

# Neurotechnology, Evidence, and Ethics

On Stewardship and the Good in Research and Practice

By James Giordano, PhD



James Giordano, PhD

### On the “Groundswell” of Neurotechnology

Recently, a reader wrote to comment on my essays regarding neurotechnology in light of the growing number of advertisements for various neurotechnologically-based devices seen in this, and other, pain journals. Writing, “...there’s been practically a groundswell [of information and advertisement]...that often is confusing, seems contradicting and, in some cases, it’s obvious that real evidence isn’t available...how can physicians and the general public, for that matter, know what’s ‘snake oil’ and what’s legitimate, and if these devices are safe, and how they ought to be used?” this reader’s thoughtful comment takes note of an increasing presence of neurotechnology in pain care, if not medicine and other dimensions of public life in general.

The medical use of machines is certainly not new, and a brief history of medicine since the second industrial revolution will reveal the steady infiltration of various devices into the clinical milieu.<sup>1</sup> This has tended to reflect the iterative technologization of much of western society. As previously noted, the aims of such technologization—namely to ease the human condition and to incur time- and cost-efficiency—married well to the expansion of medicine as a profession and practice in the early 20th century.

These incentives also wedded technology and its use(s) to a broadening influence of the market, and this fusion was mirrored—even if somewhat in caricature—by the profligate claims of “wonder devices” that could “cure” a host of disorders including, if not most typically, pain.<sup>2</sup>

To be sure, many such claims were sheer quackery, and the Flexnerian reformation of American medicine certainly lessened the frequency and abundance of these transgressions.<sup>3</sup> Yet, every new technological turn is accompanied by speculation, expectation, hopes and fears, and the outgrowth of neurotechnology following the Decade of the Brain (DoB, 1990-2000) certainly reflects this process. The astute comment provided by the reader speaks to the apparent “pop-up” of neurotech-

Neurotechnology Initiative (NNTI) and Neurotechnology Industries Organization (NIO).<sup>5</sup>

Recently, Michael Schatman and I have written that pain medicine currently faces a “crisis”—a time of change upon which rests potential future trajectories for the scope and breadth of care.<sup>6</sup> Without doubt, neurotechnology, both alone and in concert with other (e.g., geno-, nano-, and cyber-) technological advances have contributed to, and will factor into these

*“...how can physicians and the general public, for that matter, know what’s ‘snake oil’ and what’s legitimate, and if these devices are safe, and how they ought to be used?”*

nologies germane to the diagnosis and treatment of pain, attributable at least in part, to the carry-over effect of technologies developed during the DoB being focused upon practical applications during the Decade of Pain Control and Research (DPCR, 2000-2010).<sup>4</sup> Economic subsidies for research directions and biotechnological applications certainly contributed to this pattern and have also created a market niche for such neurotechnology. How (i.e., in what ways, to what ends) this niche will be filled may be contingent upon the environment fostered by the Decade of the Mind (DoM) project, its affiliated Neuroscience, Ethics, Legal and Social Issues (NELSI) agenda, and the work of the National

changes and the socio-medical milieu that results. But as we’ve noted, neither change itself, nor the nature of what emerges status-post-change are passive events, and pro-active investment of time and effort are required to assure that change is as positive as possible. A part of the crisis we’ve described rests upon ethical issues, questions and problems that arise in, and from the ways that we approach, address and utilize new scientific and biotechnological developments in research and practice.<sup>7</sup> As our reader’s commentary has implied, this “groundswell” of new development is evident, and the aforementioned ethical questions cannot be ignored. In this essay, I explicitly address the point that some neuro-

technologies have not been thoroughly studied, have been (and are being) used in ways that are based upon dubious claims regarding mechanism(s) or outcomes, are being used by improperly and/or untrained providers, and/or are simply being used in ways that are inapt. I will also discuss the ethical obligations that undergird the use of new neurotechnologies in pain research, assessment, diagnosis and treatment.

I have previously argued that pain care, like medicine writ large, is not simply applied science, but rather uses scientific tools and technologies and the information they afford in ways that uphold the fiduciary both between clinician and patient, and medicine and society.<sup>8</sup> This reflects the reciprocity of science, technology, research and clinical practice as a true “practice” (i.e., an exchange of good between agents in community, as defined by the nature of their relationship<sup>9</sup>). It is

*“...we continue to confront the fundamental “hard problem” of not understanding how consciousness and related mental processes actually occur, so any and all concepts that relate the effect(s) of a technology to a mechanism of mind remain tentative.”<sup>10,11</sup>*

in this light that the imperative to elucidate the mechanism, capacities, limitations, and evaluate the outcomes of any and all neurotechnologies that are used in clinical diagnosis and therapeutics for pain (as well as any other clinical application) becomes important.

