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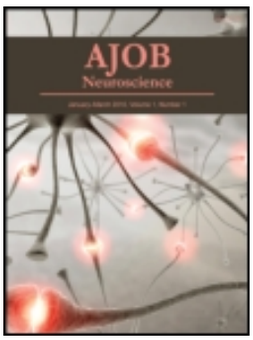

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Abstracts

Selected Abstracts From the 2015 International Neuroethics Society Annual Meeting

The editorial team of AJOB Neuroscience blind-reviewed all abstracts from the INS meeting for merit based on novelty, relevance, and contribution to the field of neuroethics. The scores were tallied and the top abstracts appear in the following.

Cochlear Implant Technology: Market Forces and Effects, and Neuroethico-Legal and Social Considerations

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Cochlear implant (CI) technology is being iteratively developed and improved. Simultaneously, there has been a rise in neuroethical issues fostered by cochlear implantation. Within the deaf community, cochlear implantation of prelingually deafened children is heavily disputed. Ongoing work by our group (see Joharchi and Giordano, INS 2013; 2014) has addressed sociocultural issues within the deaf community—as well as the extant CI debates between the medical and deaf communities—pertaining to use of CI technology.

Over the past few decades, iterations and improvements in neurotechnology have given rise to considerable competition between CI manufacturers. Manufacturers promote their products to medical professionals in an attempt to ensure brand loyalty. Given the near-permanent nature of the CI, once a patient selects and is implanted with a specific manufacturer's device, that patient will be somewhat bound to that company whenever device replacements or upgrades are needed. This situation has the potential to lead to particular manufacturers' dominance in/of medical markets. This creates a strong set of "pulling forces" that can exert effect upon and over the scientifically and ethically sound "push" for particular types of CI technology and the extent(s) of these devices' utilization.

Hence, it becomes important to (1) address if and how competition between CI manufacturers can lead to medical market dominance; (2) investigate whether and how medical dominance can influence economic and legal postures; and (3) revisit the sociocultural debate between the deaf and medical communities to address recent and potential future shifts in attitude(s) and perspective(s). To wit, we herein address—and discuss potential resolutions to—these neuroethico-legal and social issues. Inclusive among these resolution paths are increased discourse toward directive collaboration between the medical and the deaf communities, and the viability of a number of approaches (e.g., "whole child" and trajectory modeling) to depict and guide changes in policy and law(s) that could potentially direct and govern current and future CI development and use.

Public Discourses on Alcohol Addiction, Pregnancy, and Responsibility

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This presentation revisits key concerns that biological public dialogues around addiction, pregnancy, responsibility and blame shape health and social policies towards pregnant women with addictions. We discuss how brain-based models of addiction may engender inadvertent stigma toward addicted pregnant women in a context where current scientific dialogues may make "scapegoats of mothers" (Richardson et al. 2014).

Of late, increased attention has been focused on the potential for biological models to lead to unintended but harmful stigmatization of persons suffering from addiction. Hammer and colleagues (2013) suggest that framing addiction as a brain disease "is not necessary, and may be harmful," which contradicts the antistigma rationale of biological and disease-based views of addiction that have been promoted by national and international bodies. How such biological dialogues interact with public perceptions about mothers who suffer from an alcohol or drug addiction warrants particular scrutiny. Interdisciplinary literatures may help expand our understanding of how brain-based models impact perceptions of responsibility and blame of pregnant women with an addiction.

At the same time, we have become quick and eager to blame mothers for the negative lifetime outcomes of

their unborn children, a trend that is reinforced by the lack of responsible reporting of epigenetic research (Richardson et al. 2014). In turn, such complex scientific dialogues about the biology of addiction and the focus on the contribution of mothers to the outcomes of children have the potential to reinforce the blameworthiness of pregnant women with addictions. For pregnant women with an addiction to alcohol, stigma is already a significant barrier to receiving effective medical care (Eggertson 2013).

We are concerned that these dialogues may broadly influence health and social policies designed to prevent fetal harm, reinforcing the need for punitive policies and the criminalization of pregnant women (Racine et al. 2015). For instance, a recent case in the United Kingdom examined whether criminal intent could be established when a pregnant woman with an alcohol use problem later gives birth to a child with fetal alcohol spectrum disorder.

Our presentation will (1) review the interdisciplinary evidence on brain-based models of addiction and stigma; (2) discuss positions espoused regarding the responsibility of addicted mothers for their behavior; (3) demonstrate how a context of maternal responsibility emerges around a dialogue about science and neuroscience; and (4) present some ideas about how social and health policy could reflect the presence of a scientific dialogue that blames and stigmatizes mothers.

Re-Conceptualizing Vulnerability in Psychiatric Research Ethics Guidance

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Charged with exploring ethical issues in neuroscience, the Presidential Commission for the Study of Bioethical Issues (2015) recently recognized a crucial tension in neuroscientific and psychiatric research. On the one hand, there is a need for research to advance treatments for these conditions; on the other is the need to protect participants widely considered to be vulnerable. While the concept of vulnerability plays a significant role in research ethics, there is a lack of precision about what vulnerability is and who requires special protection under the rubric of vulnerability. A shared feature of research ethics policies is the inclusion of individuals who lack or have limited capacity to consent.

However, closer examination of the myriad groups designated as vulnerable suggests that other concerns underlie designations of vulnerability. As such, it has been suggested that vulnerability lacks a common organizing principle, a state of affairs that may obscure the value and usefulness of the concept in research ethics policy and practice (Hurst 2008).

In the context of neurological and psychiatric research and innovation, vagueness and imprecision about vulnerability are particularly problematic. These patients as a whole, and compared to other medical patients, tend to be considered vulnerable, in need of further protections, and as lacking the capacity to consent to research despite empirical evidence suggesting otherwise. Persons with neurological or psychiatric diagnoses may also fall into additional groups deemed vulnerable, such as the socially or economically disadvantaged, further compounding this issue. Categorical assumptions of vulnerability may harm, rather than protect and respect, these individuals, leading to their exclusion from the benefits of research. This exclusion would thereby demonstrate a lack of respect and consideration of the individual (i.e., their situation beyond mere group membership), and would reinforce existing stigma surrounding neurological and, especially, psychiatric illness.

We undertook a systematic review of research ethics policies and guidance to critically examine the conceptual foundations of vulnerability. Our sample included nationally sanctioned, authoritative guidance from Canada and countries with similar demographic, legal, and policy structures, and international guidance that applies to Canada. Our analysis focused on capturing three central aspects of the concept of vulnerability, each a key source of debate in the literature: (1) definitions, which capture how vulnerability and the vulnerable are identified; (2) justifications, which capture the ethical reasoning that grounds obligations for the special protection of vulnerable research participants; and (3) applications, which capture interpretations of this concept for neurology and psychiatry.

This research serves to provide an overview of the complexity of the concept of vulnerability grounded in policy and guidance documents. From our results we make practical recommendations for the re- conceptualization of vulnerability in policy and guidance and on its respectful application in the context of neurological and psychiatric research.

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Research Trends in Neuroethics 2007–2015: A Systematic Review of the Literature

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While use of the term "neuroethics" dates back to 1973, broad identification and public recognition of the field of

neuroethics occurred in 2002 with the Dana Foundation's landmark conference "Neuroethics: Mapping the Field." The field has now entered its second decade and it has experienced an influx of researchers and considerable output. Early description of the field described neuroethics as focused on "what is right and wrong, good and bad about the treatment of, perfection of, or unwelcome invasion of, and worrisome manipulation in the human brain" (Safire 2002).

Racine (2010) examined the published peer-reviewed literature, media discourse, and websites self-labeled as neuroethics from the 1970s to 2007 to identify topics and the frequency with which they were discussed in neuroethics. Since 2007, the field of neuroethics has continued to expand; journals that are dedicated exclusively to neuroethics have been created, and authors are increasingly identifying their work as neuroethics. Despite this growth, it has been argued that neuroethics is "recycling too many of the same themes it started with" (Illes and Wolpe 2013). This research addresses three central questions: (1) Which topics are addressed under the umbrella of neuroethics, (2) with what frequency are these topics discussed, and (3) what recommendations can be made to facilitate the continued growth and expansion of the field? While both formal and informal overviews of the neuroethics literature exist, there has not been, to our knowledge, a recent systematic review of the literature to date, nor a focus on identifying work that is self-identified as neuroethics.

