecting the public health by assuring the safety, efficacy, and security of medical devices,[109] this is often done in the breach. In June of this year, the FDA issued draft guidance on cybersecurity, and gave examples of what FDA reviewers would expect to see during pre-market review. But the draft guidance intentionally does not prescribe any particular approach or

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[106] *Id.*

[107] Talbot, *supra* note 104, at 3. *See also* Dave Lee, *Computer viruses and malware 'rampant' in medical tech, experts warn*, BBC NEWS, (Oct. 17, 2012) https://www.bbc.com/news/technology-19979936 (reporting that "I find this mind-boggling," Fu says. "Conventional malware is rampant in hospitals because of medical devices using unpatched operating systems. There's little recourse for hospitals when a manufacturer refuses to allow OS updates or security patches.").

[108] According to Dr. Fu "the problem is patches don't require further FDA review unless there's a safety issue. And that causes manufacturers to make decisions that aren't in the best interest of patients. It's common for manufacturers not to issue patches because they could require review." Fisher, *supra* note 96, at 3.

[109] FDA Mission Statement, FDA, (Mar. 28, 2018), https://www.fda.gov/about-fda/what-we-do#:~:text=FDA%20Basics-FDA%20Mission,and%20products%20that%20emit%20radiation.

technology, and instead recommends that manufacturers consider cybersecurity starting at the concept phase.[110]

Thus, regarding our BCI empowered cyborg devices, we have loose software regulations, non-enforceable software security advisories, a lower level of FDA supervision (as they are designated Class II devices), and a history of the FDA's failure to provide specific solutions to known problems.[111]

III. THE BIONIC PLAINTIFF V. THE CYBORG DEFENDANT

A. My Subconscious Made Me Do It: Creepy Charlie v. Auntie Maim

To see how a medical device problem might play out in real life, we can revisit and embellish a hypothetical I previously crafted:[112]

Imagine a toddler, we'll call him Creepy Charlie, is crawling behind the wheelchair of his disabled aunt (we'll call her Maim).[113] Instead of going forward as Auntie Maim wishes, the wheelchair reverses, perhaps due to some product malfunction and horribly injures the child. (We've seen similar sorts of situations in automobile brake failure cases.) Indeed, Toyota researchers in Japan have built a brain/computer interface to control a wheelchair via thought-control. Their wheelchair enables a person to make it turn left, right, or to move forward simply by thinking the commands – with a 125-

[110] CONTENT OF PREMARKET SUBMISSIONS FOR MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Food and Drug Administration Staff, 2018).

[111] 21 C.F.R. § 820.30(g) (stating the prevailing FDA requirement that "design validation requires that devices conform to defined user needs and intended uses, including an obligation to perform software validation and risk analysis, where appropriate"); *id.* at (i) (stating that software changes to address cybersecurity vulnerabilities are design changes and must be validated before approval and issuance).

[112] Barbara Pfeffer Billauer, *My Subconscious Made Me Do It*, AM. COUNCIL ON SCI. AND HEALTH (June 7, 2021), https://www.acsh.org/news/2021/06/07/my-subconscious-made-me-do-it-legal-issues-brain-computer-interface-15585.

[113] Many thanks to Dr. Charles Dinerstein who suggested the spelling creating the *double entendre*.

millisecond response time.[114] Auntie Maim's accident then, is not a far-fetched possibility.

This accident could happen for a variety of reasons amenable to either strict liability in tort (SLT) or claims sounding in negligence:

- Hardware failure – i.e., the connection to the wheelchair isn't configured correctly or becomes loose or damaged;
- Electrode misplacement – i.e., surgical error in implanting the electrode (in which case the surgeon might also be liable);
- A defective electrode;
- Software errors; and
- Perhaps more difficult to assess but quite worrisome, a software error in the algorithm resulting in mistranslating the received brain electrical signal into an inappropriate command.

Typically, product liability and negligence (including medical malpractice) law would be available to address issues presented by failures occasioned by negligence or defective products which are not covered under FDA's Class III designation, as is the case with wheelchairs.

However, let's further assume that Auntie Maim dislikes her pesky nephew and, for a split-second, harbors some malevolent thought about running him over. Of course, she would never voluntarily *intend* to do this, and her "free will" surely would override any wicked thoughts about harming her nephew. Instead, likely she would reorient her thoughts and make a *decision* to move her chair forward – which then becomes her *intent* – rather than the reverse direction. But what

[114] Antone Gonsalves, *Toyota Develops Mind-Controlled Wheelchair*, INFO. WEEK (JUNE 29, 2009), https://www.informationweek.com/mobile-and-wireless/toyota-develops-mind-controlled-wheelchair (stating that the system has an emergency stop that can be activated by the user puffing his cheeks).

if the device moves backwards – for some unknown reason – anyway?

Because the device is now considered a class II device, FDA pre-emption doctrine would not shield the manufacturer from liability, and they would be amenable to product liability (SLT) and negligence claims identified above. Perhaps the physician might be implicated if the electrodes were implanted improperly, although Toyota's product does not require implanted electrodes.[115] But *proof* of a product defect might be difficult, as current product liability law is trending to require a reasonable alternative design (RAD) to constitute a design defect – and as of yet, one doesn't exist. Being that electrodes can also be affixed to the scalp, envisioning physician negligence as a contributing cause might be unlikely. While the Breakthrough and De Novo review currently used as a basis for FDA approval in these products is not as stringent as a Class III review, however, compliance with whatever FDA standards might prove relevant and might even provide some defense against allegation of a defective design theory against the manufacturer.

In reality, the most likely scenario would be that Charlie's folks would sue Auntie Maim and everyone else in the causal chain, leaving them to sort it out amongst themselves. The claim against Auntie Maim would allege that she *intended* to injure their son – or that even if she didn't consciously mean him harm – subconsciously that was her true desire. Because the chair was activated by the readiness potential of which Auntie "M," herself, was not consciously aware, both she and the manufacturer would be liable. It might be difficult to prove that "M" wanted to do her nephew in intentionally – but there would be no way to rule out the causal contribution of her subconscious. At that point, *the question of who might be responsible for subconscious desires threatens to overwhelm the tort system*. Before we get there, a few procedural issues would need to be addressed – namely the admissibility of the Libet/Kornhuber research and Professor Penrose's expert opinion.

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[115] *Id.*

At this point, a *Daubert* hearing on the scientific validity of the Libet/Kornhuber studies might be in the offing. Assuming a judge allows its introduction into evidence – which might be likely,[116] the level of the child's injury likely would sway the jury. (Even though juries aren't supposed to base their decisions on emotions – they frequently do.) Such a case might seem far-fetched or weak, until one adds a small fillip to the hypothetical: Auntie Maim has taken to muttering, "if I could only make that creepy kid evaporate, I'd be one hell of a happy lady," overheard by several would-be witnesses. If the Libet/Kornhuber theory is admitted, Auntie Maim could well be implicated.

Is this fair? Is it just? Should we be accountable for subconscious thoughts? Transitory wishes? Daydreams? Are users of these devices even aware of the possibility that their thoughts might be driving their actions? Is the FDA? Is anyone even asking these questions?

At the very least, perhaps a warning should be indicated on the devices? Or maybe the device (especially a BCI powered exoskeleton or drone)[117] should be better regulated as a Class III device, with the level or risk assessed higher than currently assigned.[118] Or perhaps there should be a required fail-safe stop mechanism – as there is with the Toyota device.[119] But then again, even if the "thought" was unintentional or subconscious, would Auntie Maim be able to react fast enough to stop the

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[116] *See* Barbara Pfeffer Billauer, *Admissibility of Scientific Evidence Under Daubert: The Fatal Flaws of 'Falsifiability' and 'Falsification,'* 22.1 BOS. U. J. OF SCI. AND TECH. L. 21 (2016); *see also* Barbara Pfeffer Billauer, *The Causal Conundrum: Examining Medical-Legal Disconnects from a Cultural Perspective - or How the Law Swallowed the Epidemiologist and Grew Long Legs and a Tail*, 51 CREIGHTON L. REV. 319 (2018).

[117] *Billauer*, *The Age Of Mind-Control And The Cyborg*, *supra* note 1.

[118] *A History of Medical Device Regulation & Oversight in the United States*, FDA, (June 24, 2019) https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states (In 1997 the Food and Drug Administration Modernization Act created the "least burdensome" provisions for premarket review and established the De Novo program through which novel low-to-moderate risk devices could be classified into Class I or II instead of automatically classifying them into Class III).

[119] Done by puffing out the cheeks. Gonsalves, *supra* note 114.

wheelchair from moving backwards – by puffing out her cheeks – the Toyota "antidote"? Would she even remember to do this rather unnatural maneuver in a stressful situation?

Much has been written on product liability law as it might affect this type of suit, and hence I will not devote much time to that aspect here. But whether the intentionality of Auntie Maim, either conscious or not, gives rise to a claim, either against her or imputed to the manufacturer, presents a novel question, which I will address after postulating another hypothetical which sets the issues presented by these technologies in starker relief – and raises the question as to whether these products were misclassified as Class II.

B. Cyborg Susie v. Bionic Bob & The SKELZO-Shell Corp v. Wheely-Wheelchairs

Imagine a six-foot four-inch Vietnam veteran and current exoskeleton user, Bionic Bob, collapses from heart failure due to his recently acquired 240-pound *avoir du pois*. The accident happens while crossing a street during rush hour. Imagine further that Bob's body falls onto an old lady, nicknamed Cyborg Susie,[120] who is riding her brain-activated Wheely-wheelchair, pushing her and the wheelchair into ongoing traffic, killing her in the process. [121] Cyborg Susie's family sues Bionic Bob and the exoskeleton manufacturer, SKELZO, who in turn implead Wheely-Wheelchairs. (It bears mentioning that the European Commission is developing "Mindwalker," a mind-controlled exoskeleton for disabled people.)[122]

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[120] Susie, not being physically interconnected to her wheelchair is not strictly a Cyborg.

