

Testimony before the
Committee on Veterans' Affairs
US House of Representatives

Traumatic Brain Injury

18 July 2007

Joseph J. Fins, M.D., F.A.C.P.

Chief, Division of Medical Ethics
Professor of Medicine
Professor of Public Health
Professor of Medicine in Psychiatry
Weill Medical College of Cornell University

&

Adjunct Faculty
The Rockefeller University

Correspondence:

Joseph J. Fins, M.D., F.A.C.P.
Division of Medical Ethics
New York Presbyterian-Weill Cornell Medical Center
435 East 70th Street, Suite 4-J
New York, NY USA 10021

Telephone: (212) 746-4246
Fax: (212) 746-8738
e-mail: jjfins@med.cornell.edu

I. Introduction

Mr. Chairman, Mr. Buyer and distinguished members of the Committee: Thank you for this invitation to testify before you.

By way of background, I am Chief of the Division of Medical Ethics at Weill Medical College of Cornell University where I am practicing internist and Professor of Medicine and Public Health. I am also Director of Medical Ethics at New York Presbyterian-Weill Cornell Medical Center and a member of the Adjunct Faculty at Rockefeller University.

Over the past decade, I have collaborated with neuroscientists interested in the categorization of severe brain injuries that produce disorders of consciousness. Our efforts have examined how the brain recovers and how therapies might accelerate this natural process. My focus has been on how to translate these developments into clinical practice and to anticipate and consider their clinical, health policy policy and ethical implications. ^{i ii iii}

I am honored to appear before you to comment on the compelling needs of wounded soldiers with traumatic brain injury and their civilian brethren who have also had head trauma. I mention patients in the civilian sector because I believe any remedy for military personnel will require the mobilization of additional clinical and scientific resources within both civilian academic medicine and VA and DOD facilities.

Sadly, the challenges that our Veterans face is something that civilians have encountered as well. The War in Iraq has pointed out many things, and one of them is the pervasive neglect of those with brain injury in American society. Although it is the leading cause of disability among young people, brain injury is often ignored in policy making at all levels. Traumatic brain injury has been described as a "silent epidemic." ^{iv}

Its victims are prone to an implicit rationing system that leads many to receive "custodial care."^v

II. Scientific Developments

The pervasive neglect of these patients is especially unfortunate because of developments in neuroscience, neuroimaging in particular, that is making it possible to peer into the recovering brain and discern mechanisms of recovery. Our group at Cornell, notably led by my collaborator Dr. Nicholas Schiff, has demonstrated, with advanced imaging techniques, that patients with severe disorders of consciousness -- patients who are minimally conscious ^{vi vii} -- are capable of processing language. ^{viii} Moreover, another paper from Cornell demonstrated the capability of, what was described as "axonal sprouting" or new connections between injured parts of the brain late in the course of injury. ^{ix} The paper presents quantitative structural and functional neuroimaging data from a subject who remained in a minimally conscious state (MCS) for 19 years before he regained fluent speech.

Before that, this patient, Terry Wallis from Arkansas, ^x lingered in a nursing home bed, misdiagnosed as being in the Vegetative State, ^{xi} which he was not. Staff denied his family's requests for additional studies. His father, Mr. Wallis was told it would be too expensive and unhelpful for his son. (I should add that I have permission from the family to speak about their story.) Sadly such a societal "neglect syndrome" ^{xii} continues for many patients with severe brain injury once they are discharged from acute care facilities and placed into what is euphemistically described as "custodial care." It has been estimated that the diagnostic error rate of MCS patients as PVS may be as high as 30-40%. ^{xiii xiv xv}

I bring up Mr. Wallis--who is a public figure and has been featured in numerous press reports -- and his case for two important reasons. First, such misdiagnosis is a fate that we do not want to subject any American to, be they civilian, active military or Veteran. Second, his late recovery from the minimally conscious state is also relevant

because, along with other epidemiological data,^{xvi} it shows that recovery from brain injury takes time, often lots of time. This is true not just in severe cases, but for all TBI. Because of this, if we truly want to care for these patients, systems of care have to be developed to accommodate a long time horizon and the chronic care needs of these patients. This is something that our current acute care system is woefully unable to do. It is something that needs to be fixed in both the VA and civilian sectors.