### Confronting Uncertainty

While neuroscience provides considerable insight to the structure and function(s) of the brain, we continue to confront the fundamental “hard problem” of not understanding how consciousness and related mental processes actually occur, so any and all concepts that relate the effect(s) of a technology to a mechanism of mind remain tentative.<sup>10,11</sup> Moreover, every brain is different with regards to the network dynamics that subserve cognitions, emotions and behaviors.<sup>12</sup> Therefore, it becomes evident that employing neurotechnology in a “one-size-fits-all” approach to modifying brain-mind function is both technically and ethically inappropriate. Given the individual uniqueness of the brain-mind, it is vital to

weigh the effect of neuropsychiatric predispositions, co-morbidities, etc, when evaluating the relative ratio of benefit, burdens and risks that the use (or non-use) of these technologies might incur.<sup>13</sup> Moreover, we simply do not know how the use of these technologies might alter the long-term function or structure of the brain. This is where the “mechanistic dilemma” comes to light.<sup>14</sup> In “western” medicine, a technique or technology may not be “accepted” unless or until its mechanism is ascertained.<sup>15</sup> On one hand, this might tend to militate against the use of such technology (even if positive outcomes are, in fact, available). Yet, despite what would appear to be a negative bias, a mechanistic understanding is valuable, if not essential, to assess the potential for adverse effects.

To date, an exact set of standards to calculate individual variations in response to specific neurotechnological interven-

tions remains unavailable. Therefore, determining what and how technologies can and should be used, in whom, and in which ways is reliant upon research-based information that is communicated through the education and training of clinicians who use and administer neurotechnology in practice. We have argued that any and all neurotechnological interventions should be rendered only by trained clinical specialists who are well-qualified to employ knowledge (of brain-mind, pathology, and relevant technologies) and skills in ways that uphold right and ethically good care.<sup>16,17</sup>

### The Right and Good of Research: Epistemology and Ethics in Intersection

Ongoing research is required to afford data that 1) contribute to the extant knowledge base; that 2) enable clinicians to evaluate (and communicate) the relative value(s), benefits and risks of particular diagnostic and therapeutic technologies; and 3) empower patients to participate in well-informed decisions about the use of any such technologies in

therapeutics.<sup>18,19</sup> Findings from research inform practice, and evaluation of outcomes gained by employing various technologies in practice contributes to evidentiary knowledge to instigate and guide further study. Of course, any and all such research must be methodologically rigorous and ethically sound.<sup>20,21</sup> In other words, research must be focal to the neurotechnology in question, for its intended use(s) in assessment, diagnosis and treatment of specific conditions, in particular patient populations, and must be both iterative and current. Philosophically, this reflects the essence of science as being self-critical, self-revising, non-dogmatic and non-anachronistic as new information is acquired and incorporated into the accepted fund of knowledge.<sup>22</sup> In some instances, understanding of mechanisms will remain incomplete, uncertain, ambiguous, or frankly unknown, and this must be made explicit and, as matter of fact, may not obviate use, given that apparent benefit(s) might well outweigh possible burdens and/or risks.

The imperative for developing, implementing and promoting ongoing research to assess and evaluate the capabilities and clinical application(s) of neurotechnology is grounded upon the moral obligation of beneficence.<sup>23,24</sup> Obviously, research is instrumental in determining the technical or practical “good” of a particular technology. But even at this level, application as a meaningful biomedical “good” requires translational studies to both evaluate the wider implications of use-in-practice and determine viability in real-world medical settings. In achieving this biomedical good, the somewhat more passive maxim of non-harm can be realized, and thus the “mechanistic dilemma” may be resolved—or at very least placated—in appreciation for the primacy of patients’ best interests. Through an understanding of the actions, effects and capabilities of a given neurotechnology, we can also recognize, weigh and may be able to compensate for 1) inherent limitations of the technology in various applications, 2) potential risks of use or non-use, and 3) possible burdens incurred by the patient, as well as the medical system. This knowledge helps to illustrate the potential viability of a neurotechnology within the armamentarium that can be utilized in diagnosis and/or treatment. When related to an understanding of the mechanisms of

particular pathologies, such knowledge allows the clinician to address whether a certain neurotechnology can, and should, be employed in specific clinical situations.