[121] Such scenarios with intricate causal chains do exist. *See* Palsgraff v. Long Is. R.R. Co., 248 N.Y. 339 (1928); *see also* Derdiarian v. Felix Contacting Corp. 52 N.Y.2d 784 (1980) (showing real, but rather far-fetched, long-chain causal scenarios).

[122] Madiha Tariq et al., *EEG-Based BCI Control Schemes for Lower-Limb Assistive-Robots*, 12 FRONTIERS IN HUM. NEUROSCIENCE 1 (2018) (discussing that the development of controllers, for BCI-based wearable or assistive devices that can seamlessly integrate user intent, practical challenges associated with such systems exist and have been discerned); *see also* Jeremi Gancet, *MINDWALKER: A Brain Controlled Lower Limbs*

For now, the SKELZO Company is amenable to suit, as the traditional pre-emption doctrine protecting medical device manufacturers does not apply either to Exoskeletons or to powered wheelchairs, both designated as Class II devices. (In the future, perhaps the FDA might revise its classification. In that case, because Bionic Bob's skelo-suit exactly comported to the product approved by the FDA – perhaps it would be immune from suit.)[123] Hence, perhaps compliance with FDA standards could act as a shield from liability.[124]

Now, let's say Bionic Bob had his accident because he gained weight since the device's initial fitting – and the device failed under the weight load and specified tolerances of the device – or that his weight was mismeasured initially, suggesting human error.[125] Who bears the burden of monitoring the excess weight load? The surgeon? His physical therapist? His neurologist? The nurse who does his monthly checkups? Who is to be made aware of the tolerances allowable by the device? Do the training manuals require everyone on the team to be alerted to this information – even private health care providers who may be looking after Bionic Bob on a more routine basis?

These post-manufacture changes would affect responsibility, for sure, shielding a manufacturer from a SLT claim. But who should bear the responsibility for these post-manufacture effects? What if Bionic Bob, suffering PTSD, suddenly goes on a rampage and runs down a gaggle of girls about to compete for a marathon? Who screens the user? And

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Exoskeleton for Rehabilitation. Potential Applications to Space, RESEARCHGATE (Jan. 2011), https://www.researchgate.net/publication/265752194_ e.

[123] Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011) (emphasis added) (holding that the National Childhood Vaccine Injury Act of 1986 preempts *all* vaccine design defect claims against vaccine manufacturers, *plaintiffs design defect claims [were] expressly preempted by the Vaccine Act and that* laws which have established that vaccine manufacturers are not liable for vaccine-induced injury or death pre-empt state law, as long as they are "*accompanied by proper directions and warnings*.").

[124] *See infra* note 148.

[125] The devices have a strict weight parameter, which presumably is disclosed to wearer's – the question remains to enforceability – suggesting that a fail-safe device might be incorporated preventing the device from activating if the wearer exceeds its tolerances.

how? The questions all lead to devising proper testing of the device in real-life situations. Now, however, the focus is on helping the paraplegic regain functionality. The impact on others seems to have been ignored or at best relegated to a lesser state of concern.

Finally, let's assume that Cyborg Susie's brainwave-controlled wheelchair malfunctioned because Cyborg Susie was severely depressed (the day before confiding to her family that she intended to kill herself) and she willed the chair to overturn. Assuming Cyborg Susie's mental state was well-known, could we even prove that in some way she contributed to her accident by latent brainwaves?

To add another monkey-wrench, assuming the FDA now reclassifies the devices as Class III, realizing that an exoskeleton or a wheelchair can be manipulated into a weapon of mass-injury, if not destruction, conflict of laws between states might make the problems that much more intractable. Say Bionic Bob lives in Washington, DC, and Cyborg Susie lives in Puerto Rico. The case, brought in Federal District Court in Delaware would turn, in addition to the procedural law of Delaware, on applicable State Law in Puerto Rico and the District of Columbia, both of which are, to a large extent, immune from medical device pre-emption laws that govern CGMP requirements.[126]

IV. TORT LIABILITY IN THE AGE OF THE BIONIC PLAINTIFF AND THE CYBORG DEFENDANT

A. A Short Review of Applicable Tort Law

Tort law (of which negligence is one variety) has at least two goals, "victim specific compensation and deterrence."[127] Negligence is essentially a common law means of requiring people to think about their actions. Mindless behavior, in other words, acts arising from thoughtlessness – if damaging to others

[126] Remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico are not preempted. 21 C.F.R. § 820.1(a)(2).

[127] Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 450, 459 (2008).

– is compensable.[128] Claiming "I didn't know" will not excuse a defendant – if s/he should have known, or if others similarly situated would have known.[129] What the defendant should have, could have, or would have known, is a function of preventing foreseeable harm.[130] The required due care is measured by the probability of harm occurring coupled with the gravity of likely danger, balanced against the burden of guarding against it.[131] In sum, carelessness is a relative concept that compares the defendant's actions or omissions to those of a reasonably prudent person in similar circumstances.[132]

The major difference between product liability/SLT claims and negligence is the latter's requirement to prove the defendant was careless (negligent) in the assumed activities and resulted claims: i.e., design defect, manufacture defect, failure to warn, test, or inspect.[133] The requirement of "negligence" or

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[128] *Negligence*, AMERICAN BAR ASS'N. (Oct. 31, 2016), https://www.americanbar.org/groups/public_education/resources/law_issues_for_consumers/everydaylaw0/health_care/personal_injury/negligence/.

[129] Geoffrey C. Rapp, *The Wreckage of Recklessness*, 86 WASH. U. L. REV. 111, 133 (2008), available at: https://openscholarship.wustl.edu/law_lawreview/vol86/iss1/3.

[130] *See generally*, Barbara A. Frey, *Due Diligence to Prevent Foreseeable Harm: The International Human Rights Agenda on Civilian Gun Violence*, 60 WASH. U. J. L. & POL'Y 91 (2019).

[131] As Learned Hand articulated in United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947), the burden on the actor is equal to the probability times the gravity of harm. In Wyeth v. Levine, 555 U.S. 555, 564 (2009), the jury found "Wyeth negligent as well as strictly liable, the jury also determined that Levine's injury was foreseeable. That the inadequate label was both a but-for and proximate cause of Levine's injury is supported by the record and no longer challenged by Wyeth," and also found the clinician's actions were not an intervening cause that absolved it of liability. "The jury held that theoretic defect in Phenergan's label was the lack of adequate warning about the risks of IV-push administration," The dissent nonetheless suggests that physician malpractice was the exclusive cause of Levine's injury. *See, e.g.*, *post*, at 1 (opinion of ALITO, J.) ("[I]t is unclear how a 'stronger' warning could have helped respondent"); *post*, at 16–18 (suggesting that the physician assistant's conduct was the sole cause of the injury).

[132] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998).

[133] Iowa products liability law for design defects, as defined by the RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (1998), is not cast in terms of a product that is "in a dangerous and defective condition. Cf. *In re* Medtronic, 623 F.3d 1200, 1206 (8th Cir. 2010) (stating in terms of whether

"fault" is dispensed with in SLT, as well as under contractual warranty theory which generally requires privity or direct connection between vendor and plaintiff.[134]

Under Texas' strict liability law, for example, a plaintiff must prove that: (1) the defendant placed a product into the stream of commerce, (2) which was in a defective or unreasonably dangerous condition, and (3) there was a causal connection between the defect and the plaintiff's injuries or damages.[135] By comparison, Kentucky products liability law focuses on the strict liability of the defendant for inadequacies in the quality of the product, whereas negligence liability focuses on the conduct of the actor.[136] Kentucky SLT doctrine further assigns liability to a supplier or manufacturer based on hindsight:

> That is, it is legally responsible for risks which could not have been known or appreciated at the time of manufacture, but came to light later, which is not true in a negligence case, where the

"the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer.").

[134] Warranty claims—arising out of the Uniform Commercial Code, which governs sales transactions—ask if the product was fit for the ordinary purposes for which it was intended. If not, the product is considered 'defective.' While the two theories have a logical overlap, legally, they are distinct, with the key determinant being whether the product is fit for ordinary purposes *See* Denny v. Ford Motor Co., 87 N.Y.2d. 248, 256 (N.Y. 1995) (stating that "[w]hile the strict products concept of a product that is not reasonably safe requires a weighing of the product's dangers against its over-all advantages, the UCC's concept of a defective product requires an inquiry only into whether the product in question was fit for the ordinary purposes for which such goods are used. The court held that the jury could have simultaneously concluded that the utility vehicle was not defective, but that it was also not fit for its ordinary purposes.").

[135] Helen of Troy v. Zotos Corp., 511 F. Supp. 2d 703, 721 (W.D. Tex. 2006) (citing Houston Lighting & Power Co. v. Reynolds, 765 S.W.2d 784, 785 (Tex. 1988)).

[136] Montgomery Elevator Co. v. McCullough by McCullough, 676 S.W.2d 776, 780 (Ky. 1984).

> issues turn on what the manufacturer knew or should have known at the time of distribution.[137]

The New York courts articulated their product liability standard in *Chow v. Reckitt & Colman Inc.*,[138] which was clarified and reinforced in *Voss v. Black & Decker Manufacturing Co*.[139] Therein, the court held that the plaintiff must demonstrate "there was a substantial likelihood of harm and it was feasible to design the product in a safer manner."[140] The manufacturer may oppose by showing that:

> [T]he product is a safe product . . . that is, whether it is a product which, if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner.[141]

In other words, a non-defective product must be one whose "utility outweighs its risks when the product has been designed, so … the risks are reduced to the greatest extent possible while retaining the product's inherent usefulness at an acceptable cost."[142] The jury may impose liability when, after weighing the evidence and balancing the product's risks against

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[137] C & S Fuel, Inc. v. Clark Equip. Co., 552 F. Supp. 340, 343–44 (E.D. Ky. 1982); Hearn v. Advanced Bionics Corp., 2:06–cv–114, Oral Bench Op., at 9 (S.D. Miss. Nov. 5, 2007).

[138] Chow v. Reckitt & Colman Inc., 17 N.Y.3d 29, 34 (N.Y. 2011).

[139] Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 107, (N.Y. 1983) (holding that a "manufacturer is held liable regardless of his lack of actual knowledge of the condition of the product because he is in the superior position to discover any design defects and alter the design before making the product available to the public").