We performed a search of the peer-reviewed literature self-identifying as "neuroethics" using the PubMed and Web of Science databases published between 2007 and 2015. We analyzed the relevant abstracts for the context in which they discussed neuroethics (e.g., brain stimulation, enhancement) and the ethical, legal, or social issues (ELSI) discussed. Additionally, we identified the date of publication, the type of paper (empirical, conceptual, or meta-analysis), and the primary author's geographical location. Based on our results, we identify the main areas of focus in neuroethics since 2007 and assess the degree of change in research trends from this time based on a prior review (Racine 2010). Further, we make recommendations about which topics may be currently underserved in the neuroethics literature. An emphasis on diversifying the focus of neuroethics may facilitate further growth and interdisciplinarity within the field, and help to foster creative and impactful scholarship.

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"Who Am I When I'm In Control?": The Identity Ethics of Closed-Loop Deep Brain Stimulation for Essential Tremor

Timothy Brown, University of Washington

Essential tremor (ET) is a common movement disorder that causes a person's limbs to tremor involuntarily in a variety of situations. Pharmaceuticals (most notably, propranolol) are an effective treatment for mild to moderate symptoms, but they are often ineffective in moderate to severe cases. Deep brain stimulation (DBS)—where a low level of electrical current is applied to a targeted region of the brain—is an effective treatment for moderate to severe ET symptoms. Stimulation, however, causes side effects for some users: tingling sensations, numbness, and speech impairment. These side effects, of course, can lower quality of life in some patients. Further, several users have reported feelings of self-estrangement, alienation from others, and lack of motivation in life (Agid 2006). Several argue that these testimonies are evidence that DBS can threaten the user's identity by making it difficult act in authentic ways—that is, some users cannot be their authentic self while using DBS (Kraemer 2011). Others argue that it is misleading to say that people have an "authentic self" that they can conform to or fall out of alignment with (Mackenzie 2014). Instead, it is more accurate to say that our identities are constituted by the choices we make given the possibilities available to us, the ways we describe ourselves, and our relationships to one another. That is, people with ET who experience an identity shift post implantation are just now able to make different choices for themselves, describe themselves differently, and find that their interpersonal relationships change as a result.

Most DBS systems are "open-loop"—they apply stimulation at a steady rate for as long as the device is implanted. A user who experiences these side effects can do very little to address them. She can ask her clinician to lower the stimulation strength to a level that will lessen the side effects but still keep her tremors under control, or can ask her clinician for a device that will allow them to control the stimulation manually. These control devices, however, are bulky and hard to use while dealing with tremors. I work as an ethicist embedded in the University of Washington's BioRobotics Lab—with support from an Engineering Research Center for Sensorimotor Neural Engineering—where researchers are investigating "closed-loop" DBS systems that could give DBS users an alternative to these manual control systems (Herron 2014). A closed-loop system could, potentially, use implanted sensors to detect signals from the motor cortex and only apply stimulation when the user issues a neural command—we can call this voluntary control. Another closed-loop system could use implanted sensors to detect precursors to tremor and apply stimulation automatically as needed—we can call this involuntary control.

These control schemes, however, pose a new set of potential challenges to the end user's identity. I will explore several possible ways that volitionally controlled, closed-loop DBS systems might change users' experiences using the device: their interpersonal relationships, their self-narratives, and their ability to act autonomously in their every day lives. That is, I will explore and evaluate the ways that open-loop DBS systems could change their users' identities for the better and for the worse. In the

end, I will suggest that we ought to do empirical studies of end-user experiences in order to determine how these systems should be designed.

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Disclosure of Individual Results in FMRI Research Involving Acutely Comatose Patients

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In this paper we address the issue of disclosure of individual results in the context of functional magnetic resonance imaging (MRI) research involving acutely comatose patients. Should individual results of these studies be disclosed to families and/or healthcare professionals that treat these brain-injured patients?

Acute brain injury is a frequent cause of disability and death, and can frequently bring about coma. Prognostication of these patients is challenging, and current methods do not allow accurately discriminating between patients who will progress toward recovery of awareness and those whose outcome will be brain death or the vegetative state. In the intensive care unit setting, acute brain injury patients normally receive life-sustaining therapies, such as mechanical ventilation, and withdrawal of these therapies is the patients' main cause of mortality. However, Turgeon and colleagues (2011) showed that withdrawal rates significantly varied across six Canadian level-one trauma centers, and that this variation was not explained by parameters that could plausibly be linked to prognosis. As a result, this variation could be due to persistent uncertainty about prognosis, especially in the first days after the incident. It is hence imperative to find better prognostication tools. Functional MRI has considerable promise as a new prognostication tool (Gofton et al. 2009; Norton et al. 2012). This research raises a gamut of ethical issues, but here we focus on the disclosure of individual research results. Graham and coworkers (2015) argued that individual research results should be disclosed if the following four conditions are satisfied: (1) Disclosure does not undermine the scientific validity of the study; (2) the results are informative and reliable; (3) the potential benefits of disclosure to the participant outweigh the potential harms; (4) the participant consents to be informed of the results.

In the planning stages of each study, researchers should examine these four factors, in addition to study question, study design, and the evidence base supporting functional MRI as a prognostic measure. Then they will decide whether individual functional MRI results will be shared. If individual research results are to be shared, the study protocol should contain an adequate plan outlining when and with whom results will be shared. This plan will also specify the timing of disclosure, who will disclose the results and answer any questions, and the resources that will be available to support families receiving study results. Disclosure of individual results should be discussed both before and after the actual performance of the study, and care must be taken that the substitute decision maker is sufficiently calm to be able to understand the content of the informed consent instrument. Importantly, in studies in which the primary objective is determining the prognostic value of functional MRI in acute coma, the scientific ends of the study may require either a protocolized approach to withdrawal of life-sustaining therapies or blinding the treating physician to functional MRI results. Both approaches may serve to avoid confounding the study's outcome measure.

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Environmental Neuroethics: Setting the Agenda

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How are technological advances, new industries, economic expansion, and population growth affecting us as humans and our relationships with the environment? While fields such as environmental ethics and epigenetics examine the impact of environmental changes broadly on health and social well-being, we argue that there has been insufficient consideration of the ethical and social implications of such changes specifically on brain and mental health.

We use the literature on health impacts from unconventional gas development (UGD) as a case study for this argument. Hydraulic fracturing, also known as fracking, is a method to extract unconventional natural gas and is one of the most significant technological developments of the postmodern world, as it helps to harvest stores of gas and oil that previously were thought unfeasible to access. While fracking offers opportunities for homegrown energy supply and job creation, it may also create significant negative environmental and health consequences. The aim of our study was to determine the extent to which the growing literature on UGD and fracking discusses both the positive and negative ethical and social implications for brain and mental health.

We carried out an extensive search using Google Scholar for terms related to UGD and fracking paired with the key relevant terms 'environment' 'brain' and 'mental health'. Secondary terms were "Canada," "culture," "first nations," "ethic," and "solastalgia." The search identified 106 unique articles from both the peer-reviewed and gray literature. We used qualitative content analysis to identify the extent and context of brain and mental health discussion in the sample. In the first phase of analysis for broad themes, public health was the most dominant (n = 31), followed by regulation and policy (n = 22). Five articles of the total sample mentioned fracking as a threat to Indigenous health. In the second phase of analysis, focused on brain and mental health, 8 of 106 papers contain extensive relevant discussion. In a third phase of analysis, specifically for ethics content, 65 papers touch on issues of safety and nonmaleficence. Only two papers provide substantial ethical discussion beyond these two concerns.

The findings overall reveal limited ethical discussion of brain and mental health in the UGD and fracking literature. Through the lens of environmental neuroethics (Illes et al. 2014), we aim to explore the nature, potential sources and consequences of this phenomenon. We also set out a framework for comprehensive and critical investigations of the ethical and social implications of anthropogenic environmental change and brain health across the life span and across cultures more broadly than those of UGD and fracking, in areas such as extraction of natural resources, air pollution, use of agricultural chemicals, water contamination, proximity to noxious facilities, mining waste and nuclear plants, ocean degradation, food contamination, and habitat destruction.