How research data are incorporated within the larger fabric of clinically-relevant information is both important to its practical and ethical use, and reflects the intellectual skills, and moral integrity, that are fundamental to medicine.<sup>25-27</sup> However, it is important to recognize that a pervasive “market mindset” has fostered 1) a tendency for many purveyors of neurotechnologies to exempt an evidence-based approach and rely upon anecdotal evidence instead of the most currently validated science; and 2) more widespread use of neurotechnologies by under- or untrained individuals.<sup>28</sup> But even as more well-designed and executed multi-site studies are presented, these results are often ignored. There is a continued hesitance to accept new and iterative data that provides evidence for the effectiveness of advanced neurotechnologies in diagnosing and treating specific types of pain. At the same time, there is an amenability to accept outdated, and/or anecdotal evidence (or in some cases, “lore”) to promote and justify using such technologies in a more “blanket” approach (e.g., cognitive enhancement, “mind control”-type games and self-help products; stress reduction, etc.)

Thus, the re-assessment of what constitutes appropriate—and ethically good—research and use is of pressing importance as more neurotechnologies become available and many are being employed off-label. At a minimum, there needs to be a uniform and enforced screening for all neurotechnology product developers to ascertain whether products may incur potential risks to the general public and, more specifically, to persons with certain pathologic predispositions or disorders—such as those neuropsychiatric conditions that are so often co-morbid to chronic pain. On a more encompassing scale, guidelines, policies, and regulation(s) are required to standardize practices within the field and the NNTI and work of the NIO are solid steps in this direction.

### Toward Ethical Stewardship

Given the position that medicine is not just simply applied science, I believe that its practice involves far more than a theoretical knowledge of physiological systems, pathologies and the mechanics

of particular tests, tools and interventions. I hold that knowing “what should be done” mandates understanding of ‘how’, ‘when’, and ‘why’ something is done.<sup>29</sup> Specifically, knowing whether the use of a particular neurotechnologic device is appropriate for a given clinical case requires understanding both the technology (and its capacities and limitations), the suspected pathology, the physiological changes it incurs, and how the technology should be employed to meet these specific circumstances. This necessitates experience in differing situations and across time. Experiential knowledge can be gained through an expanding body of research findings and/or may be acquired through training and direct activity.<sup>30,31</sup> Ultimately, theoretical and experiential knowledge work synergistically when relating current cases to paradigmatic examples (i.e., the casuistic approach) and, in this way, theory and experience

unsound employment based upon suspect (or absent) evidentiary support, use by poorly trained ‘technicians’ and/or non-professionals, and unethical claims for financial reimbursement (for improper use). This reflects inadequacies or improprieties in education and training—often involving brief courses of home study, weekend seminars and/or cursory ‘examinations’ that claim to ‘certify’ individuals as capable ‘technicians’ or experts after only nominal instruction. In response, we have argued for stringent educational programs that 1) reflect the complexity and advancement of the field, 2) enables discrimination of research findings; 3) acknowledge the potential and limitations of technology in medical diagnosis and care, and 4) uphold high standards of professionalism.

Moreover, we have argued that the person prescribing, coordinating and providing any neurotechnology in clinical

*“...knowing whether the use of a particular neurotechnologic device is appropriate for a given clinical case requires understanding both the technology... the suspected pathology, the physiological changes it incurs, and how the technology should be employed to meet these specific circumstances.”*

are conjoined to determine if, how and why a specific neurotechnology can and should be utilized in diagnosing and/or treating pain in a given patient. Taken together, contextual knowledge fuses research to practice, and allows the clinician to avoid a simplistic “cookie cutter” approach to diagnosis and care.

It is my contention that “good” entails “right” (i.e., technical rectitude) and so for any new (or extant) technology to be correctly and effectively employed, and used in ways that sustain the moral dimension of care, it must be administered by individuals who are not simply repeating a task by rote (even if efficiently), but rather by those who exercise practical wisdom (phronesis) as a core professional responsibility of medicine.<sup>32-35</sup> By (Aristotelian) definition, such phronesis is not merely knowing the right things, but using that knowledge in the right ways to achieve the good.<sup>36,37</sup>

Significant ability is required to discern technical rectitude and “good” use in practice. Indeed, many criticisms of neurotechnology have centered upon

care should be a licensed physician (or, at very least, another licensed clinician working in direct collaboration—e.g., a neuropsychologist), given that 1) many pain patients seeking such treatment are taking prescription medications; 2) medication regimens often require adjustment in response to neurotechnologic intervention; and 3) potential treatment interactions require careful monitoring and may necessitate prudent adjustment.<sup>38</sup> In light of this, I propose that training in the use and capabilities (as well as caveats and restrictions) of specific neurotechnologies must be provided to licensed medical professionals through objective programs of continuing and/or post-graduate medical education.