[140] *Id.* at 108.

[141] *Id.*

[142] *Id. See also* Norma Rose et al. v. Brown & Williamson Tobacco Corp., 855 N.Y.S.2d 119, 120 (App. Div. 1st Dep't 2008) (quoting *Voss*, 59 N.Y.2d at 108).

its utility and cost, it concludes that the product, as designed, is not reasonably safe.[143]

In some states, newer SLT cases provide a different formulation, one more closely aligned with old-fashioned negligence.[144] In these states, SLT theory now requires proof of a reasonable alternative design (RAD) to prevail.[145] In the case of BCI or B2B technologies that is highly unlikely, at least for now, and hence we might assume that many product liability claims couched under a design defect theory would fail.[146] Of greater concern is that compliance with standards might provide a defense for the manufacturer,[147] even though the device may pose a real societal danger.[148] And so, with our BCI-bionic technology we have the worst of all possible worlds: no enhanced FDA inspection/approval standards under Class III,

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[143] In Pennsylvania, the case of *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 335 (Pa. 2014), held that a plaintiff could prove the existence of a product defect by showing "that (1) the danger posed by the product is unknowable and unacceptable to the ordinary consumer or (2) a reasonable person would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions."

[144] Aaron D. Twerski & James A. Henderson Jr, *Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility*, 74 BROOK. L. REV. 1061, 1062 (2009).

[145] *See generally*, David I. Levine & Carel J. Stolker, *The Reasonable Alternative Design Test: Back to Negligence?*, 5 CONSUMER L.J. 41 (1997).

[146] For an overall discussion on products liability *see* Billauer, *supra* note 93.

[147] Until recently, at least under Pennsylvania law, such evidence has been inadmissible. *See* Lewis v. Coffing Hoist Div., Duff-Norton Co., 528 A.2d 590 (Pa. 1987). *But see* Tincher v. Omega Flex, 104 A.3d 328 (Pa. 2014) (raising questions about the continued viability of *Lewis*).

[148] *In the Wake of Tincher, Can a Strict Product Liability Defendant Rely on Compliance Standards*?, HOUSTON HARBAUGH (June 26, 2017), https://www.hh-law.com/blog/2017/06/in-the-wake-of-tincher-can-a-strict-product-liability-defendant-rely-on-compliance-with-government-r/ (noting the issue is an open question, the authors state: "In a strict product liability claim, compliance with government regulations and industry standards can be powerful evidence for the defense. Such evidence traditionally has been inadmissible under Pennsylvania law based on the Pennsylvania Supreme Court's decision in Lewis v. Coffing Hoist Div., Duff-Norton Co., Inc., 528 A.2d 590 (Pa. 1987). The Court's decision in Tincher v. Omega Flex, 104 A.3d 328 (Pa. 2014), however, raises questions about the continued viability of *Lewis* and provides defendants with a compelling argument that this type of evidence should be admissible.")

and the possibility that compliance with Class II standards might provide a defense for product liability or negligence claims.

To the extent that BCI technology is examined by whether its benefits outweigh the risks to the *user* – the technology might pass legal muster and the plaintiffs would be unable to prove their claims, be they sounding in negligence or SLT. Even an FDA Class II categorization might seem reasonable. But concern for the well-being of *bystanders* or those with whom the BCI user interacts might skew the entire analysis. In other words, on a societal basis, risk-benefit analysis of these devices – especially those that could be modified for destructive purposes, say drones – might well fail a risk-benefit test.

Thus, in a desire to foster development of new products – to benefit society as a whole – a manufacturer is now only required to show that the product put into the stream of commerce is "reasonably safe" to the user (as demonstrated by the existence of a RAD). Acknowledging that all products can be dangerous – especially if used incorrectly – courts have traditionally said that manufacturers (and anyone in the distributive chain) would be liable only if the dangers were "unreasonable" – a relative concept based on comparing its risks versus its social utility.[149] If the product was used in an unintended manner, the defendant is absolved of responsibility.[150] Perhaps here we have another "out" for the product manufacturer of BCI technology – as malevolent intent would not be considered an intended use.

B. Intentional Torts, Res Ipsa Loquitur*, and Real Life*

The reverse-marching wheelchair or exoskeleton-run-amok are clearly unintended consequences. Since SLT cases would likely fail, the question becomes whom would the law

[149] Codling v. Paglia, 32 N.Y.2d 330, 342 (N.Y. 1973).

[150] A relatively recent (and much criticized) rubric seeks to add consumer's expectations to the yardstick of proper product design standards. *See* Douglas A. Kysar, *The Design of Products Liability: A Reply to Professors Henderson and Twerski*, 103 COLUM. L. REV. 1803, 1803 (2003), http://digitalcommons.law.yale.edu/fss_papers/457.

implicate under negligence law? Fore-knowledge of anti-social intentions which impugn the integrity or beneficence of the device could cast a manufacturer in the role of a liable defendant under a negligence theory – unless its FDA designation changes to Class III where the manufacturer could be shielded by the pre-emption doctrine.[151] Traditional negligence law could determine that the gravity and likelihood of harm were too high to allow the product to go to market – if its dangers to others (and the gravity of anticipated harm) were considered. The traditional "out" in such cases – imposing a warning – would be essentially useless. What would it say? Don't think bad thoughts? And what if the BCI is reacting to pre-cognition signals – what warning could even contemplate preventing that type of injury?

Let's examine a case where the action began before cognition. Let us further assume the designers knew or should have known about the possibility that signals emanating at the time the readiness potential is triggered (due to unconscious malevolent thoughts of the user) might move the device in an untoward direction. For this to happen, it would be alleged that the designers either knew or should have known about the existence of the pre-conscious signal – an allegation perhaps not difficult to prove should the studies establishing their existence be admitted into evidence. To assess the strength and capacity of such signals, extensive testing would need to be employed – and failure to test could be a viable allegation under these circumstances. To avoid or prevent such effects, the burden on the manufacturer might be to require the device to respond only to a certain intensity of thought (amplitude of brain signal) – or after the thought is actively held for a long enough period of time (duration) for the user to be consciously aware of it. Thus, Auntie Maim might have harbored unconscious disgust for her nephew, of which she may well be unaware. Without a concerted thought – at a level of consciousness – would it be fair to hold her responsible for an action generated by a thought that even years of psychotherapy might not uncover?

[151] See Wyeth v. Levine, 555 U.S. 555, 573 (2009), a Supreme Court Case that held that federal regulatory clearance of a medication does not shield the manufacturer from liability under state law.

Before addressing that situation, let's assume another set of facts. Let's examine the situation where the user consciously entertained malevolent thoughts. Let's assume Auntie Maim really did entertain the desire to harm her nephew. In real life we can consciously override – by an act of will – negative thoughts. Even conscious desires to kill one's meddling mother-in-law are generally not acted on. But the BCI-bionic interface makes such desires that much more accessible and malleable. What kind of a fail-safe STOP mechanism should be required to avoid such "accidents" of will, if not of thought? In the case of one manufacturer, an emergency brake of sorts is incorporated by the user puffing their cheeks. But will that option work in a timely enough fashion? Can the mind generate the STOP signal fast enough to overcome the GO signal? Will the user be so flustered as to forget what to do if the wheelchair starts acting "out of control"?

As noted above, practically speaking in the above hypotheticals, the plaintiff would sue everyone along the distributive or negligence chain – hardware manufacturer, software designer, physician, and BCI-bionic user, and let them sort it out. They might also raise a generic claim of *res ipsa loquitur*,[152] where the existence of the accident itself might be sufficient basis upon which to impute liability. Generally, such claims are limited to situations where all other plausible causes are ruled out – or where the injured party does not have access to the relevant information regarding causation, being under the total control and instrumentality of the defendant. Thus, in the case of *Ybarra v. Spangard*[153] the plaintiff awoke from surgery with a damaged limb not related to the surgery, damage deemed to be of traumatic cause which the plaintiff did not suffer previously. The plaintiff, being unconscious during surgery, did not have the wherewithal to divine out the cause and the

[152] *See generally* Bryan Casey, *Robot Ipsa Loquitur*, 61 GEO. L.J. 225 (2019) (claiming that obstacles to suing robots for negligence (fault) can be overcome via the doctrine res ipsa loquitur and logical inference and suggesting that "inference-based analysis can—and, in fact, already does—elegantly resolve liability determinations for otherwise confoundingly complex accidents.").

[153] 25 Cal.2d 486, 488 (Cal. 1944).

causative actor. Instead, he invoked the *res ipsa* doctrine, which has three conditions:

> (1) the accident must be of a kind which ordinarily does not occur in the absence of someone's negligence; (2) it must be caused by an agency or instrumentality within the exclusive control of the defendant; (3) it must not have been due to any voluntary action or contribution on the part of the plaintiff.[154]

The court ruled that while there were multiple defendants in the operating room, and the injury might have resulted from individual acts of any one of them, this did not excuse the defendant who had the right of control over all of them.

This doctrine may be of some use in BCI cases. However, one aspect of *Ybarra* is not satisfied in the cases of Cyborg Susie and Creepy Charlie: not all the possible actors are under the same control. In our sagas we have as defendants a BCI-device manufacturer which would include component part produces (e.g., software) who would be under that control, and independent users, Auntie Maim and Bionic Bob, who are acting independently. Indeed, contrary to instructions, Bionic Bob gained twenty pounds rendering him unfit to use the device. Likely, Bionic Bob's obvious and provable superseding intervening acts (the weight gain) would absolve the Exoskeleton manufacturer, leaving Bob (and his insurance company) "holding the bag." Likely, Bob would try to palm the responsibility onto Cyborg Susie's mental state. In this case, Bob's careening body is a clear, causative affect (cause) of Susie's death, although Susie's thoughts are perhaps more directly and proximately relevant. The question becomes how powerful – and how contributory – was that mental state in causing her death? Surely the physician who commits malpractice by prescribing an excessive drug dosage under which the patient overdosed and died cannot be absolved with the defense, "she wanted to die anyway."