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Transcranial Electrical Stimulation—A New Entheogen? Trajectories and Neuroethical Questions

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Spirituality and spiritual experiences have an archaic yet prominent history as fundamental aspects of human culture. While spirituality has been strongly associated with religious practices, it is also rooted in more secular aspects of experiential phenomena that are deeply rooted within cultural activities. Although spiritual experiences have been reported to occur spontaneously, inductive methods are commonly used to generate or foster its subjective—and often salutogenic—effects. Inductive factors include acts of repetitive verbiage (e.g., prayer), fasting, ritualistic dance, and frequently, the utilization of psychotropic substances, which are commonly referred to as psychedelics or entheogens.

Transcranial electrical stimulation (tES) is a noninvasive technique that is currently being employed in clinical and experimental, paraclinical, direct-to-consumer, and do-it-yourself (DIY) domains. This neurotechnological approach has been shown to alter sensory and perceptual aspects of consciousness, producing phenomenologically "focused," "relaxed," and/or "expansive" states. Such states—and their subjective feeling(s)—are often associated with and constituent to spiritual experiences.

Thus, we pose the question of whether and how tES might afford potential to be utilized as a neurotechnological entheogen. This prompts additional—neuroethicolegal and social—queries: namely, if tES can be used as an entheogen, could such use foster new clinical (e.g., in palliative care) and/or paraclinical use (e.g., within religious or secular organizations and/or "at home") to incur spiritual experiences and promote (some form of) salutogenesis? Might this incur a cultural trend similar to the psychedelic movement? How might such use affect individuals' and/or groups' cognitions, emotions, and behaviors? Could tES emerge as a conversional or soliciting tool?

This intersection of neurotheology and neurotechnology has sociocultural and sociopolitical implications that are important to acknowledge, and herein we specifically address these issues, and posit the need for and importance of an ongoing discourse toward developing readiness, responsiveness, and guidelines and regulation for this potentially novel use of tES.

Neuroscientific Evidence: Toward a Neuroethics of Belief

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As Paul Churchland (1985) noted, "Phenomenological features of our experience . . . constitute a problem for reductive aspirations of any material neuroscience." Things such as beliefs, like many psychological criteria on which modern personal identity is metaphysically reliant, do not have phenomenal properties as present to the intentional "mind." Such

concepts call for distinct consideration in matters of representation contributive to problems of neurologic irreducibility inherent to folk psychology and instrumental to moral agency. There is much difference in moral relevance between what constitutes/engenders a belief in something and the perception of that thing's phenomenal properties.

W. K. Clifford's (1877) strict evidentialist interpretation of norms governing development of a belief asserts epistemic obligations to pursue a high standard of evidence for our beliefs and moral obligation to sustain epistemic beliefs to constitute a good; thus, failure to sustain them is morally objectionable. However, a moderate evidentialist view obtains that our epistemic standards are best to reflect in proportion to the moral conditions affected by the resulting belief (i.e., consideration of what is morally/ethically at stake given investment in said belief).

We posit that, given that such concepts are increasingly held under the lens of neuroscientific naturalism, there is a defensible, logical obligation for epistemic responsibility to uphold the highest possible standard (i.e., best possible evidence) in and of neurosciences to more confidently explain and justify the development, maintenance, and relinquishing of beliefs.

Herein we address how such a naturalistic neuroethical stance affects both the moral significance of beliefs as a core metaphysical feature of persons (e.g., self-referential processing/encoding), and certain functional aspects of moral agency associated with their willful development. We query whether our beliefs demand a new kind or level of neuroscientific validity, and review and present the literature to date that supports a naturalistic evidentiary grounding of concepts of moral cognition and action. Although increasing neurophysiologic evidence about belief formation may most convincingly satisfy strict evidentialist demands for high epistemic standards and thus meet associated moral obligations, we argue that neuroscience's end goal is more appropriate to all-out elimination of propositional attitudes than the provision of any strong evidentiary grounding for what microphysical processes may constitute anything like beliefs, desires, fears, and the like, satisfactory to the explanatory standards of empirical science. In posing a neuroethical paradigm, we therefore assume a dialectical stance and also address whether human behavior demonstrates that moderate evidentialism yields to practical reasoning and moral implications of beliefs ultimately determine their development, maintenance, or relinquishing over and above the epistemic fortitude of neuroscientific theory. In sum, we propose a model for continued research in neural bases of moral cognition and action (i.e., a neuroscience of morality/ethics), define its validity, and offer dimensions and implications of its value.

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The Influence of Color Manipulation on Data Interpretation in Neuroimaging and Geographic Information Visualization

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The visualization of complex data routinely relies on mapping data to a color space in order to display, for example, activity changes in functional neuroimaging, or the magnitude of a certain attribute in cartographic displays. However, empirical research on how the mapping of data onto color space influences data interpretation is sparse. This is especially evident in the domain of neuroimaging, where a general lack of standardization in using color scales can be observed when compared to cartography (Christen et al. 2013). Therefore, we set out to empirically compare the effect of using different color scales, broadly used in neuroimaging and geographic information visualization (i.e., rainbow scale, heated body scale, color-intensity change scale, red–white–blue scale). We also investigated the effect of color scales on different image backgrounds (i.e., black and white) on the interpretation of data emerging from well-known paradigms in neuroscience (i.e., imaging brain activity from normal brains to locked-in state, minimally conscious state, vegetative state up to brain death) and in geography (i.e., depictions of environmental sustainability models in a country that match the employed brain state descriptions). The study used a between-group design (neuroimaging experts, $n = 134$, GIS experts, $n = 197$, lay people, $n = 486$) where one out of eight conditions per paradigm has been presented randomly to a single subject using a web-based survey. We also asked several questions to control, for example, for professional experience and to determine the detailed practice of image production in neuroimaging and labs dealing with cartography and geographic information systems (GIS). We hypothesized that domain experts would be least influenced by a particular color scale when interpreting data, such as determining whether an image trustfully conveys the fact that a person is brain dead. Contrary to our hypothesis, we found that neuroimaging experts were most strongly influenced by changes in color scales in both paradigms, that is, also in their own field. This was reflected in larger mean differences between overall evaluations and evaluations of single conditions for measures such as the trustworthiness of a particular image or when ranking states that lie between the extreme states of either scenario (e.g., placing a vegetative state condition between normal brain and brain dead condition). We also found that, irrespective of expertise, the rainbow scale usually is considered the most trustworthy scale despite its well-known property of inducing perceptual distortions (for overview see Christen et al. 2013). Our data further indicate that neuroimaging experts, compared to cartography/GIS experts, express higher confidence in imaging production software and internal lab rules and lower confidence in literature on established visualization principles. Given

the importance of neuroimages for conveying results in neuroscience, in particular in the public discourse, the study points to the need of generating increased awareness of the potential influence of data visualization methods on data interpretation, in particular also among the domain experts themselves.

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What (and How) Do We Teach When We Teach Neuroethics?

Michael DeWilde, Grand Valley State University

A small but growing number of influential philosophers and ethicists (Patricia Churchland [2011] and Joshua Greene [2013] come to mind immediately) agree that the era of "speculative" moral philosophy is over, and that those of us who teach ethics are derelict if we do not incorporate into our classrooms knowledge won by neuroscience, evolutionary biology, primatology, and so on. But for those of us who are not trained as neuroscientists the question of what and how we teach our students when we bring those scientific findings to bear is not necessarily an easy one. It is one thing, for example, to introduce the Trolley Problem as a way or working through various strengths and weaknesses of classical utilitarianism; it is quite another to introduce it as a way of suggesting that the DLPFC system may work in varying degrees of strength across populations to produce quite different decisions. It is one thing to suggest that for Kantian reasons regulation is required to stem impulsive behavior on Wall Street; it is another to look more closely at the etiology of psychopathy and ways in which, as Robert Hare (1993) and Paul Lawrence (2010) have argued, psychopaths have gained ground in running financial markets. In a classroom with limited time and the aim of enlightening students about actual decision-making processes, about justifiable claims as to what human nature is, and insights they can take from the class that can in fact inform them well into the future, what might the productive intersection be of philosophy and science (not to mention religion and psychology)?

In this presentation I take up those questions and respond from the perspective of a teacher trained in philosophy and religious studies but who is persuaded by science, and who has been introducing ethics from a more scientific viewpoint now for many years. How does teaching ethics—to graduate and undergraduate students alike—change when the mechanics of the brain are emphasized? What difference might it make that students see morality from an evolutionary point of view? Does neuroethics "take the place of" some other explanatory framework, or is it simply the structure upon which philosophy is built? Should I even attempt to teach from this point of view, given that I am not a neuroscientist?