### The Importance of Guidelines, Regulation, and Policy

Simply put, there is indubitably great value of neurotechnology in pain care, but neurotechnological progress should not be ethically undermined by capricious, unprofessional utilization engendered through improper education, training

and/or misdirection by market forces. Its use must be consonant with identifiably good ends, and must positively engage each and all groups of affected stakeholders, i.e., biotechnology engineering, research, clinical and patient communities.<sup>39</sup> To advance the appropriate use of neurotechnology in pain care will require dedication to 1) integrating research into formalized education and training, 2) instilling and ensuring high ethical standards for the use of specific neurotechnologies by competent professionals, 3) developing guidelines for clinical use, and 4) informing and initiating public policy to both assure strict control of such use, as well as provide administrative and economic support for ongoing research.

In this latter regard, we have posited that regulation—both over the industry and the level of education and specialized experience of providers—must be expanded and sustained as the field advances both technically and within an ever-growing market.<sup>40</sup> Clearly, further research, development, testing and evaluation (RDTE) of any neurotechnology is required to determine how a device may be best employed in the diagnosis and treatment of pain (and other neurological conditions). It is equally important to develop and instantiate guidelines that are based upon the most current RDTE, together with policies (and laws) to ensure that these approaches are provided by well-trained, competent clinical specialists. So, while neurotechnologies may one day allow us to answer the hard questions of neuroscience, a more urgent question is how these technologies should be regulated and used so as to sustain the good of pain research and care. ■

### Acknowledgments

This essay is based upon the author's chapter "Neurotechnology: A force among—and upon—social forces: Toward the future with prudence and precautionary process." In: Giordano J (ed.) *Advances in Neurotechnology: Ethical, Legal and Social Issues*. CRC Press, Boca Raton, forthcoming 2010, and his paper: "Neurotechnology, ethics, and prudent progress: Homo faber, redux." *J Neuroethics*, forthcoming 2010.

This work was supported, in part, by grants from the Nour Foundation, and the Office of Naval Research (Brain Disorders Management Initiative; BIDMI), and by funding from the Center for Neurotech-

nology Studies of the Potomac Institute for Policy Studies. The author thanks Don DuRousseau for intellectual collaboration, and Sherry Loveless for assistance in the preparation of this manuscript.

*James Giordano, PhD, MPhil, is Director of the Center for Neurotechnology Studies, and Chair of Academic Programs at the Potomac Institute for Policy Studies, Arlington, Virginia, USA, and Fellow of Centre Philosophical Psychology, Blackfriars Hall, University of Oxford, UK. As well, he is Visiting Professor of Neuroscience and Ethics at the Texas Tech University Health Sciences Center, Lubbock Texas, and IGERT Visiting Professor of Science, Technology, Ethics and Policy (STEP) at the University of New Mexico, Albuquerque, NM. Professor Giordano is Chair of the National Neuroscience, Ethics, Legal and Social Issues (NELSI) Initiative, and the Capital Consortium on Neuroethics, Legal and Social Issues (CCNELSI).*