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[154] *Id.* (quoting WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS 295 (1941)).

The intervention of Auntie Maim in Creepy Charlie's case poses a more complex problem. There is no intervening cause between the wheelchair and her mangled nephew. Either Auntie Maim is responsible – or the wheelchair company is, perhaps due to an errant BCI system with its multiple components. In this case, the single instrumentality and control rule espoused in *Ybarra* does not remotely exist. Here, the case of *Summers v. Tice*[155] comes to the rescue. Decided four years after *Ybarra*, the plaintiff in *Summers* was shot in the eye by two hunters acting independently – and the plaintiff couldn't prove which shot injured him. The court ruled that where there was uncertainty regarding which one caused the plaintiff's injury, both were liable in the absence of sufficient causal evidence as to either defendant.[156] Inability to identify the negligent actor has not proved an impediment to suit in recent iterations either, as novel products liability doctrine attests.[157] Again generated by California jurists, the court in *Sindell v. Abbot Laboratories*[158] pioneered the market share liability doctrine – where all manufacturers of a specific product would be held liable to the extent of their market share, when the actual product could not be identified.[159]

The problem with these cases, however, is that all putative defendants were engaged in the same activity – with the same modus of evaluating their culpability available and the same legal doctrine and standard of care involved. The onus on an injured plaintiff who is incapable – through no fault of his or her own – of identifying the actor will not bar that plaintiff from recovery where they all committed the same negligent act.[160]

The difficulties our situation presents are two-fold. The first is that the putative defendants, i.e., the BCI-device manufacturer, which includes suppliers and software designers

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[155] 33 Cal.2d 80 (Cal. 1948).

[156] *Id.* at 88.

[157] Hymowitz v. Eli Lilly & Co., 539 N.E.2d 1069 (N.Y. 1989).

[158] Sindell v. Abbott Lab'ys, 26 Cal.3d 588, 612 (Cal. 1980).

[159] *See also* Hymowitz, 539 N.E.2d 1069.

[160] Ybarra v. Spangard, 25 Cal.2d 486, 490 (Cal. 1944) ("by denying one, patently entitled to damages, satisfaction merely because he is ignorant of facts peculiarly within the knowledge of the party who should, in all justice, pay them.").

– are independent from the human adjuvant, Auntie Maim, and their relative responsibilities cannot be sorted out. This problem might be addressable by the *Summers* case, under the theory that the innocent plaintiff, Charlie, should not bear the burden of identifying the responsible party. The second problem is that the claims vastly differ. In the case of the manufacturer, the claims would lie in negligence (and perhaps product liability). *Res ipsa*, generally a paradigm applied in negligence, might well be available.[161] However, in the case of Auntie Maim, the claim would be for an intentional tort, where the determinant is the *mens rea* (guilty mind) and causal connection of the defendant's actions. In this case, her intent would be inferable from comments she's made and perhaps actions she's previously taken. But r*es ipsa* is generally not invoked in intentional tort claims. Nor in intentional tort claims can a joint-tortfeasor seek contribution from another. Hence Auntie Maim would be left holding the entire bag.[162] To compound the "injury," Auntie Maim's insurance company likely would disclaim responsibility under an intentional tort exclusion[163] – thereby effectively precluding nephew Charlie from real recovery.

1. How Much Intent Do You Need to Qualify for an Intentional Tort?

To the lay person, perhaps intent might be considered synonymous with a deliberate act to injure a particular person. Such level of deliberation or intentionality is not necessary to sustain a tort claim for an intentional tort. For example, merely

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[161] *Negligence in Tort Law: Res Ipsa Loquitur and Negligence Per Se*, LAWSHELF, https://lawshelf.com/shortvideoscontentview/negligence-in-tort-law-res-ipsa-loquitur-and-negligence-per-se/ (last accessed Oct. 1, 2021) (explaining that *res ipsa loquitur* allows negligent behavior to be inferred from surrounding circumstances).

[162] Robert A. Leflar, *Contribution and Indemnity Between Tortfeasors*, 81 U. PA. L. REV. 130, 130 (1937) https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=8568&context=penn_law_review ("In Merryweather v. Nixan, the joint tortfeasors were intentional wrongdoers, but by the great weight of modern common law authority, contribution is denied also as between joint tortfeasors whose liability is based on negligence merely, as distinguished from intentional wrongdoing.").

[163] Kirkpatrick v. AIU Ins. Co., 204 F. Supp. 2d 850, 856 (E.D. Pa. 2002).

knowing to a substantial certainty that harm will follow an action has been held sufficient to justify a claim of battery,[164] even if the party injured is not the one intended.[165] Indeed, mere knowledge that contact will occur by virtue of one's acts is enough to justify a claim for greater harm than intended ensuing by the act.[166] Thus, assume Auntie Maim admits she intended to merely nudge Charlie with her wheelchair – but didn't intend to run him over crushing his limbs in the process. She could still be held liable for battery for the entire injury. The instrumentality of Auntie Maim's action – which here is synonymous with her thoughts, conscious or not – may have been imprecise, perhaps due to a lack of precision on the part of the manufacturer. Nevertheless, it is likely Auntie Maim would end up being entirely responsible, as the device was being used in a manner for which it was not intended, also shielding the manufacturer from liability under strict liability in tort.

But then we get to the question of negligence. Is it reasonable for a BCI-device manufacturer to put into the stream of commerce a device that can be easily or clumsily manipulated by imprecise brain waves – or by subtle, inchoate thoughts – of which the actor may be marginally aware? Even if the actor was actually aware of these thoughts at the time, psychology allows us to guess such a person would deny such intent afterwards as a self-protective mechanism – such that he or she truly doesn't remember them. Can the devices be calibrated such that only deliberate clear thoughts can be implemented with the assurance

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[164] RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM §1, which defines intent thus: "A person acts with intent to produce a consequence if: (a) the person acts with the purpose of producing that consequence; or (b) the person acts knowing that the consequence is substantially certain to result."

[165] A legal fiction called "transferred intent." *See* Vincent R. Johnson, *Transferred Intent in American Tort Law*, 87 MARQ. L. REV. 903, 904 (2004). The standard even applies to an insane person who did not understand his actions. *See, e.g.*, Williams v. Kearbey, 775 P.2d 670, 674 (Kan. Ct. App. 1989) ("The fact that Kearbey did not 'understand the nature of his acts' or did not 'understand that what he was doing was prohibited by law' does not preclude the jury from finding that Kearbey acted intentionally."). *See also Chapter II: Intentional Torts—Person*, GRAND RAPIDS ORIENTATION MATERIALS, https://www.cooley.edu/sites/default/files/media/docs/Grand%20Rapids%20Orientation%20Materials.pdf.

[166] Garratt v. Dailey, 279 P.2d 1091 (1955).

that fuzzy ideas or "wishes" are over-ridden by some electrical "impulse" control (pun intended)?

The actions of Auntie Maim – if wrongful – likely would not be considered negligent. There is nothing she knew or should have known to allow her to act differently that would be considered actionable. While society expects people to control their actions, and indeed reasonable people do, no such similar standard applies to controlling one's thoughts. Thus, if she bears liability, it would only be for an intentional tort. This dichotomy, either Auntie "M" is – or is not – an intentional tortfeasor, sets her in stark comparison to the manufacturer who, given a standard of care requiring testing, would only be considered negligent for failing to do so, resurrecting the issue of identifying the proper defendant. Unless, that is, we can forge some intermediate category, where we can invoke the *res ipsa* doctrine. One such possibility is where the manufacturer's actions – while not intentional – are worse than mere negligence. This possibility might accrue under the guise of recklessness, which similarly invokes the consciousness of the actor.

2. Recklessness and Consciousness

An intermediate concept of *mens rea*, somewhere between intent and negligence, falls under the rubric of recklessness, or willful disregard for the safety of others.[167] Would a BCI-Cyborg manufacturer's conduct meet this standard if the manufacturer didn't test the implications of the readiness potential? Would failure to test the comparative response-time of an emergency fail-safe override – such as cheek-blowing – render the manufacturer reckless, or merely negligent? Knowing – with absolute certainty – the delay in response to activity (gleaned from car-braking studies), can a manufacturer assert with reasonable certainty that once an improvidently – and then regretfully – issued brain signal is activated, the fail-safe mechanism will be effectuated in a timely fashion?

Should a detailed testing program not be instituted regarding these defects, the manufacturer may well be considered reckless. In this instance, such recklessness would

[167] Rapp, *supra* note 129, at 116.

supersede comparative and contributory negligence of a plaintiff,[168] nullifying Cyborg Susie's contribution to her own death. But what about the comparative weight of the recklessness of a defendant versus comparative intentionality of a co-defendant, such as Auntie Maim? Where does the law come out here? The answer is unknown, but superimposed on determining the legality of the actions and the psychology of the *mens rea*, is a rendering of the morality of the actions or omissions.[169] And here the comparative concerns of the individual (the disabled person who cannot function without the device) and public health collide. Whose needs are morally superior? Do the needs of the many outweigh the needs of the One?[170] The morality element is crucial, in that "one can only be reckless if one has done something reprehensible and morally blameworthy."[171] However, if a manufacturer knowingly proceeded to aggressively market a BCI-device and deliberately eschewed testing the impact of a user's malevolent thoughts (aka brain signals), the inference of moral repugnance might be made – especially when coupled with robust financial statements.

In 1934 the First Restatement of Torts defined recklessness as "conduct . . . creating an unreasonable risk of bodily harm and a high probability of substantial harm."[172] Under this definition, a manufacturer's failure to test for bystander-impact could be reckless. By 1979, the Second Restatement "improved" the definition and "recklessness was characterized as physical harm caused by an actor's conscious and knowing disregard of a substantial risk."[173] This change cements liability-assessment on the part of the manufacturer –

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[168] *Id.*

[169] The "dominant vocabulary of tort" is infected with moral theory. Gerald J. Postema, *Introduction: Search for An Explanatory Theory of Torts*, *in* PHILOSOPHY AND THE LAW OF TORTS 2. *See also* Posner on Oliver Wendell Holmes.