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Separating Visions From Reality in the Cognitive Enhancement Debate

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The nonmedical use of psychostimulants like Adderall, Ritalin, or Provigil by students and researchers on various university campuses has been widely discussed in neuroethics, under the label of pharmacological cognitive enhancement. However, the picture of stimulants as "smart drugs" that originally permeated the debate is now being viewed with greater skepticism, as involving a potentially dangerous glamorization of those substances (Lucke et al. 2011; Ilieva, Boland and Farah 2013). This picture is now being replaced with a new paradigm, that of stimulants as motivational enhancers (Vrecko 2013), on the basis of which some authors have raised concerns about students medicating away their alienation and substituting willpower with pharmacology (Kjaersgaard 2015). While conceding that this new picture seems grounded in sounder empirical evidence, this paper argues that it might still not fully avoid glamorizing nonmedical stimulant use. Two key reasons are the correlation between that practice and lower grade point averages (GPAs), as well as the fact that infrequent use seems to be the norm among students, whereas the motivational enhancement paradigm seems to entail that the opposite should be true in both cases.

Rather than dismissing the debate on pharmacological cognitive enhancement as misguided, I propose to address these empirical worries by distinguishing between two main ways of tackling that debate (and other related issues, such as transcranial direct current stimulation [tDCS]): what I call the "vision" and the "reality" approaches. While the former approach discusses hypothetical interventions and makes assumptions that go beyond the available evidence, the latter avoids such assumptions and focuses on existing interventions. Unlike some of the authors who have previously stressed the role of visions in the cognitive enhancement debate, however, I defend the legitimacy of the vision approach and argue that the two approaches are complementary: Each can be helpful if applied to its proper domain. The danger lies in failing to sufficiently acknowledge which approach we are using, and in misapplying it. Finally, I suggest that the ethical issues captured so far in the literature on cognitive enhancement have tended to emerge from the vision approach, and I consider which among these remain applicable if we shift to the less "spectacular" reality one. I highlight three: safety, coercion (both actual and merely perceived), and

fairness. I conclude by inviting reflection on the possibility that even relatively small advantages might give people a decisive competitive edge in certain circumstances.

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Regulating Neuro-Enhancement Interventions

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Neuro-enhancement interventions are interventions that interface directly or indirectly with the peripheral or central nervous system to modify a person's nonpathological human traits. As medical doctors are to treat pathological states, it has been argued that although some enhancements may fall within the goals of medicine, we nevertheless have good reasons to limit the kind of interventions medical doctors are allowed or required to do. It is obvious that the use of drugs or devices for enhancement purposes does not belong to the core goals of medicine, and it is indeed questionable whether it should. However, one might argue that the use of drugs or devices for enhancement purposes should be seen as an extended goal of medicine. Members of an aging population might benefit from optimizing their intellectual capacities, so they can stay independent longer, and improving nondisease states such as low self-esteem, performance anxiety, or even aggression could improve the quality of life of the affected and related individuals a lot. These nondisease states can impair quality of life in an important way, and if doctors' duty is to improve social well-being as well, according to the World Health Organization (WHO) definition of health, then neuroenhancement could be welcomed rather than questioned because of ethical reasons. Or one might argue that the goals of medicine need to be adapted in response to new technological challenges such as the use of transcranial direct current stimulation, transcranial magnetic stimulation, or neurofeedback for enhancement purposes. While it is ethically questionable whether enhancements should be seen as part of a medical doctor's duty, individual medical doctors with the required expertise may legitimately view improvements beyond curing and preventing disease as one of the goals of their profession. However, as medical skills and expertise are scarce resources, we should not take this issue lightheartedly. Do we want to allow or promote the use of valuable medical skills and expertise for enhancement purposes, rather than reserving these scarce resources more narrowly for curing and preventing disease?

It is clearly the case that the embedding of enhancement technologies within the medical domain has important regulatory and practical implications. Most neurofeedback now is performed by nonmedical health care providers. If cognitive enhancement devices fall within the medical domain, will only medical doctors be permitted to use such devices, or nurses or psychologists under supervision of a medical doctor? Will consumers need a prescription for the acquisition and use of a cognitive enhancement device and subsequently get a device at a pharmacy-like place? Should this involve a minimum number of training hours under the supervision of a medical doctor, nurse, psychologist, or other trained expert? Which safeguards need to be in place for the use of drugs and cognitive enhancement devices if these are not exclusively embedded within the medical domain? Taking into account varied regulatory and practical issues, we discuss arguments for and against the exclusive inclusion of the prescription and use of drugs and devices for cognitive enhancement within the medical domain.

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The Intrusion of Predictive and Advisory Brain Devices: New Ethical Issues Ahead?

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The world's first-in-human clinical trial using invasive intelligent brain devices—devices that predict specific neuronal events directly to the implanted person—has been completed with significant success (Cook et al. 2013). Predicting brain activity before specific outcomes occur brings a raft of unprecedented applications, especially when implants offer advice on how to respond to the neuronal events forecasted (Gilbert 2015). Although these novel

predictive and advisory implantable devices offer great potential to positively affect patients following surgery by enhancing quality of life (e.g., provide control over symptoms), substantial ethical concerns remain. The invasive nature of these novel devices is not unique; however, the inclusion of predictive and advisory functionalities within the implants, involving permanent monitoring of brain activity in real time, raises new ethical issues to explore, especially in relation to concerns for patient autonomy. What might be the effects of ongoing monitoring of predictive and advisory brain technologies on a patient's postoperative sense of autonomy? There is a complete unknown concerning the role played by predictive and advisory implantable brain devices on the patient's feelings of autonomy following surgery. This presentation addresses this shortcoming by reporting on a pilot study that we conducted with four of the patients implanted with one of these novel brain devices.

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The Arts and Sciences of Reading: Toward an Ethic of Interdisciplinary Collaboration

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This presentation examines two recent studies about the neuroscience and cognitive psychology of reading fiction in order to argue for more thoroughly interdisciplinary work that crosses the too-often-upheld boundary between the humanities and the sciences. Along the way, I ask questions about what sorts of evidence are valued by experts and by lay publics, what problems arise when science interrogates topics traditionally in the purview of the humanities without robustly engaging those fields, and, conversely, what is lost when humanities scholars talk about the sciences without directly including its practitioners. I consider, too, how engagement across the traditional "arts" and "sciences" lines could be a powerful tool for countering "neurohype" (Caulfield, Rachul, & Zarzeczny 2010) and low scientific literacy.

The neuroscientific study by Berns, Blaine, Prietula, and Pye (2013) tracks changes in brain connectivity following sessions reading a novel, while Kidd and Castano's (2013) cognitive psychology study claims that "literary fiction" improves a reader's theory of mind, while "popular fiction" and nonfiction do not. I explore the implications of granting quantitative or neuroimaging data more weight as evidence than other forms of knowledge, for instance, several generations of humanities research dealing with the question of literary value, or even the simple feeling of pleasure or edification that readers experience. I argue that Kidd and Castano's study demonstrates the need for scientific investigators to engage with humanities scholars and suggest that incorporating humanities approaches could improve scientific study design, resulting in more culturally situated, ethical developments in neuroscience and cognitive psychology. Conversely, I draw on literary scholar Paul Gilmore's notion of "neural historicism" to emphasize how humanities fields utilizing cognitive approaches could benefit from deepened engagement with the sciences.

By comparing the press releases of the Berns and the Kidd and Castano studies and their subsequent translation into the broader media, I identify methods of science communication that may help counteract neurohype, and demonstrate how the sciences and humanities are important partners in demystifying press coverage of neuroscience and cognitive science developments. I also interrogate the appropriateness of including calls for policy change in studies, looking specifically at suggestions about education and the treatment of autism mentioned by Kidd and Castano. My ultimate aim is to begin a discussion about how we can improve science literacy and interdisciplinarity—two pursuits that I argue are inextricably linked.

Ultimately, research on topics shared between the humanities and the sciences could more deeply and fruitfully integrate work from a variety of disciplines. Studies like Berns's and Kidd and Castano's importantly engage with culturally relevant topics, and ought to continue to so. However, as data points proliferate, we need to interrogate how we translate data into policy and practice. I conclude by suggesting a variety of strategies for putting this interdisciplinary ethic into practice in academic settings.