### References

- Magner LN. *A History of Medicine, 2nd Ed.* Taylor Francis. Boca Raton. 2005.
- Greenspan RE. *Medicine: Perspectives in History and Art.* Ponte Verde Press, Alexandria VA. 2004.
- Porter R. Medical science. In: Porter R. (ed.) *The Cambridge History of Medicine.* Cambridge University Press. Cambridge. 2006. pp 136-175.
- Giordano J. *Pain: Mind, Meaning and Medicine.* PPM Communications. Glen Mills, Pa. 2009.
- Boswell MV and Giordano J. Reflection, analysis and change: The Decade of Pain Control and Research and its lessons for the future of pain management. *Pain Physician.* 2009. 12: 923-928.
- Giordano J and Schatman ME. A crisis in chronic pain care—an ethical analysis. Part One: Facts, issues and problems. *Pain Physician.* 2008. 11:54-62.
- Giordano J and Schatman ME. A crisis in chronic pain care—an ethical analysis. Part three: Toward an integrative, multidisciplinary pain medicine built around the needs of the patient. *Pain Physician.* 2008. 11: 64-73.
- Giordano J. Techniques, technology and tekne. Techniques, technology and tekne: On the ethical use of guidelines in the practice of interventional pain medicine. *Pain Physician.* 2007. 10: 1-5.
- MacIntyre A. *After Virtue: A Study in Moral Theory (2nd ed.)* University of Notre Dame Press. Notre Dame, Indiana. 1984.
- Chalmers D. *The Conscious Mind: In Search of a Fundamental Theory.* Oxford University Press. New York. 1996.
- Giordano J. Coming of age and facing the future In: Giordano J and Gordijn B (eds.) *Scientific and Philosophical Perspectives in Neuroethics.* Cambridge University Press. Cambridge. 2009. pp xxv-xxix.
- Edelman G. *Wider Than the Sky.* Yale University Press. New Haven. 2004.
- Gini A, Rossi J, and Giordano J. Considering enhancement (and/or treatment): On the need to regard contingency and develop dialectic evaluation. *AJOB-Neuroscience.* 2010 (in press).

- Giordano J. The mechanistic dilemma: On right knowledge for right use. *Synesis.* 2010 (in press).
- Giordano J, Garcia, MK, Boatwright D, and Klein K. Complementary and alternative medicine in mainstream public health: A role for research in fostering integrative practice. *J Alt Comp Med.* 2003. 9(3): 1-5
- McBride DK and Giordano J. Anticipating biotechnological trends in pain care. *Prac Pain Management.* 2009. 9(5): 74-78.
- Giordano J and Du Rousseau D. Neurotechnologies and the market: Toward right and good use. *J Cog Technol.* 2010 (in press).
- Giordano J. Good as gold? The randomized controlled trial: pragmatic and ethical issues in pain research. *Am J Pain Management.* 2006. 16: 68-71.
- Ibid. ref. 4
- Goodman KW. *Ethics and Evidence-Based Medicine: Fallibility and Responsibility in Clinical Science.* Cambridge University Press. Cambridge. 2003.
- Freedman B. Equipoise and the ethics of clinical research. *N Engl J Med.* 1987. 317: 141-145.
- Nagel E. *The Structure of Science: Problems in the Logic of Scientific Explanation.* Harcourt, Brace and World. New York. 1961.
- Pellegrino ED and Thomasma DC. *For the Patient's Good: The Restoration of Beneficence in Health Care.* Oxford University Press. New York. 1988.
- Frankena W. Beneficence in an ethics of virtue. In: Shelp E. (ed.) *Beneficence and Health Care.* D. Reidel. Dordrecht. 1982.
- Feinstein AR. *Clinical Judgment.* Williams and Wilkins. Baltimore. 1967.
- Dell'Oro R. Interpreting clinical judgment: Epistemological notes on the praxis of medicine. In: Viofora C. (ed.) *Clinical Bioethics: A Search for Foundations.* Springer. Dordrecht. 2005.
- Levine RJ. *Ethics and Regulation of Clinical Research, 2nd ed.* Yale University Press. New Haven. 1986.
- Ibid. ref. 17
- Ibid. ref. 8
- Davis FD. Phronesis, reasoning and Pellegrino's philosophy of medicine. *Theoretical Medicine.* 1997. 18: 173-198.
- Ibid. ref. 4
- Pellegrino ED, Thomasma DC. *The Virtues in Medical Practice.* Oxford University Press. New York. 1993.
- Ibid. ref. 30
- Giordano J. Moral agency in pain medicine: Philosophy, practice and virtue. *Pain Physician.* 2006. 9: 71-76.
- Ibid. ref. 4
- Aristotle. *The Nicomachean Ethics* (T. Irwin, trans.). Hackett Publishing. Indianapolis. 1999.
- Edelstein L. The professional ethics of the Greek physician. In: Temkin O and Temkin CL. (eds.) *Ancient Medicine: The Selected Papers of Ludwig Edelstein.* Johns Hopkins Press. Baltimore. 1967.
- Ibid. ref. 17
- Giordano J, Schatman ME, and Höver G. Ethical insights to rapprochement in pain care: Bringing stakeholders together in the best interest(s) of the patient. *Pain Physician.* 2009. 12: 803-813.
- Ibid. ref. 13