[170] Attributed to Mr. Spock in STAR TREK II: THE WRATH OF KHAN (Paramount Pictures 1982). A redefinition of Mill's and Bentham's Utilitarianism.

[171] Rapp, *supra* note 129, at 133.

[172] RESTATEMENT OF TORTS § 500 (1934).

[173] RESTATEMENT (SECOND) OF TORTS § 500 (1979); *see also* RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM §§ 2–3 (P.F.D. No. 1, 2005), which assigns to the reckless act a significant high-level risk and an awareness by the actor of such a degree of risk.

assuming actual knowledge of the readiness potential and its impact can be proven. The category adheres to a *conscious knowledge* of the risks and willfully proceeding in the face thereof,[174] perhaps also involving knowledge of "serious danger."[175] Here, consideration of the level of conscious or awareness translates to evaluating the manufacturer's conduct, as opposed to the user's, which might absolve the manufacturer. However, a deliberate decision not to test the quantum and duration of the user's intent (as measured by brain signals) necessary to instigate an untoward motion might also qualify as recklessness, assuming the manufacturer was aware (again a word describing consciousness) of the Libet studies.[176]

> While an act to be reckless must be intended by the actor, the actor does not intend to cause the harm which results from it. It is enough that he realizes or, from facts which he knows, should realize that there is a strong probability that harm may result, even though he hopes or even expects that his conduct will prove harmless.[177]

As Professor Rapp, relying on the Second Restatement, § 500, comment (a), explains, there are "two kinds of recklessness: deliberate (in)action in the face of a known risk; or (in)action in the face of facts that would make the risk apparent to a reasonable person, even though the wrongdoer himself need not grasp that risk."[178] Interestingly, "section 500 includes no language implicating a sense of the callousness, depravity, and self-conscious gratuitousness that lend recklessness its wrongful moral character."[179] These considerations augment the possibility of categorizing the manufacturer's actions as reckless for failing to test for dangers of which it is aware. And by

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[174] Rapp, *supra* note 129, at 119; *see also* Commonwealth v. Pierce, 138 Mass. 165, 175 (1884), *reprinted in* LANDES & POSNER, at 275 (recklessness "is understood to depend on the actual condition of the individual's mind with regard to consequences.").

[175] RESTATEMENT OF TORTS § 500 cmt. g (1934); RESTATEMENT (SECOND) OF TORTS § 500 cmt. g (1979).

[176] RESTATEMENT (SECOND) OF TORTS § 500 (1979).

[177] *Id.* § 500 cmt. f.

[178] *Id.* § 500 cmt. a; *see also* Rapp, *supra* note 129, at 130.

[179] Rapp, *supra* note 129, at 131.

categorizing acts of the manufacturer as reckless, we can bypass difficulties arising from joint defendant contribution when one defendant's acts are intentional, and the other is negligent. Insurance policies may also be activated under this determination, thereby affording the injured plaintiff a chance at effective recovery.

In our analysis, however, considerations of "neuroeconomics" might be warranted.[180] Neuroeconomics has been defined as "the study of how the embodied brain interacts with its external environment to produce economic behavior . . . using brain imaging advances, to investigate systematically how brain function causes certain behaviors."[181] Further, "neuroeconomics . . . [is based on the] understanding of the actual cognitive processes at work in human thought, [and] focuses on choice as a product of brain activity."[182]

But the discipline only highlights our ignorance. This lacuna of knowledge should render BCI devices subject to greater oversight than currently afforded, as it would seem difficult to assess culpability based on *mens rea*. According to some scholars, risk-determinations upon which we would determine the manufacturer's recklessness are contingent on both conscious and unconscious thoughts[183] – very much like the intentionality to move the wheelchair on the part of the user. But differences lie between expert schools regarding measuring conscious decision-making. One school is based on brain imaging, the other on brain signaling and both yield different results. The consilience – or lack thereof – between the two methodologies is but another example of science leaving the law

[180] *Id.* at 153-54; *see also* John B. Davis, *Behavioral Economics, Neuroeconomics and Identity*, *in* ECONOMICS & THE MIND 58 (Barbara Montero & Mark D. White eds., 2007).

[181] Rapp, *supra* note 129, at 157.

[182] *See generally* Peter Coy, *Why Logic Often Takes a Backseat; The Study of Neuroeconomics May Topple the Notion of Rational Decisionmaking*, BUS. WEEK, Mar. 28, 2005, at 94.

[183] Rapp, *supra* note 129, at 158.

far behind,[184] exemplifying our ignorance of a technology that we are now blandly marketing to an unsuspecting public.

3. Other Concerns: Privacy

Other concerns raised by these devices should also invite greater consideration. These include *privacy* issues.[185] Merely examining the brain waves used in these products enables a researcher to identify the owner – even thoughts are used in other situations.[186] "Extracting" knowledge via electrical impulses from brain waves might be considered akin to "theft," especially of "intellectual property" (pun intended), which raises a related question – who owns the thoughts generated in brain-to-brain or BCI interfacing? Further, what about merely entering someone's mind because you are curious? Would the statutory misdemeanor of voyeurism suffice to redress what should undoubtedly be a crime? Is spectating the naked mind somehow less invasive than watching a naked body?[187] Further, it bears noting that "to date there is no legislation regulating informed consent and protecting personal data extracted via BCIs, much less BTBIs, either therapeutically or outside of the clinical and research context. Further, no formal protocols are in place for how to conduct research using these technologies, with humans or animals."[188]

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[184] *See* Deborah W. Denno, *Crime and Consciousness: Science and Involuntary Acts*, 87 MINN. L. REV. 269, 272 (2002) ("[M]odern neuroscientific research has revealed a far more fluid and dynamic relationship between conscious and unconscious processes. If such fluidity exists, human behavior is not always conscious or voluntary in the 'either/or' way that the voluntary act requirement presumes. Rather, consciousness manifests itself in degrees that represent varying levels of awareness.").

[185] Dearen, *supra* note 62 ("'Once I know what the readings look like from your brain in a certain situation, I'll be able to recognize you by that pattern again later on,' neuroscientist warns amid rise of computers that can read our minds.").

[186] *Id.*

[187] *See generally* Michael S. Pardo & Dennis M. Patterson, *Philosophical Foundations of Law and Neuroscience*, 2010 U. ILL. L. REV. 1211 (2010).

[188] Trimper et al., *supra* note 66.

In sum, these hypotheticals alert us to several considerations: 1. They highlight the dangers to bystanders – which may not have been fully considered by the manufacturers or the FDA. 2. They raise the difficulties posed by BCI-devices employing thoughts – which may be inchoate or imprecise – to power actions that could be unintentionally dangerous, requiring heightened testing. 3. They alert us to dangers which may have not been considered, such as privacy issues. 4. They suggest that the focus not only address alleviating the medical status of the neurologically impaired, but also the potential to wreak harm on public health, suggesting greater research is needed before concluding these devices pose low to moderate risk.[189] 5. And finally, they alert us to considerations of *mens rea* on the part of the actors or putative defendants, demonstrating our ignorance of intentionality in acting and to determine who is liable and for what?

Overcoming litigation obstacles at least may provide recompense to the injured and motivate manufacturers to implement broader testing protocols. Yet, we still must confront difficulties posed by FDA classification. I argue here that the dangers incident to errant and uncontrollable brainwaves militate the FDA's recalibration of these devices as Class III devices, rather than Class II which is devoted to items posing low to moderate risk. However, reclassification of these devices as Class III may bring difficulties of their own that deprive plaintiffs of a compensable remedy – the invocation of the pre-emption clause that accompanies designation as a Class III device.

I next turn to discussion of the pre-emption clause as invoked by Class III devices, its history and rationale, with the objective of determining if "cracks" exist to allow both this higher level of classification and permit litigation for bystander injury.

V. PRE-EMPTION OF MEDICAL DEVICES UNDER THE FDA

[189] Oliver R. Goodenough & Kristin Prehn, *A Neuroscientific Approach to Normative Judgment in Law and Justice*, LAW & THE BRAIN, at 77, 89-90.

A. Rationale for FDA Oversight

If we are desirous of maximizing product-development generally and motivating development of new drugs and novel devices, in particular, we might wish to minimize lawsuits. Indeed, since the late 1980s, product liability litigation severely impacted the medical device industry, bankrupting some device manufacturers and shutting down some medical-product manufactures entirely.[190] Suppliers of raw materials used in medical devices withdrew from the market merely because the threat of costly litigation outweighed the business advantage. Reportedly "one of only two raw material suppliers of ultra-high molecular weight polyethylene . . . informed medical device manufacturers that it will no longer supply the material for use in surgical implants."[191] Those that continued component manufacture drastically increased prices. In 1995, companies that make catheters, heart valves, and other devices reported that silicone prices skyrocketed to $100 a pound from $6 a pound. Pierre Galletti, President of the Division of Biology and Medicine at Brown University, called the situation a "public health emergency."[192]

The legislative record and history, however, do not seem to comport with the business events on the ground:

> *Indeed, nowhere in the materials relating to the Act's history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices.* To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision;

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[190] *See* JACK C. FISHER, SILICONE ON TRIAL, BREAST IMPLANTS AND THE POLITICS OF RISK (for example Dow Chemical was named in some 13000 lawsuits based on the sale of silicone gel and components to breast implant manufacturers).

[191] *Biomaterials supply line shrinks*, BULLETIN OF THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, (Jan. 1996), http://www2.aaos.org/bulletin/jan96/supply.htm.

[192] Douglas J. Behr, *Medical Device/Component Liability and Tort Reform*, KELLER AND HECKMANN, LLP (1998).

> furthermore, *any such concern was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices*. . . . There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices.[193]

The conflict in assessing the then-prevailing conditions generating the FDCA and Medical Device Act (MDA), in particular, makes it difficult to fashion an appropriate remedy to address the problems set forth above. Because medical devices are sold on the national market, Congress recognized that *national uniformity* is essential to effective regulation of medical devices.[194] Otherwise, it was feared that a hodgepodge of state standards would eradicate the uniformity necessary to regulate medical devices.[195] That rationale may well be the predicate needed for invoking Class III designation for these devices.