III. Recommendations

To start to repair this broken system of care, I have several recommendations that I would like to share with the Committee:

First, we need to break down research barriers between DOD, the VA and civilian centers like ours to enable the movement of patients so they can be properly diagnosed, if resources are not available in DOD or the VA, or if there is a clinical study in a civilian hospital that is scientifically meritorious and warrants inclusion. This will entail creative financing mechanisms for payment of care across these sectors and re-examination of and clarification of regulatory rules about participation of active military and others in clinical research when direct subject consent can not be obtained.^{xvii xviii} These can be restrictive and undermine woefully needed access.

Second, we should use the epidemic of brain injury from this war, what your colleague Congressman Bill Pascrell, Chair of the Congressional Brain Injury Caucus has described as the signature injury of the War.^{xix} We should use this tragic epidemic to study the epidemiology and natural history of brain injury and establish long-term registries that track patients over months, years and decades. This information will be essential to deepening our scientific understanding of how the injured brain recovers and developing evidence-based criteria for how to longitudinally follow patients using new technologies like neuroimaging. (As remarkable as it may seem, to date *there is no reliable information about the number of patients who are in the minimally conscious state.*^{xx} As basic demography is the first step in health care planning and determining the

natural history of these conditions, determining the epidemiology of these states should be a robust first priority.)

Third, we need to delineate these evaluative elements and place of appropriate clinical trials in conjunction with the relevant NIH institutes: e.g. NINDS, NIMH, NIA, NIBIB, NINR as well as NIDDR/Dept of Education. We should seek to identify research opportunities and questions that the relevant NIH institutes could then formulate into RFA and program areas from basic public health and epidemiology of these disorders to the neural mechanisms of recovery to clinical assessment, prognostication and communication. Congress should also seek to determine -- perhaps through a comprehensive IOM study -- whether this area of neuroscience has been adequately resourced as a study area and whether new study sections need to be created to assess the proposals of the interdisciplinary scientific community, which conducts this research. Anecdotal evidence suggests that proposals addressing the needs of this oft-marginalized population of patients are discounted and not adequately assessed.

Fourth, we need to identify infrastructural needs required to ensure appropriate assessment by qualified practitioners with appropriate institutional support. (And if I may, Mr. Chairman, may I direct the Committee to the *Mohonk Report of 2006*,^{xxi} written at the request of the Congressional Brain Injury Caucus, and ask that it be included in your deliberations?) Regarding the state of the traumatic brain injury infrastructure, we need to ask a number of key questions: Are the needed resources/personnel necessary for assessment where the patients are? If not, how might they be brought together?

Beyond these logistical questions about fostering proper evaluation, Congress should also consider the infrastructural barriers to research with this population, so widely dispersed in so many venues. Because these patients/subjects require support for activities of daily living and are institutionalized, to conduct research on this population requires infrastructure to support their needs (and the needs of their families) while they

are away from skilled nursing or rehabilitation facilities. This engenders additional costs that need to be factored into calculations of indirect costs.

Fifth, we need to collaborate with CMS and TriCare and other payors to establish and pay for scientifically informed standards of clinical evaluation, when and if they are established. In addition, it would be helpful to coordinate issues related to cost-recovery - -whether TBI patients are receiving Medicaid and/or Medicare, are active military, in the VA System, or covered by Tri-Care -- and also enrolled into diagnostic and/or therapeutic clinical trials that require a change in venue. Research would be facilitated if care normally billed to such payors could continue to be covered when patients were in research settings. This is necessary to offset the additional costs of room and board, which are normally paid for those who require institutional care. In addition supportive services like OT and PT, and usual medical care costs, should be covered for those enrolled in off-site clinical trials, be they observational or therapeutic.

IV. Conclusion

Thank you for this opportunity to share my perspective with you. I am most grateful for your commitment to the care of those who have served our Nation so well. I look forward to working with you in order that we may collectively serve them as well as they have served all of us.

I would be pleased to respond to any questions.

ⁱ Fins JJ. Ethics of Clinical Decision Making and Communication with Surrogates. In, Posner J, Saper C, Schiff ND and Plum F. Plum and Posner's Diagnosis of Stupor and Coma, 4th edition. New York: Oxford University Press, 2007.

ⁱⁱ Fins JJ. Rethinking Disorders of Consciousness: New Research and Its Implications. *The Hastings Center Report* 2005; 35(2):22-24.

