# To The Editor

The articles in the *JLME* Fall 2005 issue on the obligation of therapeutic beneficence in clinical research and whether the physician investigator and research volunteer relationship is fiduciary, provided only a cursory overview of the prevailing legal and ethical debate.

In the Litton and Miller article,[1] "Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care," the authors contend that the duty of therapeutic beneficence[2] in clinical research is incongruous with moral principles implicit in our accepted societal practices in other contexts. The authors bolster their argument by pointing to the practice of medicine in a military and occupational context, stating that in these settings physicians deviate from the individual loyalty that we expect. They argue that these medical practices reflect the principle that the duties binding physicians should change depending upon the societal role that they fulfill in a particular context; thereby rejecting the principle that physicians are always governed by the medical care ethic. Litton and Miller's reference to the practice of medicine in a military context brings to mind the events of physicians stationed at Guantanamo Bay and Abu Ghraib and the chilling allegations that physicians had breached their professional ethics and the Geneva Convention by participating in the abusive interrogation of prisoners.[3] According to the International Red Cross and other investigative committees, physicians divulged vital medical information to military intelligence personnel, and assisted in the design of interrogation strategies, including sleep deprivation, and other coercive methods tailored to each detainee's medical conditions. Pentagon officials and military physicians assert that the doctors working at the detention camps did not breach medical ethics because the doctors are acting as combatants, not physicians, when they put their knowledge to use for military ends. "When a doctor participates in interrogation, he's not functioning as a physician, and the Hippocratic ethic of commitment to patient welfare does not apply."[4] Critical observers point out that in denying their status as physicians, military doctors divert attention from an urgent moral challenge to manage conflict between the medical profession's therapeutic and social purposes. They contend that the therapeutic mission is the profession's primary role and the core of physicians' professional identity. "If this mission and identity are to be preserved, there are some things doctors should not do."[5] I agree.

Furthermore, Litton and Miller's reference to the practice of occupational medicine as an accepted deviation from the medical care ethic ignores considerable case law on the physician's fiduciary duty to warn an examinee of a medical condition and to refer the examinee for further evaluation and treatment.[6]

In the article, "The Clinical Investigator as Fiduciary: Discarding a Misguided Idea,"[7] E. Haavi Morreim offers a limited introduction to fiduciary doctrine and then applies it to the physician investigator – research volunteer relationship. Morreim proposes that in order to understand why clinical investigators are not, and can not be, fiduciaries to research volunteers, we must first understand what a fiduciary is. However, Morreim argues from the premise that the characteristics that determine a fiduciary relationship are universally held. But in fact, fiduciary doctrine varies considerably among common law jurisdictions. For example, normative and legal deconstruction of fiduciary doctrine reveals that in Canada, the Supreme Court has formulated broad guidelines as to when fiduciary duties can arise. The Canadian notion of fiduciary obligation is a considerably more flexible concept not readily applied in American jurisprudence. This point is an important one because it greatly informs and advances the debate among clinical research ethicists, and legal scholars, many of whom are quoted in the Fall 2005 *JLME* articles.

In Canada, fiduciary duties attach to an array of relationships; the case law establishes that a finding of a "special relationship" creates fiduciary duties, especially in a physician-patient relationship. For instance, in *Norberg v. Wynrib*,[8] the Supreme Court of Canada reaffirmed not only that a physician has a fiduciary duty to the patient but also it is the inherent nature of the relationship as defined by the patient that gives rise to the fiduciary duty. Additionally, with respect to the fiduciary obligation of a physician investigator, in the disclosure case, *Halushka v. University of Saskatchewan*,[9] the Supreme Court described the relationship between researcher and research volunteers as one of "trust and confidence" and that the physician-investigator's duty to research subjects was "at least as great, if not greater than the duty owed by an ordinary physician or surgeon to his patient.[10] Also, in the *Gomez* case,[11] the court affirmed that biomedical research and medical acts are not in opposition to one another, and that clinical research is an integral part of medicine and is undertaken by physicians whose first professional duty is the protection of the health and well-being of individuals. Similarly, in New Zealand, several notable breach of fiduciary duty cases involving physician investigators have initiated debate on extending the scope of a physician investigator's legal liability to include breach of confidence, con-



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flicts of interest, conflicts of duty, and the taking of profits.