B. Pre-Emption

Enacted in 1976, the MDA granted the FDA authority to regulate medical devices and created a comprehensive "regime of detailed federal oversight,"[196] providing that *all* actions to enforce the Act shall be by and in the name of the United States.[197] While seeking to ensure that safe and effective innovative medical devices would be readily available to treat patients in need of life-saving or disability-averting care, Congress recognized the "undu[e] burden" differing state

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[193] Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD AND DRUG L. J. 113 (2010). *See also Buckman*, 531 U.S. at 354 (Stevens, J. & Thomas, J., concurring).

[194] H.R. Rep. No. 94-853, at 12.

[195] *Buckman*, 531 U.S. at 350 ("As a practical matter, complying with the FDA's detailed regularity regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants").

[196] *Riegel*, 552 U.S. at 316.

[197] *See, e.g.*, Wyeth v. Levine 555 U.S. 555, (2005).

regulation would impose. Hence a general "prohibition on non-Federal regulation" of medical devices was envisioned by incorporating an express pre-emption clause into the Medical Device Amendments.[198] That provision, §360k(a), expressly pre-empts any claim that imposes a *state law* "requirement" with respect to a medical device that is "different from, or in addition to" a *federal* requirement imposed by the FDA.

In so doing the MDA enacted an express exemption clause which "swept back" state requirements that augment or conflict with (i.e., that are "different from, or in addition to") federal requirements.[199] The MDA was thus crafted to eliminate conflicting state requirements and replace them with a uniform federal regulatory framework.[200] To ensure that medical devices would not be "stifled by unnecessary restrictions," Congress included an express pre-emption clause in the Medical Device Act.[201] As the Third Circuit noted, "[a]llowing juries to perform their own risk-utility analysis and second-guess the [agency's] conclusion would disrupt the expert balancing underlying the federal scheme."[202]

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[198] Andrew Tauber et al., *How to Argue Medical Device Preemption*, FOR THE DEFENSE (Oct. 2012), available at https://www.mayerbrown.com/-/media/files/news/2012/11/how-to-argue-medical-device-preemption/files/how-to-argue-medical-device-preemptionfor-the-defe/fileattachment/how-to-argue-medical-device-preemptionfor-the-defe.pdf.

[199] *Riegel*, 552 U.S. at 316.

[200] Steven Boranian, *The BAAA – A Powerful Punch in Sheep's Clothing*, DRUG AND DEVICE L. BLOG (Mar. 5, 2021), ("The Biomaterials Access Assurance Act of 1998 (or 'BAAA') [21 U.S.C. § 1604 et seq.] creates a complete defense for companies that provide biomaterials used in manufacturing implantable medical devices. The manufacturer of the device itself may be liable, but the company that provided raw materials or component parts generally is not." (citing Connell v. Lima Corporate, No. 19-35797, 2021 WL 609599 (9th Cir. Feb. 17, 2021))) https://www.druganddevicelawblog.com/2021/03/the-baaa-a-powerful-punch-in-sheeps-clothing.html.

[201] H.R. Rep. No. 94-853, at 12 (1976); *Riegel*, 552 U.S. at 316 ("Congress intended that the MDA's express pre-emption clause would act as a "general prohibition on non-Federal regulation."); H.R. Rep. No. 94-853, at 45 (1976).

[202] Tauber et al., *supra* note 198.

Few would doubt that Congress has the authority to regulate commerce,[203] under which pre-emption would be triggered. However, the competing doctrine of state's rights, vesting in the states superior rights to safeguard public health, might allow for state law (tort) to supersede pre-emption when it comes to issues of safeguarding the public health.[204] Nevertheless the frisson between pre-emption and product liability suits marches on.[205]

Indeed, §360k(a) does not apply to all medical devices. Rather, as interpreted by the Supreme Court, §360k(a) applies only to devices designated as "Class III" under 21 U.S.C. §360c – i.e., those that support or sustain human life or otherwise present a potentially unreasonable risk of illness or of injury – and more specifically to only those Class III devices that have received Premarket Approval (PMA) pursuant to 21 U.S.C. §360e.[206] The designation of a product as Class III is dependent

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[203] *See* Sharkey, *supra* note 127, at 450 n.2 Few would challenge Congress's ultimate constitutional authority under Article I to regulate products in the national economy. *See* U.S. CONST. art. I, § 8, cl. 3 ("The Congress shall have power to . . . regulate Commerce . . . among the several States . . . ."). And of course, once enacted, "the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby . . . ." U.S. CONST. art. VI, cl. 2." *See also* JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 424 (5th ed. 2004).

[204] *See, e.g.*, Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))). *See also* Barbara Pfeffer Billauer, *Fundamentalism in Roman Catholic Diocese v. Cuomo: The Court's Farrago of Religious Freedom, Public Health Law, and Scientific (Il)Literacy*, SSRN.com, 3787319 on superiority of regulation by the federal government under the Commerce Clause vs. state's rights to regulate public health.

[205] Sharkey, *supra* note 127, at 455. *See also* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 529 n.27 (1992) (defending a narrow construction of an express pre-emption clause "in light of the strong presumption against pre-emption.").

[206] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (noting "neither the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of a device originates with its manufacturer." Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners at 20, Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (Nos. 95-

on a risk-benefit analysis. Class III medical devices, then, usually novel devices, also require the submission of PMAs (pre-market approvals). These devices tend to have a higher risk or raise new safety and effectiveness questions that must be answered before being approved for marketing. Data in a PMA application must demonstrate a "reasonable assurance" of safety and effectiveness.[207]

As noted above, most BCI interface technology, exoskeletons and motorized transports such as wheelchairs, are currently designated as Class II devices and exempt from Class III approval mechanisms.[208] Indeed, these devices are now regulated under the Breakthrough and De Novo pathway, which permits "the classification of novel, low-to-moderate risk devices into Class I or II (rather than Class III) without first having to submit a 510(k) [premarketing approval],"[209] allowing an expedited or facilitated system of review.

Nevertheless, I suggest that because of the potential for danger for these devices when integrated with BCI or B2B technology, designation of these devices should be reconsidered.

754, 95-886), 1996 WL 118035, at *20. Specifically, it argued that the FDA's premarket notification process, whereby it had approved petitioner's device as "substantially equivalent" to those on the market, did not preempt the plaintiff's design defect claim. Sharkey, *supra* note 127, at 475. *Cf. Riegel*, 2008 WL 440744, at *10).

[207] 21 C.F.R. Part 814 (Pre-market Approval of Medical Devices), 21 C.F.R. Part 860 (Medical Device Classification Procedures) and 21 C.F.R. Part 803 (Medical Device Reports).

[208] Bobby Marinov, *FDA Classifies Exoskeletons as Class II*, EXOSKELETON REPORT (Mar. 7, 2015), https://exoskeletonreport.com/2015/03/fda-classifies-exoskeletons-as-class-ii/.

[209] *A History of Medical Device Regulation & Oversight in the United States*, FDA, https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states. *See also Breakthrough Devices Program, De Novo Program*, FDA, https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program (under which the latest BCI device was approved). The FDA streamlined approval of the device under the Breakthrough Device program, which speeds up "development, assessment, and review while preserving the statutory standards for premarket approval, 510(k) clearance, incorporating De Novo marketing authorization. The De Novo regulatory pathway is a premarket review for low- to moderate-risk devices of a new type." *See* Billauer, *supra* note 112.

Further, I venture that it is not unlikely that they will be bumped up to Class III category, or that additional review steps be assigned some time in the future. Should this be the case, of course, a higher level of review will be warranted on one hand. On the other, such classification carries with it the possibility of pre-emption of manufacturers from state law claims[210] if the medical device manufacturer (or supplier of component parts)[211] followed FDA regulations (including strictly adhering to production of the device as approved by the FDA).

So, if that's the case, how come the largest Kentucky jury verdict of 2013[212] (over seven million dollars – including punitive damages) was returned against a medical device manufacturer? And how come this isn't an isolated event: over forty cases are pending against the same manufacturer, and a class action is being investigated against another.[213] And would this bode well for a lawsuit against a manufacturer of a BCI-bionic?

The answer is that there are exceptions to the pre-emption rule – albeit limited ones. Hence, as potent as the pre-emption doctrine is in barring suit, there are instances where it won't lie. As to when these exceptions will lie – that, ofttimes, depends on the circumstances. As Justice Alito said in *Wyeth v. Levine*,[214] when allowing the medical pre-emption doctrine to be

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[210] Tauber et al., *supra* note 198. "The Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA) contain an express pre-emption provision, 21 U.S.C. §360k(a), authoritatively construed by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 316 (2008). The FDCA also contains a no-private-right- of- action clause, 21 U.S.C. §337(a), which, the Supreme Court held in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), impliedly preempts state law actions that attempt to enforce provisions of the FDCA."

[211] Biomaterials Access Assurance Act of 1998 ("BAAA"), 21 U.S.C. §§ 1601-1606.

[212] In *Sadler v. Advanced Bionics, LLC*, 929 F. Supp. 2d 670 (W.D. Ky. 2013), a four-year old deaf girl who received cochlear implants which leaked, suffered three severe electrical shocks – in large measure due to the failure of the physicians to recognize the problem and address it to minimize the consequences of the failed device.

[213] *Cochlear Implant Class Action Lawsuit*, NORMANDIE LAW FIRM, https://www.losangelespersonalinjurylawyers.co/cochlear-implant-class-action-lawsuit/ (last visited Sept. 15, 2021).

[214] Wyeth v. Levine, 555 U.S. 555 (2009).

breached, "tragic facts make bad law." Generally speaking, however, the exceptions are narrowly construed and in *every* pre-emption case, Congress's intent "is the ultimate touchstone,"[215] determined via federal statutes.[216]

To assess whether pre-emption would be a boon or a detriment regarding BCI technology, a short review is necessary.