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Addiction, Maladaptive Behavior, and Responsibility

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Are addicts responsible for their addictive behavior?

Some philosophers, neuroscientists, and bioethicists have argued that we should understand "free will" from a biological–evolutionary perspective: Free will is the ability to select the most adaptive behaviors from a range of

possible behaviors in response to an ever-changing environment. Organisms are personally responsible for their behavior insofar as they can alter their behavioral choices in response to new environmental information such that they can still select the most adaptive.

One consequence of this point of view is that addicts become responsible for their actions, for at each choice point, there is a very real sense in which the addict could have selected not to use or abuse. Hanna Pickard (2012) in particular advocates for this conclusion. She urges that addictive behavior is voluntary, and, in many cases, it is rational as well. This view is not uncommon among addiction treatment specialists either.

We advocate for a different and more complex way of thinking about addiction, one that aligns it with other complex chronic illnesses, like heart disease, diabetes, chronic pain, and obesity (Egli et al. 2012; McLellan et al. 2000). We present data that suggest that addiction is a behavioral disorder in which both executive functioning and motivational systems are impaired (Koob and Volkow 2010; Pfefferbaum et al. 2001). As a result, addicts cannot align their behavior with their long-term or short-term goals, nor can they truly consider the range of possible behaviors available to them.

Furthermore, we suggest that the types of maladaptive decisions that addicts and other sufferers of complex chronic illnesses make bear a strong family resemblance to the sorts of decisions healthy humans engage in most of the time. We conclude that the biological–evolutionary picture of free will is an oversimplified and neuropsychologically inaccurate portrait of the basic human capacities for behavioral choice. As a result, many treatment approaches to addiction are faulty, as is how our criminal justice system manages criminal behavior tied to addiction.

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Recurrent Violence in Childhood: Caveats—and Neuroethico-Legal Considerations—for Diagnosis, Classification, and Treatment

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Current *DSM-5* (American Psychiatric Association 2013) classification of the Antisocial Behavior (ASB) Spectrum entails a range of conducts, inclusive of violence. However, overt, recurrent violent behavior (RVB) in youths less than 18 years of age is not diagnostically categorized under the ASB spectrum, but rather is codified as Conduct Disorder (CD) in both the *DSM-5* and ICD-10-CD (APA 2013; World Health Organization [WHO] 2013). However, it is important to note that youths diagnosed with CD represent 57% of arrests for violent crimes, and approximately 50% of RVB youths diagnosed with CD progress to being diagnosed with ASB at age 18 years (Cocker 2014; Mordre 2011). We posit that this reveals RVB in youths to be poorly contained, and highly precipitative of increased incidence, severity, and chronicity of adult violent behavior, and thus a therapeutic challenge.

We assert that RVB as CD is not effectively treated due to (a) inadequate representation in nosology, diagnosis, and prognosis and (b) overemphasis on sociolegal intervention rather than increasing the effectiveness of neuropsychiatric intervention(s).

Thus, we herein raise the possibility of reclassifying RVB in children as Violent Conduct Disorder, with concomitant reexamination and potential redirection of both assessment and intervention to (1) maximize therapeutic as well as social benefit, and in this way (2) be more aligned with ontological claims and ethical obligations of psychiatry qua medicine as a public good. Simply put, we pose the question: If RVB is classified as a psychiatric condition, why is greater effort not being invested in providing psychiatric interventions to mitigate its effects in individuals, and society at large? To wit, we argue for prudent employment of noninvasive assessment (e.g., correlative neuroimaging, genetic, and behavioral studies) and interventional neurotechnologies (e.g., transcranial electrical and magnetic stimulation, novel approaches to neuropsychopharmacology, inclusive of improved agents and methods of delivery) as aligned both with missional focus of the BRAIN initiative, and with recent calls for a more pragmatic integration of neuroscience and technology within psychiatry (Philips 2009). Certainly, we acknowledge and address the possibility for this approach to be criticized as being overtly materialistic, overly pathologizing, and medicalizing violence—and its treatment. Accordingly, we also address the possible risks—and need for scrutiny—when using neurotechnology to effect sociolegal actions. In sum, we discuss the benefits and burdens of this proposed revision to psychiatry classification, and offer what we hold to be a defensible claim in support for such redress.

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"The Master of Suspense": Using Movies and fMRI to Decode the Phenomenology of Conscious Experience in Vegetative State Patients

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The objective of this project is to investigate the ethical implications of recent neuroimaging studies that purport to provide a "neural index" for conscious human experience. Neuroscientists have long suspected that the network of brain regions involved in "executive function" may provide a window into conscious experience. However, the numerous processes involved in conscious experience make it difficult to relate patterns of brain activity to specific higher or lower order functions. A recent study addressed this problem by having subjects watch an engaging and suspenseful movie, providing viewers with a shared conscious experience (Naci et al. 2014). The results of initial investigations on healthy controls showed that the timing of activity in the relevant regions of the brain was predictable based on participants' highly similar qualitative experience of the movie's moment-to-moment executive demands. The neural activity across healthy participants was synchronized, indicating a similar conscious experience. Moreover, in a patient who was thought to be in a vegetative state (VS), moment-to-moment executive processes highly similar to those of healthy individuals were detected.

In light of these results, this project aims to answer the following questions: (i) Is it reasonable to suppose that the covertly aware experience the world as the subject of their own narratives—a "covert narrative competence"—thereby satisfying a fairly rigorous definition of moral personhood? (ii) Is there a morally relevant difference between neuroimaging patients who exhibit volitional modulation of brain activity and those exhibit covert narrative competence? (iii) What do these findings tell us about the conscious experience in the covertly aware? For example, can covert narrative competence be used a potential diagnostic for decision-making capacity? The answers to these questions are of paramount importance, both for gaining much-needed insight into the moral and legal standing of the covertly aware, and for improving the quality of their care.

What Can Neuroscience Contribute to the Problem of Neonatal Pain?

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Management of pain in neonates is hampered by lack of awareness and skepticism among health care professionals that neonates are capable of experiencing pain, and by concerns about the adverse effects of analgesic and anesthetic use. Newborns routinely experience pain associated with invasive procedures such as blood sampling, injections, and circumcision. Preterm and sick infants may experience many more painful diagnostic, therapeutic, and surgical procedures. Neonates exhibit greater hormonal, metabolic, and cardiovascular responses to painful stimuli, compared to older children, and repetitive untreated pain predicts immediate and long-term negative effects on behavioral and neurological outcomes. Yet pain remains undertreated in many newborns.

The network of brain regions that encode affective and sensory aspects of pain experience has not been well studied or described in newborns. That, coupled with the newborns' inability to verbalize their pain experiences, has led to the development of numerous physiological and behavioral infant pain assessment tools. Evidence from recordings of brain activity, however, suggests that infants may experience pain without exhibiting behavioral signs. More objective measures of newborn pain are clearly needed, as is an understanding of how infants experience pain. A recent functional magnetic resonance imaging (fMRI) study shows extensive similarities between brain activations in neonates and those in adults in response to painful stimuli, and suggests that newborns may be up to four times more sensitive than adults to similar noxious stimulation. The results indicate that neonates experience both the sensory and affective aspects of pain, and underscore the need for better clinical pain management.

We review how the neuroscience of pain relates to two questions relevant for ethical decisions: (A) To what extent do invasive procedures cause neonates to suffer? (B) To what extent do painful experiences in neonates lead to future problems related to pain? In regard to (A), we discuss the neuroscientific evidence that neonates experience the sensory, affective, and evaluative components of pain. In regard to (B), we discuss evidence that top-down modulatory systems that help mitigate the impact of pain in adults are not fully developed in neonates, and consider how the fact that neonates might thereby experience much more pain from weaker stimuli could lead to future adverse conditions, including lifelong increased pain sensitivity. We conclude that neuroscience bolsters the case that great caution is needed when considering whether to expose neonates to potentially painful procedures.

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Investigator-Initiated Neurotechnology-Based Clinical Research: Neuroethico-Legal and Social Concerns and Paths Toward Resolution

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Industry-funded device-based clinical trials have made tremendous strides in the application of deep brain stimulation (DBS) technology to disorders such as Parkinson's disease, dystonia, and essential tremor, as well as intractable depression and certain types of chronic pain. These academic–commercial partnerships have forged the regnant model for device-based research and development in the neurosciences. Greater than 50% of clinical research focal to the use of neurotechnology is funded by industrial sponsors (Dorsey et al. 2006). To date, the majority of industry-driven device-based clinical trials have targeted diseases for which market incentives justify the large cost and liability associated with medical device research and development. Regulatory pathways, such as that for an investigational device exemption (IDE), necessitate applications and maintenance that incur time and cost expenses that are often prohibitive for industry-independent investigations, which, when taken with additional costs of conducting a clinical trial and follow-up, often exceed funding available through federal agencies or foundations.