An in-depth comparative analysis of fiduciary doctrine reveals a fundamental shift from the classical fiduciary position to a "conscious-oriented" approach in jurisprudence that focuses on trust and confidence as the foundations of the law of fiduciary obligations. As a result certain jurisdictions recognize that a fiduciary duty can arise *not only* in relationships of established social significance, such as between agent and principal but in any relationship involving a requisite degree of trust and confidence.

Understanding the fiduciary doctrine of other common law jurisdictions illuminates the normative underpinnings of a given argument including the obligations physician investigators have towards the people who volunteer for clinical research trials. Reconciling diverse fiduciary doctrine is valuable beyond advancing theoretical analysis, it is imperative for the advancement of biological and scientific research. The increase in cross border multi-centered trials and international research in general, demands that ethicists and jurists progress to a discourse that seeks to reconcile conflicts of ethical principles and law and facilitate greater collaboration within the international scientific research community.

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1. P. Litton and F. G. Miller, "A Normative Justification for Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care," *Journal of Law, Medicine and Ethics* 33, no. 3 (2005): 566-574.
2. Litton and Miller use therapeutic orientation, therapeutic beneficence and medical care ethic interchangeably.
3. M. G. Bloche and J. H. Marks, "When Doctors Go to War," *N. Engl. J. Med* 352 (2005): 3; See also E. Wiesel, "Without Conscience," *N. Engl. J. Med.* 352 (2005): 15.
4. *Id.*
5. *Id.* at 5.
6. *State v. Fishel,* 228 Md. 189, 179 A 2d 349 (1962); *Betesh v. United States,* 400 F. Sup. 238 (D.C. 1974); *Parslow v. Masters* [1993] 6 W.W.R. 273;
7. E. H. Morreim, "The Clinical Investigator as Fiduciary: Discarding a Misguided Idea," *Journal of Law, Medicine and Ethics* 33, no. 3 (2005): 586-598.
8. *Norberg v. Wynrib* (1992) 92 DLR (4th) 449 a physician who supplied painkillers to a patient he knew was addicted in return for sexual favors was liable for breach of his fiduciary obligation to her.
9. *Halushka v. University of Saskatchewan,* [1966] 53 D.L.R. (2d) 436 (C.A.)
10. *Id.* at 445; see also, *Frame v. Smith* (1987) 42 DLR (4th) 81 at 99, the seminal Canadian case that sets out three general characteristics of relationships in which a fiduciary obligation may be imposed.
11. *Gomez v. Comite executif Conseil des Medecins, Dentistes et Pharmaciens de l'Hopital Universitaire de Quebec,* (2001) J.Q. No. 5544

## *Paul Litton and Franklin G. Miller Reply to Madeline M. Motta*

Motta's criticisms are directed towards a straw man, not our article.[1] Our argument does not, in any way, imply that physicians are free from moral constraints when they are not acting as medical care providers. Without question, physicians have significant ethical obligations in the research setting and when serving other important roles. Indeed, we argued that the importance of medical research and the most scientifically rigorous means of achieving it provide reasons to formulate a moral framework for research that departs from clinical care ethics. However, we also argued at length that such a moral framework appropriate to clinical research must include robust protection of the rights and well-being of participants, albeit without embracing the ethics of medical care.

As an adjunct to our main argument, we pointed out that in addition to conducting research, physicians serve legitimate roles other than medical care provider, such as military medicine. Yet Motta's insinuation that this point would appear to license physician participation in abusive interrogation practices is entirely erroneous. Just as physicians can violate their moral obligations in research, it is possible for them to violate moral obligations in other settings. That there is a legitimate role for physicians in the military setting does not, in any way, license such *abuses* of military medicine. One does not need to posit that military physicians are bound strictly by clinical care ethics in order to account for the wrongness of physician contributions to such abusive and degrading behavior. The same holds for occupational medicine and forensic psychiatry in the criminal justice system.

Instead of voicing any real criticism of our actual arguments, Motta's letter, however, suggests an important issue that deserves systematic attention; namely, how should we think about the duties of physicians in divergent medical roles?

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1. P. Litton and F. G. Miller, "A Normative Justification for Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care," *Journal of Law, Medicine & Ethics* 33, no. 3 (2005): 566-574.