C. Tragic Cases Trigger Exemptions

In 2008 *Riegel v. Medtronic*[217] paved a tunnel through the pre-emption barrier. There, the Supreme Court addressed requirements for a Class III medical device that had received PMA for the purposes of § 360k(a)(1).[218] Noting that a device that received PMA must "*be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness*,"[219] the court concluded that substituting an unapproved component part manufacturer was sufficient to breach pre-emption protection[220] (although the component part manufacturer, itself, was immune from suit). In other words, the court ruled that this divergence from the device approved by the FDA was sufficient to pass through the "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied pre-emption."[221]

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[215] *Lohr*, 518 U.S.at 485-86; *Cipollone*, 505 U.S. at 516.

[216] *See, e.g.*, CSX Transport, Inc. v. Easterwood, 507 U.S. 658, 673-75 (1993); *Cipollone*, 505 U.S. at 520-29.

[217] 552 U.S. 312 (2008).

[218] Whitney, *supra* note 193, at 118-19.

[219] *Id. See also* Sharkey, *supra* note 127, at 487 n.179 noting while the PMA is tantamount to the FDA approving the device on safety grounds, pre-market notification is not. ("While § 510(k) is 'focused on *equivalence*, not safety,' premarket approval is focused on safety, not equivalence." (quoting *Lohr*, 518 U.S. at 493)); *id.* ("[The PMA process] *is* federal safety review.").

[220] *Id.* at 118, (through these restrictions, premarket approval "imposes requirements" on Class III devices: "the FDA requires a device that has received premarket approval to be made with *almost no deviations* from the specifications in its approval application." (emphasis added)).

[221] Bryant v. Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010) (as the Eighth Circuit put it, "Riegel and Buckman create a narrow gap through

As stated in *Franzese v. St. Jude Medical Center*:

> [t]o shoot this [narrow gap through which a plaintiff's state-law claim must fit to escape pre-emption], the "plaintiff must be suing for conduct that violates [federal law] . . . but the plaintiff must not be suing *because* the conduct violates federal law, because he has no private right to bring such a claim." [citations omitted].[222] "Stated differently, 'section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, but it does not extend protection from liability where the [state tort] claim is based on a violation of federal law.'"[223]

Thus, while the specific pre-emption package has largely protected manufacturers, lately, it seems the doctrine has become wobbly. Following Michigan's law enacted in 2000 protecting manufacturers from private actions covered by the FDCA[224] and later 2006 FDCA amendments sealing the wall closed, cracks in the pre-emption doctrine appeared – first, in

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which a plaintiff's state law claim must fit if it is to escape express or implied preemption"); Herrnandez v. Stryker Corp., 2014 WL 7044171, (W.D. Wash. 2014); Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

[222] Gale v. Smith & Nephew, Inc., 989 F. Supp. 2d 243, 2013 WL 563403, at *3 (S.D.N.Y. Feb. 13, 2013) (quoting *In re* Medtronic, Inc. v. Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (emphases and alterations in original)).

[223] Franzese v. St. Jude Medical, Inc., 2014 WL 2863087 (E.D.N.Y. 2014) (quoting Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010) (alteration in original)); Walker v. Medtronic, Inc., 670 F.3d 569, 577 (4th Cir. 2012); Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011).

[224] Jason C. Miller, *When and How to Defer to the FDA: Learning from Michigan's Regulatory Compliance Defense,* 15 MICHIGAN TELECOMMUNICATIONS AND TECHNOLOGY LAW REVIEW, 565 (2009); *see also* MICH. COMP. LAWS § 600.2946(5) (2000). It may not be a coincidence that the only manufacturers of the Anthrax vaccine, with its problematic formulation and warnings, Emergent Technologies, was based in Lansing Michigan. It is also no secret that Emergent's Board was unusually politically connected, especially with then President Clinton.

allowing actions against drug manufacturers for improper labelling (i.e., failure to warn).[225]

1. Cochlear Implant Cases

Much of the body of law allowing state claims to survive, notwithstanding the pre-emption doctrine arises from the cochlear implant cases,[226] which bear similarities with BCI technology and cyborg devices such that the difference in designation is puzzling.

Cochlear implants (CI) assist hearing in patients with damage to the cochlea's sensory hair cells, and often enable better understanding of speech. Surgically implanted, the electronic device can provide a sense of sound to a person who is profoundly deaf or severely hard of hearing. Although in commercial use for only 25 years or so (and first approved by the FDA in 2000), roughly 96,000 people (58,000 adults and 38,000 children) have received the device in the US (32 per hundred thousand people) with 324,000 recipients worldwide.[227]

Like other recently approved cyborg-devices, the cochlear implant has two parts, an internal device and an external portion. The transmitter, the external component, is a coil held in position by a magnet that sits behind the external ear, transmitting power. The processed sound signals across the skin to the internal device via electromagnetic induction. Surgically placed under the skin behind the ear, the implant is composed of microphones, which detect ambient sound, and a speech processor, which first filters sounds prioritizing audible speech, and then splits the sound into channels before sending it – now in the form of electrical signals – through a thin cable to the transmitter. An implanted receiver and stimulator secured in bone beneath the skin converts the signals into electric impulses

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[225] Herrnandez v. Stryker Corp., 2014 WL 7044171, *6, 7-8 (W.D. Wash. 2014).

[226] *See, e.g.*, *Sadler v. Advanced Bionics, LLC*, 929 F. Supp. 2d 670 (W.D. Ky. 2013).

[227] *Cochlear Implants*, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS, https://www.nidcd.nih.gov/health/cochlear-implants (according to the Food and Drug Administration (FDA), numbers are as of December 2019).

and sends them through an internal cable to multiple electrodes, which send the impulses to nerves in the brain via the auditory nerve system.[228]

As life-enhancing as the device might be, there have been serious claims of avoidable malfunction;[229] risks are not insignificant, (including infection such as meningitis[230] and necrosis),[231] but they are largely avoidable or controllable.[232]

Bypassing pre-emption was accomplished in the cochlear implant cases because component parts were substituted in contravention of data furnished to the FDA, causing the product to be labeled "adulterated." Claiming the product was adulterated is one way to bypass the pre-emption bar, although this may be insufficient[233] without explaining how

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[228] *Id. See also* Ulrich Anderhub, *Cochlear Implant Introduction*, YOUTUBE (Jan. 11, 2008), https://www.youtube.com/watch?v=-WA7-k_UcWY (providing an excellent instructional video on how the device works. The four manufacturers for cochlear implants each use a different number of electrodes and different signal processing algorithm, signaling a reasonable, feasible alternative exists if one manufacturer's device proves substantially safer).

[229] *See, e.g.*, Purcel v. Advanced Bionics Corp., No. 07–CV–1777, 2008 U.S. Dist. LEXIS 62131, 2008 WL 3874713 (N.D. Tex. 2008).

[230] Susan Boswell, *Cochlear Implant Recipients Have Increased Risk of Meningitis*, 8 THE ASHA LEADER, no. 17, (Sept. 2003), https://leader.pubs.asha.org/doi/10.1044/leader.RIB.08172003.3. *See also Hearing Loss in Children: Bacterial Meningitis Studies*, CDC (June 8, 2020), https://leader.pubs.asha.org/doi/10.1044/leader.RIB.08172003.3.

[231] Elias D. Stratigouleas, Brian P. Perry, Susan M. King, Charles A. Sims, *Complication rate of minimally invasive cochlear implantation*, OTOLARYNGOLOGY–HEAD AND NECK SURG.135 (3), 383–6 (2006). *See also* V.G. Schweitzer & M.J. Burtka, *Hyperbaric Oxygen Therapy in the Management of Cochlear Implant Flap Necrosis*, J. HYPERBARIC MED. 5 (2), 81–90 (1990).

[232] "The Cochlear Implant Controversy, Issues and Debates." NEW YORK: CBS News. September 4, 2001. Retrieved 2008-11-09, Solomon, Andrew (1994-); *see also Defiantly Deaf*, THE NEW YORK TIMES. Interestingly, the major opposition to use of the device comes from the deaf community who argue that the culture of the deaf community is being invaded by the hearing majority.

[233] Demetria D. Frank–Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 453, 470 (2011).

that adulteration contravened federal law.[234] If not properly invoked these exceptions would be inapplicable[235] to cases where no identifiable *cause* of damage can be identified – other than evidence of mis-intentionality of the user, such as could be the case in BCI technology involving a robotic arm or a wheelchair or exoskeleton.

In sum, Section 360k does not preclude states from imposing different or additional *remedies*, but only different or additional r*equirements*.[236] Indeed:

> In 1996, the Supreme Court determined that this language does not preempt common law negligence and strict liability claims alleging injuries caused by a medical device authorized for marketing via the § 510(k) process. . . . The Court further held that the common law claims were not preempted by general FDA labeling and manufacturing requirements.[237]

2. Allowable State Claims: Fraud

Whether pre-emption provides a virtually airtight defense or just another pleading obstacle often depends on who is authoring the opinion or law review article. Some say the usual product liability common law causes of action would be permissible, *provided they are properly alleged*. Thus,

> for a state law claim to survive express and implied pre-emption, the claim may be premised on conduct subject only to general requirements.

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[234] *Purcel*, 2008 WL 3874713 at 3, 4.

[235] Certainly, allegations that the manufacturer knew of the risk of leakage but delayed making it public because company insiders were poised for a big pay-off after the company was sold contributed to the large punitive damage award. But did the actual cause of the harm – the substitution of one component part manufacturer from the one approved by the FDA – justify allowing the claim – and the dozens of others based on the same chain of events? The court in Eggerling v. Advanced Bionics, 20 No. 3 WJMEDDEV 6, *Cochlear Implant Maker's Documents Remain Sealed in Iowa Suit* ruled that it did.

[236] Whitney, *supra* note 193, at 119.

[237] *Id.* at 118. *See also* Tauber et al., *supra* note 198.