-
- ⁱⁱⁱ Fins JJ, Schiff ND and Foley KM. Late Recovery from the Minimally Conscious State: Ethical and Policy Implications. *Neurology* 2007;68:304-307.
- ^{iv} Winslade WJ. Confronting Traumatic Brain Injury: Devastation, Hope and Healing. New Haven: Yale, 1998.
- ^v Fins JJ. Clinical Pragmatism and the Care of Brain Injured Patients: Towards a Palliative Neuroethics for Disorders of Consciousness. *Progress in Brain Research* 2005;150:565-82.
- ^{vi} Giacino JT, Ashwal S, Childs N, et al. The minimally conscious state: definition and diagnostic criteria. *Neurology* 2002;58(3):349-353.
- ^{vii} Unlike vegetative patients, the minimally conscious demonstrate unequivocal, but fluctuating, evidence of awareness of self and the environment. Assessment of MCS patients, however, is complicated by the fact that these MCS behaviors are episodic and inconsistent, so when patients are not exhibiting them, they may be mistaken as being in the vegetative state. See, Giacino JT, Ashwal S, Childs N, Cranford R, Jennett B, Katz DI, Kelly JP, Rosenberg JH, Whyte J, Zafonte RD, Zasler ND. The minimally conscious state: definition and diagnostic criteria. *Neurology* 2002;58(3):349-53.
- ^{viii} Schiff ND, Rodriguez-Moreno D, Kamal A, Kim KH, Giacino JT, Plum F, Hirsch J. fMRI reveals large-scale network activation in minimally conscious patients. *Neurology* 2005;64(3):514-23.
- ^{ix} Voss HU, Ulug AM, Dyke J et al. Possible axonal regrowth in late recovery from the minimally conscious state. *JCI* 2006;116(7):2005-2011.
- ^x Schiff ND and Fins JJ. Hope for “Comatose” Patients. *Cerebrum* 2003; 5(4): 7-24. Reprinted as: Schiff ND and Fins JJ. Hope for “Comatose” Patients. “A Cerebrum Classic” in The Dana Foundation’s Cerebrum 2007. Read CA, Editor. New York: Dana Press, 2007. pp. 185-203.
- ^{xi} Jennett B. The Vegetative State. New York: Cambridge University Press, 2002.
- ^{xii} Fins JJ. Constructing an Ethical Stereotaxy for Severe Brain Injury: Balancing Risks, Benefits and Access. *Nature Reviews Neuroscience* 2003;4: 323-327.
- ^{xiii} Wilson, FC, Harpur J, Watson T et al. Vegetative State and Minimally Responsive Patients – Regional Survey, Long-term case outcomes and service recommendations. *NeuroRehabilitation* 2002: 17: 231-236.
- ^{xiv} Andrews K, Murphy L, Munday R, et al. Misdiagnosis of the vegetative state: retrospective study in a rehabilitation unit. *British Medical Journal* 1996; 313:13-16.

-
- ^{xv} Childs, NL, Mercer, WN and Childs HW. Accuracy of Diagnosis of Persistent Vegetative State *Neurology* 1993; 43:1465-1467.
- ^{xvi} Lammi MH, Smith VH, Tate RL, et al. The minimally conscious state and recovery potential: a follow-up study 2 to 5 years after traumatic brain injury. *Arch Phys Med Rehabil* 2005;86(4): 746-754.
- ^{xvii} Fins JJ and Miller FG. Enrolling Decisionally Incapacitated Subjects in Neuropsychiatric Research. *CNS Spectrums* 2000;5(10):32-42.
- ^{xviii} Miller FG and Fins JJ. Protecting Human Subjects in Brain Research: A Pragmatic Perspective. Neuroethics: Defining the Issues in Theory, Practice and Policy. Illes, J. editor. New York: Oxford University Press, 2005.
- ^{xix} Fins JJ. A Review of In an Instant: A Family's Journey of Love and Healing by Lee and Bob Woodruff. New York: Random House, 2007. *Journal of the American Medical Association* 2007; 297(23): 2642-2643.
- ^{xx} Fins JJ, Master MG, Gerber L and Giacino JT. The Minimally Conscious State: A Diagnosis in Search of an Epidemiology. *Archives of Neurology*. In Press.
- ^{xxi} Berube J, Fins J, Giacino J, Katz D, Langlois J, Whyte J and Zitnay GA. The Mohonk Report: A Report to Congress Improving Outcomes for Individuals with Disorders of Consciousness. Charlottesville, VA: National Brain Injury Research, Treatment & Training Foundation, 2006.