Indubitably, industry plays a vital role in studies and applications of devices to neurological care. However, industrial sponsorship also raises concerns for the scientific understanding and clinical application of medical devices. For example, studies in the pain, cardiology, and orthopedic literatures have demonstrated associations between industry funding and positive results, which have been attributed to multiple factors, including publication bias and patient selection.

Herein we argue that investigator-initiated clinical device research (IIR) can provide a crucial alternative for advancing scientific knowledge and therapeutic applications, specifically for small market, orphan or rare disease, and pediatric patient populations that have been historically underserved by medical device use, and equally hampered by poor market incentives and regulatory barriers.

Herein, we (1) define focal neuroethico-legal issues that arise from extant barriers to IIR (inclusive of right-of-reference letter requirements) that impede investigators' access to the very tools of research, and (2) posit ways that regulatory mechanisms may better address the unique challenges to funding and approval for IIR, in an effort to expand and sustain recent Food and Drug Administration (FDA) initiatives toward improvement in this area. We specifically discuss the need for and propose means toward alignment of federal funding sources and regulatory agencies, reduced regulatory burdens, and insurance coverage for federally approved clinical device trials, and illustrate how such steps and processes uphold neuroethical responsibilities for and in neurotechnological research.

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Smartphone Therapy: Ethical Considerations for Mental Health Mobile Technology

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This research investigates ethical and policy considerations for the growing use of smartphone applications to record and regulate mental health. Hundreds of mobile health (mHealth) applications have been developed to allow users to collect and transmit data in real time as smartphones become more ubiquitous in our increasingly technology-oriented society. A growing number of these applications aim to record and regulate mental health, and these may require higher standards for information privacy and special considerations for self-monitoring and emotional triggering when used by psychiatric populations. This research provides a systematic literature review of mHealth mental health studies, as well as findings from an ongoing, internationally distributed survey examining users' experience and expectation for privacy during real-time data collection. Combined, this work highlights the limitations of inferring mental states from passive and active data collection methods, informs ways that data storage may be improved to protect participant privacy, and develops an ethical framework for a growing number of patient-consumers who participate in mobile mental health data collection as a form of self-monitoring.

More Than Tremor. Goals and Benefits Associated With DBS From the Patient's Perspective

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Background: Integral to the Patient-Centered Outcomes Research Institute is the notion that patients' values and perspectives matter. This concept is particularly important in the context of functional neurosurgery where patients choose to undergo elective neurosurgery to improve their quality of life. We systematically elicited the goals patients with Parkinson disease (PD) articulated as most important in their decision to pursue deep brain stimulation (DBS) and the impact of DBS on those goals.

Method: Fifty-two subjects completed a baseline semi-structured research interview with rating scales to identify their top three symptom and activity goals for seeking out DBS. All subjects rated the severity of those symptoms or indicated the extent to which their PD symptoms interfered with accomplishment of those goals on a Visual Analog Scale. The relationships between the research severity and standard of care measures were examined using Pearson correlations. The research interview and ratings were readministered at 3 and 6 months post DBS ($n = 42$). Changes in severity ratings following DBS for the various symptom and activity categories were assessed using a mixed-effects linear model.

Results: Most subjects were men (75%) with an average age of 61.3 years and a mean age at diagnosis of 52.1 years. Tremor was the most often cited symptom goal, followed by gait and nonmotor symptoms. Hobbies/leisure pursuits was the top activity goal, followed by work, activities of daily living, and social. The symptom and activity severity measures were significantly correlated with each other prior to DBS but were not consistently significantly correlated with the traditional standard of care outcome metrics reported in the research literature. The results of the mixed effects linear model analyses revealed significant improvements in severity ratings for both the subject-identified symptoms (Chi2(2) = 80.95, $p < .001$) and activities (Chi2(2) = 105.5, $p < .001$) following DBS. More detailed examination of the impact of DBS on different categories of symptoms revealed evidence of greater improvements in tremor, gait, dyskinesias, medication side effects, nonmotor, and other motor symptoms following DBS versus the much smaller improvements evident in rigidity from the subjects' perspective (Time × Category Interaction Chi2(12) = 82.37, $p < .001$). DBS resulted in more modest improvements in activities of daily living ratings per the subjects' severity ratings compared to greater improvements evident in the remaining activity categories (social, hobbies/leisure pursuits, work, driving, other; Time × Category Interaction Chi2(10) = 23.17, $p = .01$).

Conclusions: Our data reveal the diversity of patients' goals and highlight that these goals are not consistently captured with the existing DBS outcome metrics widely reported in the research literature. These data illustrate the breadth of benefits patients experienced following DBS. Interestingly, these patient-perceived benefits included improvements in nonmotor symptoms, whose responsiveness to DBS is not as well established as that of motor symptoms. These data challenge us to consider who and how we should define successful outcome and for what purpose following DBS.

Neuroethics Now and Then. A Quantitative Approach to the Current Disciplinary Self-Understanding of Neuroethics

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Alongside the distinguished disciplines of neuroscience and moral philosophy, neuroethics has emerged as a label for interdisciplinary research concerned with ethical issues related to the brain. With this development of neuroethics within the last two decades has emerged a complex and partly confusing scenery of scholars, scientific institutions, ethicists, and practitioners who have different disciplinary backgrounds and commit themselves to different research agendas and different interpretations of neuroethics as a field.

Definitions of neuroethics not only vary concerning a canon of topics relevant to the field but also with regard to the question of whether neuroethics is simply a kind of applied ethics or whether it also requires a distinct ethical framework that takes current research in neuroscience more seriously. According to these differing definitions, neuroethics is sometimes characterized as ELSA research about emerging neurotechnologies, sometimes as a subfield of medical ethics, and sometimes as the normative part of a general "philosophy of living informed by our understanding of underlying brain mechanisms" (Gazzaniga 2005, xv).

In our contribution, we bypass this dispute about definitions by simply assessing these research agendas from an empirical point of view. We present a study that tracks the development and instutionalization process of neuroethics between 1995 and 2012 by the use of scientometric methods we applied to the Mainz Neuroethics Database, an online bibliography compiled and hosted at the University of Mainz (https://teamweb.uni-mainz.de/fb05/Neuroethics/Lists/Bibliography/Show.aspx). This quantitative approach allows for displaying the temporal development, structure, and disciplinary institutionalization of the field and for analyzing the reciprocal shaping of neuroethics and its related disciplines. Thereby, we compare the varieties of self-understandings of neuroethics and its criticisms with the factual development of the field and show that none of these research agendas has yet become dominant. We show that from this empirical perspective, current neuroethics differs in several respects from the views currently held in textbook definitions of the field. Not only is neuroethics a considerably conservative discipline when it comes to research topics, but despite technological developments in the recent years it still has its main anchors in medical ethics. Additionally, theoretical approaches to neuroethics from a broader neurophilosophical framework are still largely unrelated to the practical questions related to the ethics of emerging neurotechnologies and complex clinical ethics.

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Mad and Dangerous: Neuroscience in U.S. Judicial Opinions

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I examined judicial opinions from the years 2010-2012 that substantively engaged the interpretation of neuroscience evidence for making legal determinations in a criminal case. I

was interested in how judicial opinions shape and are shaped by cultural understandings of the brain, neuroscience, and criminal behavior. Judicial opinions are shaped by and must appeal to the relevant legal standards, as well as accepted cultural narratives regarding criminal behavior. Looking at judicial opinions, one can see how neuroscience evidence interacts with a preexisting ambivalence about behavioral evidence and punishment, how it interacts with the need to establish moral agency, and how it is also employed to construct a vision of the criminal as unchanging and unchangeable. In judicial opinions, judges may put forth views that reflect popular and lay understandings of neuroscience and behavior, but also, importantly, as a way of affirming the legitimacy of their decision, they must put forth ideas that affirm what appears to be the convention wisdom. I examine two major themes in the judicial opinions: (1) the relative weight of neuroscience against other types of behavioral evidence and (2) the "double-edged sword." These themes offer insights into how neuroscience evidence is being managed as part of the work of criminal justice—enveloping what kinds of brains neuroscience applies to; how neuroscience is managed as "real" evidence of behavior and causation; and how the double-edged sword motif is helps manage ambivalence around the use of neuroscience in the courtroom. The issue of brain plasticity emerges as a crucial concept in judicial opinions, as ideas of whether a defendant can change influence judgments regarding culpability and punishment.