> . . . The overall methodology for framing a non-preempted claim is to first identify conduct which violated the PMA or other specific requirement related to safety or efficacy. If such conduct can also be stated in terms of a breach of a parallel common law duty (e.g., failure to warn under strict liability or negligence, manufacturing defect, breach of warranty or fraud), then it would appear the claim is not preempted. Alternatively, regardless of a specific violation, common law remedies are not preempted by general CGMP requirements.[238]

a. Fraudulent Omission

The "FDA has long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation,"[239] especially in cases involving fraudulent omission of information. Kentucky courts, for example, have held that federal laws can support the existence of a duty of care in a negligence action that survives pre-emption.[240] This ruling includes parallel state law claims raising fraudulent omission where the "defendant acquired information subsequent to the FDA approval of the [medical device] and before implantation of the device that would lead a reasonable manufacturer to warn patients and the medical community."[241] Other courts have held that the pre-emption doctrine does not prohibit state law fraud claims alleging "the concealment of information from patients and physicians as the cause of Plaintiff's injuries," because these "claims sound in state tort law

[238] Whitney, *supra* note 193, at 119 (quoting Medtronic v. Lohr, 518 U.S 470, 495 (1996) ("Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.")).

[239] Whitney, *supra* note 193 (citing Wyeth v. Levine, 129 S. Ct. 1887, 1202 (2009)).

[240] *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670 (W.D. Ky. 2013). *See also* T & M Jewelry, 189 S.W.3d 532.

[241] Kemp v. Medtronic, Inc., 231 F.3d 216, 236-237 (W.D. Ky. 2000).

and would exist even without these federal regulations."[242] Indeed the Sixth Circuit district courts have held that *Buckman* pre-emption does not prohibit state law fraud claims, precisely on this ground.[243]

b. Failure to Train

A legitimate state-law action also may focus on the manufacturer's alleged failure to train physicians in the correct manner of implantation of a device. Such a theory is distinct from an action founded on inadequate FDA-approved training. Claiming that the FDA approved inadequate training would not provide the narrow window to supersede pre-emption,[244] but *failure to abide by* FDA-approved training guidelines was held to be minimally adequate to state a legally sufficient, non-preempted request for relief under 29 21 C.F.R. § 820.65.[245] This failure to train might include failing to teach the patient how to address unwanted thoughts or unintentional actions.

c. Current "Good Manufacturing Practice" (CGMP)

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[242] Fulgenzi v. Wyeth, Inc., 686 F. Supp. 2d 715, 724 (N.D. Ohio 2010). *But see* Cupek v. Medtronic, Inc., 405 F.3d 421, 424 (6th Cir. 2005) (regarding pre-emption of state law failure to warn claims).

[243] Fulgenzi v. Wyeth, Inc., 686 F. Supp. 2d 715, 718 (recognizing that the FDA requires "as part of [an] application, [that] the manufacturer . . . demonstrate through pre-market trials and other relevant evidence that the drug is safe, and that the proposed labeling properly sets forth the correct dosage and possible risks."). *See also Cupek*, 405 F.3d at 424 ("Any claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the FDA . . . would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process."). In *Purcel II*, the Texas District Court reasoned that "[t]o hold that voluntary fraudulent statements are preempted 'would turn FDA approval of some statements into a free pass to deceive consumers by making other statements.'" 2010 WL 2679988, at *7 (quoting *Riley*, 625 F. Supp. 2d at 788). This Court disagrees, because the FDCA and MDA endow the FDA with ample power to regulate medical device manufacturers, such that manufacturers cannot have a free pass to deceive customers.

[244] Kemp v. Medtronic, Inc., 231 F.3d 216, 236-37 (W.D. Ky. 2000). *See also* Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012 (2001).

[245] Rollins v. St. Jude Medical, 583 F. Supp. 790, 801-2, 804 (W.D. La. 2008).

Regardless of pre-emption, the device manufacturer is required to follow Current Good Manufacturing Practice (CGMP) regulations.[246] Failure to do so might allow the plaintiffs to bypass pre-emption and institute claims for strict liability. A breach of express warranty claim can also escape pre-emption based on an allegation that the device failed to meet the promises of the label and package inserts, which was the "basis of the bargain." Hence "[A] state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA," and therefore is not preempted.[247]

3. Testing and Simulated Use

Perhaps the most critical of the FDA requirements for our purposes is testing. The prime focus of the testing requirement is that the device is safe and effective. As one expert FDA practitioner noted:

> Obtaining FDA clearance through the 510(k) process . . . requires some form of device testing, likely to a known standard. . . . These critical items prove the safety and efficacy of the device . . . Two common tests in this category address electrical safety and electromagnetic compatibility (EMC). These tests apply to a wide range of medical devices that require a source of electrical power to function.[248]

And here is the voice of Julie Jacono, product manager for Invacare Corp:

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[246] FDA, CURRENT GOOD MANUFACTURING PRACTICE (CGMP) REGULATIONS, https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations.

[247] Whitney, *supra* note 193, at 136 (quoting Mitchell v. Collagen Corp., 126 F.3d 906, 915 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998)).

[248] Stuart Goldman*, Medical Device Testing Requirements for 510(k) Submissions*, INCOMPLIANCE MAG. (May 31, 2017), https://incompliancemag.com/article/medical-device-testing-requirements-for-510k-submissions/.

> We have a comprehensive product qualification testing lab in-house which performs mechanical and electrical testing. External testing is typically used for specialized test requirements, such as crash testing. Minimally . . . these tests must ensure that the production design can fulfill the performance specifications as deemed appropriate by the FDA and CMS.[249]

These examples demonstrate that the FDA mindset seems to be geared to safety and efficacy as they apply to the *user*. The dangers I raise here, however, are beyond those parameters – as they focus on safety to the public at large. In this situation, it is possible that state law claims for product liability claims may not be barred by the pre-emption clause. The exculpatory concept would be the language that requires that testing is to be done "under actual or simulated use conditions."[250] By couching the requirement in this fashion, failure to detect danger *to others* would be determinable by proper testing. If the injuries happen because such testing was not implemented, then the claims could lie.

Thus, as the court in *Purchase v. Advanced Bionics* noted:

> The Sixth Circuit made it clear that CGMP regulations may impose requirements on a manufacturer with regard to a Class III device that are in addition to requirements outlined in

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[249] *Putting Powerchairs to the Test*, MOBILITY MANAGEMENT (Feb. 2009), https://mobilitymgmt.com/Articles/2009/02/01/Putting-Powerchairs-to-the-Test.aspx.

[250] *See* Sadler v. Advanced Bionics, 929 F. Supp. 2d 670; 21 C.F.R. § 820.30(g) FDA (Apr. 1, 2020), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=820.30 (requiring product testing "under actual or simulated use conditions," is specific enough to support a parallel claim, because it "'impose[s] a concrete requirement on a manufacturer that embodies a standard of care related to the safety and effectiveness of the device.'"); *see also* Littlebear v. Advanced Bionics LLC, 896 F. Supp. 2d 1085 (N.D. Okla. 2012) WL 898152 at *11 (noting failure to perform testing under actual or simulated use conditions with the AstroSeal feedthru are not pre-empted).

> the PMA. In this respect, a manufacturer could be "liable even in circumstances where it complied fully with the specific [processes and specifications] approved by the FDA."[251]

Because state product liability law recognizes that inadequate testing can be the basis of a claim based on negligence, strict liability, or implied warranty, parallel claims may well lie.[252]

VI. CONCLUSION: A NEW REGULATORY-LITIGATION MODEL FOR BIONICS

Expedited approval processes are designed to be implemented where the benefits to the user – in terms of survival or quality of life – are high, and the risks to the user are perceived to be low. Such is the predicate upon which exoskeletons, powered wheelchairs, and BCI technology employed to communications or transport, can be granted approval under De Novo and/or Breakthrough programs allowable for Class II devices. But when these cyborg-bionic or even plain-powered concoctions, be they transport-assist, communication devices, or robotic arms, are coupled with BCI technology, the potential for danger increases exponentially – as the audience which may be affected by the technology or device is greatly enlarged. A stylus meant to transcribe markings on a screen can be thrown with marked efficiency at an attendant, a wheelchair can run over a toddler, an exoskeleton can crush a child.

Further, the determination of the cause of the harm (to prevent future events) becomes extremely complicated.

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[251] Purchase v. Advanced Bionics, LLC., 896 F. Supp. 2d 694, 697-698 (W.D. Tenn. 2011) (internal citations omitted); *see also* Johnson v. Advanced Bionics, LLC., 2011 U.S. Dist. WL 1323883 (W.D. Tenn. Apr. 4, 2011).

[252] Inadequate testing, that is, testing that is not undertaken or that is performed in an inadequate manner, that results in a defect that causes harm can be the basis for liability. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. m (1998); *id.* at cmt. n ("In connection with a claim under §§ 1 and 2 and related provisions of this Restatement, the evidence that the defendant did or did not conduct adequately reasonable research or testing before marketing the product may be admissible (but is not necessary is not necessarily required) regardless of whether the claim is based on negligence, strict liability, or implied warranty of merchantability.").

Hardware problems, perhaps, can be easily ruled out. Detecting and rectifying software problems may take more effort. Disentangling AI black-box learning- technology glitches from errant mind-control and mis-intentionality on the part of the user, however, probably is totally beyond our ken. This makes determining who is responsible for an accident problematic – from both a legal and engineering point of view. It also makes repairing the problem virtually impossible – at least for now. A robotic arm guided by a mind thousands of miles away can be a godsend – alternatively it can be misused in a subtle fashion – causing unexpected damage to a remote recipient.

Designating these devices as Class II may be a boon to the paraplegic for whom the devices will become available sooner. But at what cost? It would seem that the FDA might wish to upgrade the classification of BCI-powered devices to Class III – allocating a higher level of review and warranting greater data submission before approval. Additionally, cracks in the pre-emption doctrine are appearing regarding medical devices, and evidence indicates that the doctrine may not have been conceived to be applied as widely as some currently believe. Further, additional national requirements might be imposed under a Class III designation – although should this be done it likely would trigger pre-emption – and the tradeoff needs to be considered. Screening of recipients might also be indicated.[253] The same goes for continuous psychological monitoring. After all, if the brain is going to be doing the heavy work, assurance of mental health should be a pre-requisite for use. Use in those with PTSD might be evaluated separately, leading to the conclusion that enhanced testing of brain control should be required. Finally, these devices should trigger greater attention and discussion regarding the meaning and classification of "intent" and "recklessness" under tort law.

[253] Similar to required psychological screening of kidney donors.