The Freedom to Become an Addict: Are Addiction Vaccines an Assault on Free Will?

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Advances in biomedical research and neuroscience have created new preventative options within the field of addiction (Kinsey, Kosten, and Orson 2010; Pentel 2014). The development of potential "addiction vaccines" has been praised as groundbreaking by many, but they carry their own significant ethical burden. One predominant question surrounding these vaccines is how they will affect an individual's autonomy and, more specifically, whether a person can ever be free to allow herself to be vaccinated. The idea of vaccinating one's child against addictive substances has been gaining traction among parents, and many have voiced the desire to vaccinate their child soon after birth, as we do for many other deadly diseases (Hall and Carter 2003). This poses an ethical dilemma with enormous implications, as it is clearly removing a level of choice from the child; however, one wonders whether it is important to allow a person the choice of becoming an addict. This is a "choice" that we take away from the child when it comes to diseases such as measles, mumps, and rubella because we view these strictly as harms with no potential for good. Even those parents who do not vaccinate their children do not make this choice because they believe the child will want to experience those diseases. It is fair to say that the same point for drug addiction could be easily made; however, there are other levels to the addiction vaccine that are not found in vaccines of infectious diseases. The vaccine does not just prevent one potentially fatal disease; in fact, it does not prevent addiction at all. Rather, it prevents the individual from feeling the effects of the substance in question, which many believe will in turn prevent addiction.

Even if one were to suggest that we just provide the vaccine to consenting adults we still remain in a similar ethical quagmire. It is difficult to accept that one is providing fully informed consent to a person about a vaccine against nicotine, for instance, if the consenting individual has never tried a nicotine product. However, the question of whether a person in the throes of addiction can truly freely consent to any sort of treatment, especially a permanent one such as this, is also important. It seems as though there is no ethically "right" time that one could introduce the vaccine, but that does not necessarily mean that it is useless. These types of vaccine have the potential to do tremendous good, but as ethicists we need to be aware of the extremely murky waters surrounding such treatments and help medical professionals and policymakers arrive at the best solution for everyone involved.

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Considerations for Use of Deep Brain Stimulation in the Management of Chronic Neuropathic Pain: Proposed Revisions to the "Analgesic Ladder"

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The assessment, treatment, and management of patients suffering from chronic neuropathic pain pose a number of neuroethical, legal, and social issues and problems, not least of which is ongoing debate about the utility and liability of employing escalating doses of opioids and interventional anesthetic procedures. Recent studies have supported the viability of using deep brain stimulation (DBS) to treat certain types of pain (e.g., thalamic pain syndrome etc.). Building upon this evidence, current work is focusing upon the potential of extant—and near-term future iterations—of DBS technology and techniques to be of value in treating other forms of severe chronic pain. However, the validity and viability of DBS in treating chronic pain foster additional questions regarding whether, in whom, and how such approaches

should be employed. In this light, we posit that before chronic neuropathic pain management can undergo a "neurotechnological revolution," it will be important to address these questions and formulate patient management protocols that specifically engage the clinical, ethical, and practical issues surrounding DBS, so as to insure that this technologic approach is not overlooked, misused, or squandered.

Here, we critically examine the technical aspects of advanced techniques and technologies of DBS to be used for severe chronic painp; define and address key neuroethical issues associated with such potential use; and posit a role that DBS could and should play in the clinical management of chronic neuropathic pain syndromes. In so doing, we propose and describe a revised "analgesic ladder," modified to incorporate iterative forms of neurotechnology (e.g., transcranial magnetic stimulation, and ultimately DBS) that is based upon current clinical guidelines, established neuroethical principles, and prior research regarding the advantages and potential drawbacks to the use of DBS. We argue that upon prudent assessment of key factors (i.e., determining expression and sustenance of pain, patient characteristics, goals and values, etc.), DBS may be an optimal approach to treating a defined subset of chronic pain patients. We consider the place and role of DBS in this revised analgesic ladder, and argue for DBS occupying an important niche in the management of chronic neuropathic pain, both as a stand-alone intervention and in concert with other therapeutic techniques and tools.

Teen and Research: Should We Enroll Adolescents in Clinical Trials of Deep Brain Stimulation for Anorexia Nervosa?

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Anorexia nervosa (AN) is a challenging, chronic, refractory illness with the highest mortality rate of any psychiatric condition. About 1% of female adolescents have AN, yet it is the most common cause of death among young women ages 15 to 24. An estimated 0.5 to 3.7% of women suffer from AN in their lifetime. Full recovery rate is about 60% with prolonged treatment. About 20% make only partial recoveries; the remaining 20% do not improve, even with treatment. The mortality rate is about 4% (National Association of Anorexia Nervosa and Associated Disorders [ANAD] 2015). Young patients and their families seek a better cure.

With promising results in trials of deep brain stimulation (DBS) on depression and obsessive–compulsive disorder (OCD), researchers are exploring the possibility of using DBS in the treatment of AN. Evidence from trials of DBS for depression and OCD support the notion that DBS treats AN, too, and a phase I study of six patients with AN showed that DBS was safe and moderately effective (Lipsman et al. 2013). In addition, there have been at least two trials in China testing the efficacy of DBS specifically for AN (Wu et al. 2013; Wang et al. 2013). Both showed positive results.

All study participants were young adults. One trial in China even enrolled minors. Given the morbidity and mortality of AN among teenagers and the promise DBS has shown in young patients, it is worth considering whether we should enroll adolescents in DBS trials for AN as research continues.

Even asking this question may seem off-limits to some ethicists, as there is near unanimous agreement that trials of DBS for psychiatric illnesses select study participants very carefully, enrolling only adults with decisional capacity (Grant et al. 2013). But that limit may be arbitrary. Some 16- or 17-year-olds may suffer from AN for 3 or 4 years and have treatment-refractory cases. AN is the third most common chronic illness among adolescents, yet ethicists and regulations insist that all DBS research should enroll only adults.

There are reasons for concern, of course. Even aside from the fact that teens may not consent legally, it is unlikely that teens with AN will meet criteria for informed consent. Standardly, it is up to parents to provide consent for research participation, with adolescents' assent. This, too, is dangerous, as desperate parents may be lured by the promise of a cure and understate risks. Most importantly, the long-term effects of DBS in a developing adolescent brain are unknown.

All this considered, I think it's worth discussing whether older adolescents who meet medical and scientific standards for research should be considered for trials. There would need to be stringent ethical and legal safeguards for this especially vulnerable population, and I suggest some, but this vulnerable population should part of the conversation, too.

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Uncertain Coverage for Off-Label Deep Brain Stimulation: Neuroethical Challenges—and Possible Inroads—to Research and the Provision of Care

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Off-label use of deep brain stimulation (DBS) under Food and Drug Administration (FDA)-approved Humanitarian

Device Exemption (HDE) or Investigational Device Exemption (IDE) often affords an intervention of last hope for patients with certain severe, medication-refractory neurological (e.g., Tourette's syndrome) and/or psychiatric disorders (e.g., depression, obsessive–compulsive disorder). Such use of DBS is not uniformly reimbursed by third-party payers; thus, treating physicians frequently seek preapproval of coverage—typically involving documenting medical necessity via a peer-to-peer review process engaging a medically trained representative of the insurance provider. However, preprocedure agreement on medical necessity following peer-to-peer review does not uniformly result in postprocedure reimbursement. In these cases, patients and providers must contend with incurred costs (and bills) in excess of $50,000 USD. Anecdotal evidence reveals that this has prompted some reluctance on the part of neurosurgical teams to perform off-label DBS for patients with particular types of insurance coverage.

To define the prevalence of preapproved but subsequently not covered DBS treatments, a 10-year retrospective analysis of all off-label DBS procedures performed at the University of Florida Center for Movement Disorders was conducted. This analysis revealed that during 2004–2014, 18 DBS lead implantation procedures and 56 implantable pulse generator (IPG) implantations or battery replacement procedures were performed on 26 individual patients for non-FDA-approved indications. Seven patients were treated for Tourette syndrome (TS), 5 for Alzheimer's disease (AD), and 14 were treated for obsessive–compulsive disorder (OCD). The costs of 7 lead implantations and 16 battery surgeries were covered via dedicated research grants. Of the remaining procedures requiring third-party coverage, 8 out of 11 lead implantations (72%) and 25 out of 40 IPG procedures (62.5%) were not reimbursed, despite preapproval of all cases. A striking finding of our study was that greater than half of non-reimbursed procedures could be attributed to a government insurance provider's failure to pay.

We posit that these data indicate a trend in discontinuity of economic support for sustainable translation of DBS into novel, yet clinically indicated and viable, domains of use. In this light we address neuroethical constructs that may be useful to inform both a posture of sound and clinically meaningful patient-based neurological research as consistent with stated goals of the BRAIN initiative, and economic extra- and infrastructures of health care that would be necessary to its articulation and sustainability. To this end, we propose neuroethically informed solutions that may be useful to reform the prevailing U.S. funding model for off-label DBS procedures, as well as other nascent and future neurotechnologically based interventions.

Neural Correlates of Guilt in Criminal Offenders With Antisocial Personality Disorder: Toward Further Elucidation of Moral Cognition

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Antisocial behavior is related both to difficulty empathizing with others, and to experiencing and attributing guilt. The current study investigated feelings of guilt in criminal offenders with antisocial personality disorder (ASPD) in an attempt to further demonstrate putative neural bases of moral cognition. Ten healthy male subjects (mean age = 32.44 years, SD = 11.34, range = 23–69 years) and 10 male criminal offenders with ASPD recruited from a forensic psychiatry (mean age = 47.80 years, SD = 9.66, range = 35–62 years, meeting clinical criteria of SCID II) were evaluated. We employed an imagination protocol to shift perspective. During functional neuroimaging sessions, participants were exposed to 15 written social scenarios rated in preliminary tests to elicit high levels of feelings of guilt; 15 neutral scenarios served as control stimuli. Stimuli were presented in two runs; between runs, offenders were instructed to take the perspective of an ordinary person.

Statistical analyses of neuroimaging data were performed using SPM software. Preprocessing included three-dimensional motion correction, realignment, spatial normalization, and spatial smoothing (8-mm full width at half maximum [FWHM]). Each condition was modeled by a boxcar function convolved with canonical hemodynamic response function. Individual contrast images for processing guilt were used in two random-effects general linear models. Contrasts were computed using *t*-tests with significance of $p < .001$ and a cluster-level correction of p (FWE) $< .05$.

In healthy subjects, processing guilt-related sentences incurred stronger involvement of the bilateral superior temporal suclus (STS), left middle temporal gyrus, and posterior cingulate cortex compared to neutral sentences, while no significant differences between conditions were found in criminal offenders with ASPD. Direct contrast of the samples revealed differential processing in the right STS. When instructing to perform like an ordinary subject, the processing of guilt in offenders was modulated with stronger involvement of the left subcallosal gyrus, inferior frontal gyrus, and pre- and postcentral gyrus.

In particular, the STS has been proposed as putative neural correlate of reasoning about others' mental states. When integrated to the existing conceptualization of cognitive processes in ASPD, our findings support the hypothesis that antisocial behavior is subserved, at least in part, by impaired empathic abilities that function in social interactions. As well, we posit that such neurocognitive processes may be involved in emotional dissonance against sociomoral norms. Effects of perspective taking in offenders offer a preliminary prospect that subjective imagination might be a valuable means to modify moral cognition. Yet despite trends toward using neuroimaging to inform

clinical and legal decision making, we advocate prudent interpretation of such findings, and advocate their utility only when taken together with other psychological and social assessments.

A Pragmatic Analysis of the Regulation of Consumer Transcranial Direct Current Stimulation (tDCS) Devices in the United States

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Several recent articles have called for the regulation of consumer transcranial direct current stimulation (tDCS) devices (e.g., Dubljević 2014; Maslen et al. 2013), which provide low levels of electrical current to the brain. Some have proposed extending medical device regulation in Europe (Maslen et al. 2014), whereas others have recommended greater engagement with the do-it-yourself (DIY) brain stimulation community (Fitz and Reiner 2013). However, most of the discussion to-date has focused on ethical or normative considerations; there has been a notable absence of scholarship regarding the practical nature of regulation and how it has impacted—and may in the future impact—the consumer tDCS market.

This article aims to fill that gap. First, I suggest that a better understanding of the consumer tDCS device market is necessary for empirically grounded discussions of regulation. I therefore present a short history of the DIY tDCS movement, chronicling the rise of various consumer devices. Second, I consider how the Food and Drug Administration (FDA) definition of a medical device has shaped the consumer tDCS landscape: it is the intended purpose of the device, not its mechanism of action, that is of paramount importance for the law. Third, I discuss how courts have understood the FDA's jurisdiction over medical devices in cases where the meaning of "intended use" has been challenged. Fourth, I analyze the only instance of tDCS regulatory action to-date, in which the California Department of Public Health (CDPH) forced a firm to recall several hundred consumer tDCS devices. Although there exists a common perception that the FDA has not been involved with the regulation of consumer tDCS devices, I demonstrate that the CDPH's actions were instigated entirely by the FDA. Finally, I discuss the multiple U.S. authorities, other than the FDA, that can regulate consumer brain stimulation devices.

On the whole, this paper dispels the notion of a "regulatory gap" with regard to consumer noninvasive brain stimulation (in the United States). Thus, rather than calling for additional regulation, I suggest a pragmatic approach to consumer brain stimulation devices, one that clearly defines the issues, considers multiple ways of addressing them, and assesses the feasibility of each pathway. To that end, this paper provides a foundation on which to situate practical, fact-based discussions of consumer noninvasive brain stimulation devices and the relevant U.S. regulatory framework.

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Public Opinions on Legal Agency Determination in Taiwan: Does Cultural Value and Neuroscience Matter?

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Background: Empirical findings have been controversial on how neuroscience findings might influence lay persons' opinions on issues regarding human agency. The author conducted a telephone survey in Taiwan of the public's attitudes toward these issues.

Method & Analysis: With the input from lay-person focus groups and experts in law, neuroscience, and public survey, the author drafted, revised, and finalized the questionnaire. The telephone survey of a representative sample of people in Taiwan was conducted in November 2013. Following descriptive analysis, chi-squared analysis and logistic regression were conducted to explore whether Confucian value uptake and neuroscience evidence have impacts on the public's attitudes toward legal agency determination.

Results: One thousand and thirty-six valid telephone survey interviews were completed for people ages 18–70 years. Twenty percent of surveyed people had knowledge of neuroscience and 84% reported upholding Confucian values. Whether or not neuroscientific explanations were offered, the majority of surveyed people (more than 85%) hold responsible criminals with alcoholism, brain tumor, or psychopathy. Similarly, the majority (more than 70%) hold civilly competent people with alcoholism, brain tumor, or psychopathy. People holding Confucian values are more strict toward criminals with brain tumor than those who do not ($p < .01$) in chi-squared analysis. People holding Confucian values are more likely than those who do not to hold psychopaths civilly competent, even when told psychopaths had abnormal brain findings ($p \leq .05$). However, the significance of brain tumor or psychopathy with neuroscientific bases vanished once the surveyees were told that the actors were cognitively and volitionally capable. In logistic regression, compared to those people not holding Confucian values, people who do are more likely to attribute responsibility to criminals with brain tumor ($p \leq .05$) and more strict with psychopaths who are cognitively and volitionally capable ($p \leq .01$). Up to 90% of surveyed people agree that neuroscience findings cannot replace

human judgment in legal agency determination and more so in those who hold Confucian values ($p \leq .001$ for criminal responsibility and $p \leq .01$ for civil competency).

Conclusion: The current survey demonstrates that in Taiwan where Confucian values still dominate, the public tends not to take psychiatric or neurological diagnoses as excuses for criminal irresponsibility or civil incompetency. Furthermore, surveyees upholding Confucian values are more likely than those not holding them to hold someone criminally responsible or civilly competent even if told of related abnormal neuroscience findings. Further exploration into the direct power of neuroimages in changing people's construal of other-agency in East Asian culture is necessary.

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